

SCIENCE, POLICY, AND REGULATORY PEER REVIEW

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I. INTRODUCTION

On June 29, 2001, just outside of Klamath Falls, Oregon, an angry mob of farmers gathered around the closed floodgates of a federally-operated agricultural irrigation ditch.¹ Defying federal government orders, the crowd busted open the floodgate locks, returning the flow of water to the thirsty soils of their croplands. The mob stayed put and made camp for the next few days, defying federal officials time after time by unlocking the gates as soon as they had been closed. The crowd finally dispersed under the stern direction of United States Marshals. The battle lines could not have been more clearly drawn: the gates had to be shut and farmlands go dry, the federal government insisted, to save endangered fish in the lake from which the irrigation water was drawn and in the downstream river system. The following March, however, amidst the flash of news cameras, the Secretaries of the Departments of Agriculture and of the Interior triumphantly opened the same floodgates. What made the first liberation of water an act of civil disobedience and the latter a high-profile example of wise federal governance? Improbably, the answer came from a room full of scientists and a practice called peer review.

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¹ For an account of the events described in this paragraph, see Ted Williams, *Salmon Stakes*, 105 AUDUBON 42 (March 2003), available at <http://magazine.audubon.org/incite/incite0303.html>.

The Klamath River Basin straddles the Oregon-California border.² There, for over 100 years, the Bureau of Reclamation (BOR) has operated a federal irrigation water diversion project at a dam impounding Upper Klamath Lake. During that time, two local species of sucker fish and a population of coho salmon inhabiting the river and tributary system below the dam have dramatically declined. They have been listed under the Endangered Species Act (ESA) and thus are monitored and protected under the watchful eyes of the federal government, specifically the United States Fish and Wildlife Service (FWS) for the suckers and the National Oceanic and Atmospheric Administration (NOAA) for the salmon.³ In 2001, a year of severe drought, both the FWS and NOAA determined that BOR's plans for continued flow of irrigation water out of the system would jeopardize the continued existence of the species, thus violating the ESA.⁴ In order to comply with the statute's strict mandates for federal agency actions, the BOR closed the floodgates and, while the fish enjoyed more water, hundreds of farms dried to dust. Following public outcry over the "fish-versus-humans" decision and the standoff between farmers and federal officials at the floodgates, the Secretaries of the Departments of the Interior and Commerce, which oversee FWS and NOAA respectively, asked the National Academy of Science's National Research Council (NRC) to convene a committee of experts to conduct a peer review of the agencies' decisions—the first ever to be conducted of a discrete agency decision of this magnitude under the ESA.

The initial results of the Klamath Committee's peer review sparked a firestorm of controversy.⁵ Reviewing the information available to the agencies at the time of their respective decisions, the experts concluded that "no sound scientific basis" existed for the conclusions FWS had reached regarding the effects on the suckers of reduced lake levels or for the conclusions

² This brief recitation of the history of the Klamath River Basin is not intended to be comprehensive. It is derived from personal knowledge J.B. Ruhl gained through work on the National Research Council's Committee on Endangered and Threatened Fishes in the Klamath River Basin (Klamath Committee), which thoroughly studied the area's land use and water management history. See NATIONAL RESEARCH COUNCIL, ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN: CAUSES OF DECLINE AND STRATEGIES FOR RECOVERY 46-94 (2004) [hereinafter KLAMATH COMMITTEE FINAL REPORT] (describing, in depth, the land-use and water management of the Klamath River area). The Klamath Committee also provided detail in an interim report. See NATIONAL RESEARCH COUNCIL, SCIENTIFIC EVALUATION OF BIOLOGICAL 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 Daniel J. McGarvey & Brett Marshall, *Making Sense of Scientists and "Sound Science": Truth and Consequences for Endangered Species in the Klamath Basin and Beyond*, 32 *ECOLOGY L.Q.* 73 (2005); 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); Holly Doremus & A. Dan Tarlock, *Fish, Farms, and the Clash of Cultures in the Klamayth River Basin*, 30 *ECOLOGY L.Q.* 279 (2003); 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); 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).

³ For a description of the regulatory and other authorities FWS and NOAA administer under the ESA, see *infra* notes ___ - ___ and accompanying text.

⁴ Specifically, the BOR's plans would have, according to FWS and NOAA, violated the ESA's provision that each federal agency "insure that any action authorized, funded, or carried out by such agency...is not likely to jeopardize the continued existence of any endangered species or threatened species." 16 U.S.C. § 1536. For an analysis of the FWS and NOAA opinions, see KLAMATH COMMITTEE INTERIM REPORT, *supra* note ___.

⁵ See KLAMATH COMMITTEE INTERIM REPORT, *supra* note ___.

NOAA had reached regarding the effects of reduced river flows on the salmon.⁶ Soon after, the floodgates were dramatically re-opened.

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 their future in the face of increasing water resources allocated to protect endangered species.⁷ The findings also catapulted the Klamath into “Exhibit Number One” for critics charging that the ESA is fundamentally flawed because it allows the agencies to work on the basis of so-called “junk science.”⁸ As closely as the popular press followed both these developments, however, it completely missed the other, potentially more important, consequence of the Klamath story—the rise of what we call *regulatory peer review*.

When the collision of two important but conflicting federal regulatory policies—providing a secure supply of irrigation water to Western farmers versus providing the same water to endangered fish in Western lakes and rivers—led to stalemate, the federal government turned to peer review to break the tie. After the Klamath Committee issued its decisive opinion, the question many observers began to ask was whether peer review could be used to guide decisions in other regulatory settings. Indeed, since the Klamath controversy, renewed calls for improving agency science-based decisions have been heard frequently from the White House⁹ and throughout Congress.¹⁰

This so-called “sound science” movement claims that procedural safeguards to ensure better use of scientific data will improve agency decisions, making them more rational and objective.¹¹ Of course, concerns about the transparency, reliability, and accountability of agency

⁶ *Id.* at 3–4 (finding no scientific evidence supporting requirement of increased lake levels or increased stream flow).

⁷ See Doremus & Tarlock, *supra* note __, at 333–34 (connecting the desire for easier economic development with more stringent scientific support for endangered species protection).

⁸ See McGarvey & Marshall, *supra* note __, at 79–80. The Klamath Committee also was the target of much criticism, including from scientists hired by different interest groups involved in the battle for water, and the situation soon deteriorated into what some observers referred to as “combat biology.” Robert F. Service, *Combat Biology on the Klamath*, 300 SCI. 36, 36 (2003). The lack of established structure for carrying out the peer review probably contributed to the ways in which the findings were used and abused, and that is one reason for our proposal *infra*.

⁹ See, e.g., Summary of Fiscal Year 2004 Budget Request Prepared by EPA, 34 Env’t Rep. (BNA) S-112 to S-121 (2003) (reproducing EPA’s February 3, 2003 summary of its proposed budget including “Goal 8,” which the agency described as “Sound Science, Improved Understanding of Environmental Risk and Greater Innovation to Address Environmental Problems”).

¹⁰ See, e.g., Sound Science for Endangered Species Act Planning Act of 2002, H.R. 4840, 107th Cong. (2d Sess.) (2002).

¹¹ 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 at Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science*, 52 KAN. L. REV. 897 (2004). The discussion and debate regarding the use of “sound science” in environmental law is pervasive—we found over 9300 web sites 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 from a Troubled Marriage: Science and Law in Environmental Policy*, 302 SCI. 1926 (2003). Professor 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*, 66 LAW & CONTEMP. PROBS. 63 (2003) [hereinafter *Bad Science*]; Wendy Wagner, *Congress, Science, and Environmental Policy*, 1999 U.

decision making has fueled the rise of administrative procedures since the New Deal.¹² But the sound science movement seeks more than the protections afforded by the conventions of administrative law—they want agencies to use better science, and more of it, but above all else they want agencies to be subject to regulatory peer review.

Peer review is generally described as a scientifically 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.¹³ Peer review is commonplace, indeed, fundamental, to the practice of science.¹⁴ It is the gold standard for determining publication and general acceptance of scientific research.

Just as scientific peer review involves independent evaluation of scientific research, regulatory peer review as we define it¹⁵ refers to the outside evaluation of an administrative agency's search, selection, or use of scientific data to support a proposed regulatory decision such as a rule, standard, permit, or other policy. Regulatory peer review 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. If peer review works for science, so goes the argument, it should work for agency decisions that purport to rely on science, as well.

Yet not everyone is willing to accept that seemingly straightforward logic. A growing debate over agency use of sound science, and of regulatory peer review in particular, has become increasingly polarized, with strong claims made on both sides.¹⁶ For example, to Greg Waldron, an Oregon member of Congress, the case for peer review is obvious.

ILL. L. REV. 181 (1999); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995) [hereinafter *Science Charade*].

¹² See JAMES O. FREEDMAN, *CRISIS AND LEGITIMACY: THE ADMINISTRATIVE PROCESS & AMERICAN GOVERNMENT* (1978); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667 (1975).

¹³ NAT'L RESEARCH COUNCIL, *PEER REVIEW IN ENVIRONMENTAL TECHNOLOGY DEVELOPMENT PROGRAMS* 2 (1998), available at <http://www.nap.edu/books/0309063388/html/index.html>. 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.*

¹⁴ For a discussion of the use and perception of peer review in science, see *infra* notes __-__ and accompanying text.

¹⁵ Some critiques of the use of peer review in regulatory contexts attack practices that we do not consider within the scope of regulatory peer review. For example, Wendy Wagner argues against allowing members of the public to petition an agency to make corrections to data the agency disseminates, on the ground that such a process "places interested parties in the role of peer reviewer." See Wagner, *Bad Science*, *supra* note __, at 69. She uses this procedure, and her claim that it is a form of peer review, as the basis for her critique of using peer review in administrative law in general. See *id.* at 72-84. Regardless of how one feels about such data correction petition procedures, however, they are *not* peer review processes, as they lack the independence of reviewer that is essential to properly conducted peer review. We critique poorly designed proposals for regulatory peer review in Part VII *infra*, but we do not believe one can condemn regulatory peer review in general simply because politicians or agencies have advanced poorly designed proposals, or by suggesting that other procedural requirements fit within the scope of regulatory peer review when they clearly do not.

¹⁶ The Bush Administration has aggressively advanced "sound science" principles, such as data quality. 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). 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). A counter-movement also has emerged. For example, a group of legal scholars openly skeptical of its motives has formed to, among other things,

If you went to a doctor and he said to you, “we are going to have to cut off your right leg,” you’d probably want a second opinion. Right now under the Endangered Species Act, plants, animals and people don’t have the chance to seek a second opinion; you just get cut off at the knees.¹⁷

By contrast, the nongovernmental organization, Public Citizen, contends that mandating the uniform use of peer review by federal agencies would:

favor regulated industry and introduce potentially massive costs and delay, thus injecting paralysis by analysis into the regulatory process... It is no overstatement that strict application of [regulatory peer review] would bring many ordinary functions to a grinding halt, including the government’s obligation to present public health, environmental and other information on a timely basis.¹⁸

The increasing heat of this debate reflects action heating up on the ground as well. A series of bills requiring regulatory peer review have been proposed in Congress,¹⁹ and the Office of Management and Budget (OMB) has finalized peer review requirements for “information products” regulatory agencies use in classes of regulatory decisions likely to have significant economic or other impacts.²⁰ That regulatory peer review has moved so quickly from the newspapers to the law books attests to the potentially important ramifications it could have. Indeed, regulatory peer review may be the sleeping giant of the sound science movement.

Yet as loudly as the Klamath saga rang the alarm that awoke the issue, it also raises three fundamental questions that ought to be addressed before rushing to any conclusion. The first is how many agency policy decisions that are supposed to be based in part or entirely on science have no or insufficient scientific basis? Increased use of peer review will undeniably impose costs to agencies. One cannot justify those costs without a firm sense of how extensively agencies reach decisions without sufficient scientific support. In other words, how many Klamaths are there? Second, if indeed the Klamath experience is widespread and agencies frequently fail adequately to justify policy decisions on scientific grounds, which if any such instances present a concern about the merit of the policy outcome? The Klamath Committee, for example, never condemned the federal government’s decision to close the floodgates, and even went so far as to explain that the decision may or may not have been justified on policy grounds, just that it wasn’t justified on scientific grounds.²¹ If the policy decision is on target, does it matter that it was not scientifically justified, or does the lack of a scientific basis inherently call into question the risk of policy failure? Finally, if instances such as the Klamath do pose a

monitor and challenge the “sound science” movement. See Center for Progressive Regulation, <http://www.progressiveregulation.org/index.html> (last visited ____).

¹⁷ Walden Testifies on Need for Endangered Species Act Reform (Feb. 2004) (testimony of rep. Greg Walden (R-Or), bill sponsor of HR. 1662), available at http://www.house.gov/apps/list/press/or02_Walden/pr_040205_esa.html.

¹⁸ Public Citizen letter to Office of Management and Budget, Dec. 15, 2003, available at http://www.progressiveregulation.org/articles/peer/Public_Citizen_PR_Comments.pdf

¹⁹ See, e.g., Sound Science for Endangered Species Act Planning Act of 2003, H.R. 1662, 108th Cong. (2003). The ESA bills are discussed in more detail *infra* at notes ____ and accompanying text.

²⁰ See Office of Management and Budget, Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005) [hereinafter OMB Final Bulletin]. OMB’s policy unfolded through several iterations. See Office of Management and Budget, Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (Sept. 15, 2003) [hereinafter OMB Proposed Bulletin]; Office of Management and Budget, revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23230 (Apr. 28, 2004) [hereinafter OMB Revised Bulletin]. The history and details of OMB’s policy are discussed *infra* at notes ____ and accompanying text.

²¹ See KLAMATH COMMITTEE FINAL REPORT, *supra* note ___, at 35.

significant risk of policy failure, how can we best avoid more Klamaths in the future? Even if agencies' poor use of science is a problem demanding action, does regulatory peer review provide an effective safeguard? Put differently, even if agency use of science is a significant problem for the fulfillment of desired policy, is regulatory peer review the solution?

Despite the raucous public debate over regulatory peer review, none of these questions has been adequately addressed in scholarly literature, much less by the folksy wisdom and Chicken Little cries of the interest group combatants. The issue has received little attention in legal scholarship, with most contributions opposing the use of regulatory peer review.²² As useful and insightful as some of this work has proven, however, we believe the issue is far from put to rest. No scholarly study has ever demonstrated whether use of regulatory peer review would have detected many other instances like the Klamath under the ESA or similar regulatory statutes, whether the benefits of detecting those instances would have justified the costs of the peer review programs, and whether it would have mattered from the standpoint of reaching sound policy decisions.²³ No scholarly study has done this because, quite simply, there hasn't been enough regulatory peer review conducted to draw any reliable conclusions.

This Article defines, evaluates, and designs regulatory peer review in a way we hope addresses these questions directly and thereby will inform the debate over the use of regulatory peer review in agency decision making. Part II of the Article describes scientific peer review and its practical application in journal publication, grant awards, and agency settings, and illustrates the distinction between those applications and regulatory peer review. The obvious difference between the use of peer review in scientific research settings versus in agency regulation settings is that science does not purport to involve normative policy decisions, whereas regulation explicitly does. Yet, if agencies are expected to base regulatory decisions in part or exclusively on science, as many are, how can they do so without employing what scientists believe is one of the most essential ingredients of science? Thus is posed the dilemma of regulatory peer review: on the one hand, introducing peer review into regulation might obstruct the normative *policy* function of agencies, but leaving it out might obstruct the non-normative *science* function of agencies.

Reflecting this conundrum, the next two sections of the Article address the current debate over regulatory peer review, setting out the arguments in favor of peer review in Part III and their

²² For a general discussion of the role of peer review in regulatory law, see Lars Noah, *Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1045 (2000). The Klamath saga prompted several scholars to examine the use of peer review in the context of endangered species protection. See McGarvey & Marshall, *supra* note __, at 107-11; Burke, *supra* note __, at 506-14. Holly Doremus and J.B. Ruhl have each more broadly discussed the merits of using peer review in connection with administration of the Endangered Species Act. See Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Best Available Science Mandate*, 34 ENVTL. L. 397 (2004); J.B. Ruhl, *Prescribing the Right Dose of Peer Review for the Endangered Species Act*, 83 NEB. L. REV. 398 (2004). Wendy Wagner has critiqued proposals for regulatory peer review in the broader context of environmental law in general. See Wagner, *Bad Science*, *supra* note __, at 67-84; Wagner, *Science Charade*, *supra* note __, at 1700. OMB's peer review policy, which extends to a wide range of regulatory agencies, has also been the subject of scholarly analysis. See Sarah Grimmer, *Public Controversy Over Peer Review*, 57 ADMIN. L. 275 (2005); Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 34 ENVTL. L. Rep. (Envtl. L. Inst.) 10064 (2004).

²³ Although Wendy Wagner asserts that "there are surprisingly few examples" of poor use of science by agencies, she offers no empirical foundation for the claim and, more tellingly, excludes from the claim "the larger universe of regulatory decisions involving the grant of permits and licenses." See Wagner, *Bad Science*, *supra* note __, at 72-73. Ironically, her basis for excluding what amounts to the bulk of administrative regulation is that "these decisions rest in large part on unvalidated industry science," *id.* at 73, which, if true, would in our view make the case for applying regulatory peer review to them even *stronger*. It is, of course, this "larger universe" of regulatory decisions that is fueling proposals for more use of regulatory peer review, and which is thus the focus of this Article.

critiques in Part IV. Ironically, claims pro and con about regulatory peer review generally rely on very few data points—any rigorous peer review of their merits would fault them for this. In order to inform our evaluation, therefore, we conducted a survey of environmental law attorneys to reveal the perceptions of practitioners whose clients are or would be affected by regulatory peer review.²⁴ As reported *infra*, we found a remarkably intense divergence of opinion between private and public sector attorneys regarding the prevalence of poor use of science by regulatory agencies and the need for and efficacy of regulatory peer review in response.²⁵ Generally, representatives of industry and also, increasingly, of environmental groups believe agencies are misusing science, whereas agency representatives defend their performance. The debate that has been fueled in the White House and Congress, in other words, is not merely political rhetoric—it reflects a sharp division of opinion among the front line practitioners of administrative law who have the experience to evaluate the prospects of regulatory peer review, but who disagree vehemently over its merits.

In Part V of the Article we step back from the intensity of the debate over regulatory peer review to re-assess its role in the regulatory process, suggesting a different way to think about its potential costs and benefits and its appropriate applications. Contrary to most scholarly literature on the topic, we argue that the science-policy snarl in which most agencies find themselves does not pose an insurmountable barrier to effective use of regulatory peer review. Rather, regulatory peer review can help inform the public about where an agency's use of science ends in terms of support for a proposed decision and where the agency's use of professional judgment and normative policy choices begins. The argument that agencies must make policy decisions in the face of incomplete and uncertain scientific data, and thus should not be bound to the rigors of peer review, turns the issue on its head. Rather, regulatory peer review can help reveal how much scientific uncertainty exists with respect to an agency decision, and thus demand of the agency that it explain how the gap was filled. This function, we argue, can lead to greater transparency

²⁴ We sent our survey to 900 randomly-selected members of the American Bar Association's Section of the Environment, Energy, and Resources (SEER), of whom almost 200 responded. 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, and. 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 The Florida State University College of Law. We thank FSU Department of Statistics Professor Kai-Sheng Song and graduate student Han Yu for their assistance in compiling and analyzing the survey data.

²⁵ One of the underlying premises of proposals for regulatory peer review is that there is, or at least may be, a prevalence of poor use of science by regulatory agencies. 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 perceptions surveys. As we explain in Parts III and V 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 by practice setting, client base, and political predisposition, because of the effect those perceptions will have on the demand for regulatory peer review and in shaping the legitimacy of the agency's decisions.

in agency decision processes and greater legitimacy of agency decisions with the public, legislatures, and the courts.

Finally, in Part VI of the Article we evaluate different proposals for the design of regulatory peer review, finding them either over-inclusive, as in proposals in Congress to subject all ESA decisions to regulatory peer review, or under-inclusive, as in OMB's policy limiting peer review to decisions of extreme economic or other impact. The problem in each case is that, while there is good reason to believe that regulatory peer review can effectively serve salutary purposes in administrative law, the scope of the problem—poor use of science by agencies—is not competently defined. There is no evidence that *all* agency decisions suffer from poor use of science, or that only the “big” ones are suspect. On the other hand, the scope of problem cannot competently be defined *without* peer review—that's the very point of peer review. Without conducting regulatory peer review, in other words, one can't reasonably conclude whether agencies ought to be required to conduct regulatory peer review. Of course, to a scientist this dilemma has an easy solution in the practice of random sampling. In other words, whereas at present there is no institutional structure in place for systematically reviewing *any* regulatory decisions of most agencies, it is not necessary that *all* decisions be subject to peer review in order to derive useful information about agency performance. Hence, in order to assist policy makers in defining the problem, if there is one, we propose the use of mandatory “randomized peer review” by agencies, through which a small number of decisions in particular categories of agency actions would be routinely subjected to peer review in order to determine whether more frequent or widespread application of peer review for that class of actions or the agency as a whole is needed. This diagnostic, adaptive approach, we argue, delivers the greatest benefits of regulatory peer review while minimizing the costs.

II. WHAT IS PEER REVIEW AND WHERE IS IT USED?

As the underlying premise of regulatory peer review boils down to what's good for science is good for regulation, it is critical to any assessment of regulatory peer review to understand the use and benefits of peer review in science and the different context its practice would face if employed in regulatory settings. If the case for regulatory peer review is not established simply by the efficacy of peer review in science, then neither can the case against regulatory peer review necessarily be made based on the on the bare fact that regulation is not science. A deeper understanding of both sides of the coin is called for.

A. Conventional Applications of Scientific Peer Review²⁶

Peer review is most strongly associated with scientific journal publication decisions, where it has been in use for over 300 years, but it is also employed in a wide array of settings, including grant funding decisions and faculty evaluations.²⁷ Within science, peer review is widely considered “essential to the integrity of scientific and scholarly communication.”²⁸ Indeed for many scientists, peer review “does not merely reflect the scientific method, it is the scientific method.”²⁹

When peer review is used in the context of journal publication and grant award decisions, the journal or granting institution acts as a “middleman” to find independent reviewers with

²⁶ This discussion of the use and perception of peer review in science also appears in substantially the same form in Ruhl, *supra* note __, at 407-09.

²⁷ See ANN C. WELLER, EDITORIAL PEER REVIEW: ITS STRENGTHS AND WEAKNESSES 1–7 (2001).

²⁸ *Id.* at 322.

²⁹ Noah, *supra* note __, at 1045.

relevant expertise who will review the science, not the scientists, and the merits of publication. The journal review process has been summarized as follows:

An aspiring author sends a manuscript to a journal's editorial office. The journal editor, or for large journals one of the associate editors, logs in the manuscript, selects two or three reviewers to evaluate the manuscript, and sends each a copy. Reviewers are asked to assess the manuscript and make a recommendation to accept, accept with revisions, or reject the manuscript. The editor or associate editors then decide if they will accept the recommendation of the reviewers.³⁰

Grant funding peer review follows a similar process.³¹ In both cases, the procedures seek to ensure "a documented, critical review performed by peers who are independent of the work being reviewed."³² 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.³³

³⁰ WELLER, *supra* note __, at 1. See also Fytton Rowland, *The Peer Review Process: A Report to the JISC Scholarly Communications Group 1* (2002), available at http://www.jisc.ac.uk/uploaded_documents/rowland.pdf (JISC is the Joint Information Systems Committee, the UK's higher education support agency). When a submitted report first arrives at the editorial office of a journal, it is first vetted by the editor, who may reject it out of hand—either because it is "out of scope" (not dealing with the right subject matter for that journal) or because it is manifestly of such low quality that it cannot be considered at all. Papers that pass this first hurdle are then sent to experts in the field of the paper—usually two—who are generally asked to classify the paper as publishable immediately, publishable with amendments and improvements, or not publishable.

³¹ For example, the National Science Foundation advises persons submitting grant proposals as follows:

Proposals received by the NSF Proposal Processing Unit are assigned to the appropriate NSF program for acknowledgement and, if they meet NSF requirements, for review. All proposals are carefully reviewed by a scientist, engineer, or educator serving as an NSF Program Officer, and usually by three to ten other persons outside NSF who are experts in the particular fields represented by the proposal. Proposers are invited to suggest names of persons they believe are especially well qualified to review the proposal and/or persons they would prefer not review the proposal. These suggestions may serve as one source in the reviewer selection process at the Program Officer's discretion. Program Officers may obtain comments from assembled review panels or from site visits before recommending final action on proposals. Senior NSF staff further review recommendations for awards.

National Science Foundation, *NSF Proposal Processing and Review*, available at <http://www.nsf.gov/pubs/2003/nsf03041/3.htm> (last visited April 5, 2004). Variations exist with respect to whether the journal or grant institution uses reviewers from a standing board or selects reviewers from a list compiled by recommendations. See WELLER, *supra* note __, at 2.

³² NATIONAL RESEARCH COUNCIL, *PEER REVIEW IN ENVIRONMENTAL TECHNOLOGY DEVELOPMENT PROGRAMS 2* (1999), available at <http://www.nap.edu/books/0309063388/html/>. 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.* 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.* See also OMB Proposed Bulletin, *supra* note __, 68 Fed. Reg. at 54,024 (defining peer review as "a scientifically rigorous review and critique of a study's methods, results, and findings by others in the field with requisite training and expertise. Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses.")

³³ WELLER, *supra* note __, at 207.

Substantively, the peer review process is not a “de novo” review, to borrow from a legal model, but rather more like appellate review. The journal *Ecology*, for example, advises its reviewers that their comments should address ten factors:

- (1) importance and interest to this journal's readers;
- (2) scientific soundness;
- (3) originality;
- (4) degree to which conclusions are supported;
- (5) organization and clarity;
- (6) cohesiveness of argument;
- (7) length relative to information content;
- (8) whether material should be moved to the digital appendices;
- (9) conciseness and writing style; and
- (10) appropriateness for the targeted journal and specific section of the journal.³⁴

Even when a peer reviewer employs all of these criteria, the intensity of journal and grant peer review is nothing like de novo review. There is no independent research to verify whether the data are accurate. *Ecology* explains, for example, that in assessing “scientific soundness” the reviewer should examine the methods, data presentation, and statistical design of the paper, but the instructions do not include engaging in independent data authentication.³⁵ Indeed, peer review would grind itself and journal publication to a screeching halt were it to require peer reviewers to engage in independent testing and data analysis.

For those submissions deemed worth pursuing, the suggested changes by the reviewers will generally be forwarded to the authors (with the reviewers’ names usually deleted) who then revise their proposals accordingly. While not nearly as probing as a de novo analysis, it is widely believed that this “appellate style” peer review provides tremendous benefits.³⁶ First, peer review serves as a filter, ensuring quality control. Better articles and grant proposals are judged more favorably by peer review than weaker ones. Second, peer review prioritizes, allowing editors and grant makers to rank articles and proposals. In the face of more articles submitted than can be published, and more grant proposals than can be funded, peer review provides an effective means to rank them against each other.

While less widespread than in scientific publications or grant making, peer review also employed by a number of federal agencies that have primarily science-based missions. A 1999 study by the Government Accounting Office (GAO), for example, found widespread peer review employed primarily by science agencies such as NASA and the National Institutes of Health.³⁷ Peer review procedures nonetheless were ad hoc, with no uniform definitions or procedures. Peer review was used for many purposes, ranging from grant awards and pre-publication review of research to budget review and program and employee evaluation.³⁸ Procedures included outside mail reviewers, internal and external standing panels, and workshops.

³⁴ ESA Publications, *Instructions for Reviewers*, <http://www.esapubs.org/esapubs/reviewers.htm> (last visited April 4, 2004). These criteria are representative of the scientific journal industry in general. See WELLER, *supra* note __, at 160–63.

³⁵ See *id.* As Holly Doremus has explained, “[p]eer reviewers are not expected to authenticate the data presented to them. Rather, their role is to evaluate the methods employed and the facial plausibility of the conclusions drawn.” Doremus, *Listing Decisions*, *supra* note __, at 1147.

³⁶ There is some empirical evidence in support of this belief. See WELLER, *supra* note __, at 51-53.

³⁷ U.S. GENERAL ACCOUNTING OFFICE, GAO/RCED-99-99, PEER REVIEW PRACTICES AT FEDERAL SCIENCE AGENCIES VARY 1-10 (Mar. 1999).

³⁸ Some specific examples subject to peer review included NOAA fisheries stock assessments, Agricultural Research Service project plans, and National Institutes of Health reviews of intramural research. See *id.* at 18-39.

B. Extending Peer Review to Regulation

The use of peer review is far more limited and variable in agencies with *regulatory* responsibilities. There is a strong tradition of expert advisory panels advising agencies on specific topics, ranging from the Environmental Protection Agency's Science Advisory Boards and the Food and Drug Administration's Technical Advisory Committees to the Consumer Product Safety Commission's Chronic Hazard Advisory Panels.³⁹ These standing panels, however, tend to focus more on how the agency should set priorities or think about particular topical areas than on specific regulatory decisions.

Peer review is used much less frequently in regulatory settings such as standard setting, and almost never in permitting and licensing. One reason for this, presumably, is that discrete regulatory decisions are where policy meets the real world, and thus peer review would involve an assessment of how an agency used available scientific data in reaching a particular application of policy rather than a scientific decision about whether a research hypothesis is confirmed by data. This requires adapting conventional scientific peer review in three respects. First, it will often be the case that the agency is not actually doing the science that produces the data upon which it relies for its decision, but rather uses data already made available through other scientific research efforts. Thus, regulatory peer review will often involve reviewing how the agency incorporates pre-existing scientific knowledge into its own scientific processes. Second, it will not always be the case that the data upon which the agency relies are the result of peer-reviewed studies.⁴⁰ Regulatory peer review, therefore, must also provide some review function of those studies in the form of an evaluation of the agency's choices as to which data to use. Finally, many regulatory decisions are not simply extensions of the scientific method – i.e., they involve using science to inform, but not control, the exercise of the agency's professional policy judgment.

To make these distinctions more concrete, it is helpful to revisit the context of the Klamath and the ESA. The ESA is a science-based statute dedicated to conserving and restoring populations of endangered species and, as a result, provides numerous opportunities for agency officials to rely on scientific data in a policy setting.⁴¹ Section 4 of the Act, for example, authorizes FWS and NOAA to identify “endangered” and “threatened” species, known as the

³⁹ For information on EPA's Science Advisory Board, see <http://www.epa.gov/sab/about.htm>. For information on the FDA's Advisory Committees, see http://www.fda.gov/fdac/features/2004/104_adv.html. For information about the CPSC's Advisory Panels, see [JIM].

⁴⁰ Indeed, as Wendy Wagner points out, case-specific regulatory decisions usually rely, at least in part, on “unvalidated industry science.” Wagner, *Bad Science*, *supra* note __, at 73.

⁴¹ We each have had the pleasure of being asked to make presentations and write commentary for publication about the ESA more than several times. Out of necessity, the materials in this “background” section of this Article are a variation, tailored for the instant purposes, of a template one of us has developed and used to inform readers not familiar with the ESA of the statute's basic structure. Similar treatments, in other words, appear elsewhere. See, e.g., Ruhl, *supra* note __, at 412-17. Like the other work, this Article is not intended to provide a comprehensive overview of the ESA. Rather, it uses the ESA in this section as a case study for understanding how peer review would operate in regulatory contexts. For comprehensive treatments of the ESA, several of which are referred to frequently *infra*, see LAWRENCE R. LIEBESMAN AND RAFE PETERSEN, *ENDANGERED SPECIES DESKBOOK* (2003); *ENDANGERED SPECIES ACT: LAW, POLICY, AND PERSPECTIVES* (Donald C. Baur and Wm. Robert Irvin eds., 2002); STANFORD ENVIRONMENTAL LAW SOCIETY, *THE ENDANGERED SPECIES ACT* (2001); TONY A. SULLINS, *ENDANGERED SPECIES ACT* (2001); MICHAEL J. BEAN AND MELANIE J. ROWLAND, *THE EVOLUTION OF NATIONAL WILDLIFE LAW* (3d ed., 1997).

“listing” function,⁴² and then to designate “critical habitat”⁴³ and develop “recovery plans” for the species.⁴⁴ Section 7 requires all federal agencies to ensure that actions they carry out, fund, or authorize do not “jeopardize” the continued existence of listed species or “adversely modify” their critical habitat.⁴⁵ Section 9 requires that all persons, including all private and public entities subject to federal jurisdiction, avoid committing “take” of listed species of fish and wildlife.⁴⁶ Sections 7 (for federal actions) and 10 (for actions not subject to Section 7) establish a procedure and criteria for FWS and NOAA to approve “incidental take” of listed species.⁴⁷

Each of these provisions involves an intersection between policy decisions and a multitude of scientific determinations. In the standard setting role of listing species, for example, FWS and NOAA must decide whether a species is in danger of extinction throughout all or a significant portion of its range (endangered) or likely to become so in the foreseeable future (threatened)?⁴⁸ This requires a series of scientific determinations about the species’ taxonomy, if indeed it is a species,⁴⁹ its range, the present and threatened injuries to its habitat,⁵⁰ whether it is

⁴² 16 U.S.C. § 1533(a)(1) (2000). For a description of the listing process, see SELS, *supra* note __, at 38–58; LIEBESMAN & PETERSEN, *supra* note __, at 15–20; SULLINS, *supra* note __, at 11–25; J.B. Ruhl, *Section 4 of the ESA: The Keystone of Species Protection Law*, in LAW, POLICY, AND PERSPECTIVES, *supra* note __, at 19.

⁴³ 16 U.S.C. § 1533(a)(3) (2000). For a description of the critical habitat designation process, see SELS, *supra* note __, at 59–69; LIEBESMAN & PETERSEN, *supra* note __, at 20–24; SULLINS, *supra* note __, at 26–28; Federico Cheever, *Endangered Species Act: Critical Habitat*, in LAW, POLICY, AND PERSPECTIVES, *supra* note __, at 47; Murray D. Feldman & Michael J. Brennan, *The Growing Importance of Critical Habitat for Species Conservation*, 16 NAT. RESOURCES & ENV’T 88 (2001). See also *infra* notes __-__ and accompanying text.

⁴⁴ 16 U.S.C. § 1533(f) (2000). For a description of the recovery plan process, see SELS, *supra* note __, at 71–77; LIEBESMAN & PETERSEN, *supra* note __, at 24–26; SULLINS, *supra* note __, at 34–38; John M. Volkman, *Recovery Planning*, in LAW, POLICY, AND PERSPECTIVES, *supra* note __, at 71.

⁴⁵ 16 U.S.C. § 1536(a)(2) (2000). For a description of the consultation process, see SELS, *supra* note __, at 83–103; LIEBESMAN & PETERSEN, *supra* note __, at 27–39; SULLINS, *supra* note __, at 59–86; Marilyn Averill, *Protecting Species Through Interagency Cooperation*, in LAW, POLICY, AND PERSPECTIVES, *supra* note __, at 87.

⁴⁶ 16 U.S.C. § 1538(a)(1) (2000). For a description of the cases developing the legal standards for what constitutes “take,” see SELS, *supra* note __, at 104–12; LIEBESMAN & PETERSEN, *supra* note __, at 39–45; SULLINS, *supra* note __, at 44–53; Gina Guy, *Take Prohibitions and Section 9*, in LAW, POLICY, AND PERSPECTIVES, *supra* note __, at 191; Steven P. Quarles & Thomas R. Lundquist, *When Do Land Use Activities “Take” Listed Wildlife Under ESA Section 9 and the “Harm” Regulation?*, in LAW, POLICY, AND PERSPECTIVES, *supra* note __, at 207; Alan M. Glen & Craig M. Douglas, *Taking Species: Difficult Questions of Proximity and Degree*, 16 NAT. RESOURCES & ENV’T 65 (2001).

⁴⁷ 16 U.S.C. §§ 1536(b)(4), 1539(a)(1) (2000). “Incidental take,” although not the subject of a specific statutory definition provision, is described elsewhere in the statute as a take that is “incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.” *Id.* § 1539(a)(1)(B). The FWS and NOAA have adopted this meaning for purposes of the regulations implementing section 7. 50 C.F.R. § 402.02 (2003). For a description of the incidental take authorization procedures, see SELS, *supra* note __, at 127–73; LIEBESMAN & PETERSEN, *supra* note __, at 46–50; SULLINS, *supra* note __, at 87–102.

⁴⁸ These are the definitions of endangered species and threatened species. 16 U.S.C. §§ 1532(6), (20) (2000).

⁴⁹ For a comprehensive comparison of the biological and legal conceptions of “species,” see Blake Hood, *Transgenic Salmon and the Definition of “Species” Under the Endangered Species Act*, 18 J. LAND USE & ENVTL. L. 75, 78–98 (2002) (“The scientific consensus on ‘species’ . . . is that no complete consensus exists and that different definitions suit different purposes.”) Hood, *supra* note 65, at 78. The default position in science as to what constitutes a species relies on Ernst Mayr’s “biological species concept,” which focuses on reproductive isolation. See *id.* at 81–82. Still, actually defining the boundaries of a species, and deciding whether a particular organism belongs to one or another, involves complex observational, morphological, and genetic considerations. See *id.* at 82–83. For additional discussion of the

being over-utilized for commercial or other purposes, or threatened by disease or predation, whether these threats are enough to cause it to go extinct, and if so, when? A similar law-science mesh appears in policy application settings such as enforcement of the jeopardy prohibition found in Section 7, which was the driving legal standard in the Klamath River Basin. The statute requires FWS and NOAA to assess whether the direct and indirect effects of a proposed federal agency action will jeopardize the continued existence of the species⁵¹ by appreciably reducing its chances of recovery and survival in the wild.⁵² To reach a decision on that question, FWS and NOAA must determine as a scientific matter the nature and magnitude of impacts the action will have on reproduction, numbers, or distribution of the species and how much any such impacts will reduce the species' chances of surviving and recovering in the wild?⁵³

Regulatory agencies such as FWS and NOAA thus can't easily avoid the science component of their mandates in regulatory applications. Indeed, to manage these and other necessary scientific judgments the agencies must make under the ESA, the statute mandates a "best scientific data available" standard. For example, when deciding whether to list a species, FWS and NOAA must consider factors such as loss of habitat⁵⁴ using only "the best scientific and commercial data available."⁵⁵ Similarly, the biological component of the decision whether to designate critical habitat must use the "best scientific data available."⁵⁶ And the "no jeopardy" and "no adverse modification" directives to federal agencies, which rely on a case-specific consultation procedure between the action agency and ESA agency with jurisdiction over the species in question,⁵⁷ adopt the same standard.⁵⁸

Nevertheless, while these provisions clearly infuse a science-based mandate in the agencies' regulatory functions, they just as clearly provide that the agencies will *use* science rather than *do* science.⁵⁹ Peer review is associated more with the latter, that is, with the actual practice of science and presentation and defense of scientific conclusions. Regulatory agencies might rely on the output of scientific peer review, but they generally do not engage in original scientific research to make regulatory decisions.

Arguably, therefore, regulatory peer review could be either redundant or an outright obstruction to a regulatory agency's policy mission. Indeed, in practice few regulatory agencies subject regulatory decisions to peer review, and those that do limit the practice principally to standard setting decisions.⁶⁰ For example, under a policy FWS and NOAA adopted in 1994 with respect to species listing decisions, the agencies promise to "incorporate independent peer review

debate surrounding how to define a species, both legally and scientifically, see SELS, *supra* note __, at 31–38; LIEBESMAN & PETERSEN, *supra* note __, at 11–15; SULLINS, *supra* note __, at 6–11; Doremus, *supra* note __, at 1087–1112. Several cases turn on whether FWS or NOAA has correctly defined what constitutes a species within the meaning of the statute. See LIEBESMAN & PETERSEN, *supra* note 1, at 11–15 (providing comprehensive discussion about definition of species).

⁵⁰ This and the remaining questions posed for the listing function are taken from the statutory criteria. 16 U.S.C. § 1533(a)(1)(A)–(E) (2000).

⁵¹ This is the statutory prohibition of jeopardy. *Id.* § 1536(a)(2) (requiring agencies to ensure no agency action jeopardizes a listed species).

⁵² The agency regulations elaborate on the statute with this definition of "jeopardize." See 50 C.F.R. § 402.02 (2003) (defining jeopardy).

⁵³ These are the criteria set forth in the regulatory definition. 50 C.F.R. § 402.02 (2003).

⁵⁴ 16 U.S.C. § 1533(a)(1)(A) (2000).

⁵⁵ *Id.* § 1533(b)(1)(A).

⁵⁶ *Id.* § 1533(b)(2).

⁵⁷ *Id.* § 1536(a)(2), (b)–(c).

⁵⁸ *Id.* § 1536(c); 50 C.F.R. 402.14(g)(8) (2003).

⁵⁹ See *Southwest Ctr. for Biological Diversity*, 2002 WL 1733618 at *9 (D.D.C. 2002).

⁶⁰ See Noah, *supra* note __, at __.

in listing and recovery activities.”⁶¹ Notably, the policy does not apply to any of the agencies’ action-specific permitting authorities, such as jeopardy consultations under Section 7 or incidental take permitting under Sections 7 and 10 of the statute.⁶²

On the other hand, standard setting and permitting decisions arguably are precisely where peer review is most needed. For example, although the ESA leaves this “best scientific data available” standard of evidentiary quality undefined,⁶³ its “obvious purpose . . . is to ensure that the ESA not be implemented haphazardly, on the basis of speculation or surmise.”⁶⁴ Science is, in other words, *intended* as a check on a regulatory agency’s exercise of policy discretion, which is at its greatest potential for abuse in regulatory applications such as setting standards and ruling on permit applications. As an essential ingredient of science, therefore, shouldn’t peer review be a practice regulatory agencies routinely employ?

As Parts III and IV of this Article discuss, this is the tension that fuels the debate over regulatory peer review: it is praised by some as the most important ingredient of science’s check against runaway agency discretion, and it is condemned by others as science’s stranglehold on the exercise of sound policy judgment. Both sides have it wrong. To be sure, we agree that, to play an effective role, regulatory peer review must disentangle the policy judgment from the underlying science if it is to remain true to the scientific spirit of peer review. Yet, whereas many of its advocates appear to hope this will not happen, and many of its critics believe it is not possible, we show in Part IV that this is precisely what regulatory peer review will do if properly designed and given the chance.

III. THE CASE FOR PEER REVIEW

Despite the controversy 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. Improving agency decision making is hardly a new concern, of course. Indeed, many basic methodologies to ensure sound agency decisions are already firmly embedded in the basic standards of administrative law prescribed under the Administrative Procedure Act (APA).⁶⁵ These rules require the courts to apply considerable deference to the agency’s decision. A reviewing court may not substitute its judgment for the agency, but must undertake a “thorough, probing, in-depth review” of the agency’s decision.⁶⁶ Thus, a court will reject an agency’s decision if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”⁶⁷ An agency decision is arbitrary and capricious if the agency either “has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of

⁶¹ Endangered and Threatened Wildlife and Plants: Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities, 59 Fed. Reg. 34,270, 34,270 (July 1, 1994). This process, they explain, will involve “[s]olicit[ing] the expert opinions of three appropriate and independent specialists regarding pertinent scientific or commercial data and assumptions relating to the taxonomy, population models, and supportive biological and ecological information for species under consideration for listing.” *Id.* We assess the results of this ESA peer review in Section IV, *infra*.

⁶² For example, neither FWS nor NOAA instituted peer review for their respective decisions in the Klamath controversy.

⁶³ Although several other environmental statutes use the phrase or something close to it, all leave it undefined. See Doremus, *supra* note __, at 1034 n.9 (collecting statutes); Michael J. Brennan et al., *Square Pegs and Round Holes: Applications of the “Best Scientific Data Available” Standard in the Endangered Species Act*, 16 TUL. ENVTL. L.J. 387, 402 n.81 (2003).

⁶⁴ *Bennett v. Spear*, 520 U.S. 154, 176 (1997).

⁶⁵ 5 U.S.C. § 706 (2000).

⁶⁶ *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971).

⁶⁷ 5 U.S.C. § 706(2)(A) (2000).

the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise,”⁶⁸ or if it has failed to “articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”⁶⁹

A scientist would be accused of practicing unsound science in research if he or she declared that relevant data was ignored or altered in reaching the research conclusion simply because the data did not support the conclusion.⁷⁰ Likewise, under the foregoing rules of judicial review an agency would be chastised for doing the same in reaching the decision of a rulemaking or adjudication. Such conduct would be arbitrary and capricious, and any court acting on judicial review of the decision would know to strike it down as a violation of the APA. A court would not need to employ new principles or methodologies to justify such a ruling.

This is a powerful rebuttal to the general advocacy of “sound science” for agency decision making, but it does not adequately address arguments specifically for regulatory peer review. The fact is, peer review is neither mandated by most environmental laws nor required through the default administrative law doctrines of the APA. Arguments that peer review, in some form or another, already is present in conventional administrative law processes miss the point. Public participation in regulatory decisions through notice and comment for rulemaking or representation in adjudicatory proceedings provides a form of outside review, but it does not screen out biased members of the public and is not limited to experts.⁷¹ Indeed, quite the opposite is true. Only biased members are *likely* to get involved. Judicial review of agency decisions ensures a form of close review by an ostensibly unbiased party, but it cannot approach the same level of expertise provided by peer review and, in any event, judges must adhere to the review standards of the APA, not those of scientific peer review.⁷² Peer review, in other words, is the one clear demand of the “sound science” movement that administrative law does not already require.

Still, the fact that regulatory peer review is not already required does not compel the case for requiring it. What does peer review offer regulation that other procedural safeguards do not? The promised benefits of integrating peer review into the regulatory decision-making process, its advocates claim, are both substantive and procedural. In short, the argument is that providing independent expert feedback will generally improve the quality of regulatory decisions.⁷³ Like Representative Walden’s folksy reference to a doctor’s second opinion,⁷⁴ in its initial proposal for mandatory peer review OMB asserted that peer review can “provide a vital second opinion on the science that underlies federal regulation.”⁷⁵ Proponents argue that the use of independent, outside experts in regulatory peer review should also enhance the legitimacy of the regulatory process by reducing the appearance of agency bias and conflict of interest.⁷⁶

⁶⁸ *Motor Vehicle Mfrs. Ass’n of the United States v. State Farm Mut. Auto. Ins. Co. (State Farm)*, 463 U.S. 29, 43 (1983).

⁶⁹ *Id.* (citation omitted).

⁷⁰ See, e.g., Gretchen Vogel et al., *Ecologists Roiled by Misconduct Case*, 303 SCI. 606 (2004) (reporting developments concerning allegations that a world-renowned ecologist fabricated data in a published study of genetic fitness traits).

⁷¹ See Noah, *supra* note __, at 1074–76. OMB makes the point, in its final peer review policy, that “peer review should not be confused with public comment and other stakeholder processes.” OMB Final Bulletin, *supra* note __, 70 Fed. Reg. at 2665.

⁷² See Noah, *supra* note __, at 1076–77.

⁷³ See Lars Noah, *Peer Review and Regulatory Reform*, 30 *Envtl. L. Rep. (Envtl. L. Inst.)* 10606, 10608 (2000).

⁷⁴ See *supra* note __.

⁷⁵ See OMB Proposed Bulletin, *supra* note __, 68 Fed. Reg. at 54,024.

⁷⁶ See OMB Proposed Bulletin, *supra* note __, 68 Fed. Reg. at 54,024.

Other than pointing to the Klamath experience, however, what theoretical or empirical support do advocates of regulatory peer review advance for the claim that what is good for science is good for regulation? In this section we lay out the central chain of reasoning behind leading regulatory peer review proposals. There are, in fact, good reasons to believe that agencies face institutional biases and pressures that could lead employees to fall short of adequate use of science in regulatory settings. In addition, we found in our survey that practitioners of environmental law working primarily in the private sector harbor a deep distrust of agencies in this regard, distrust based, we presume, not primarily on political theory but rather on personal perspective and practical experience. The thrust of regulatory peer review in Congress and the White House has clearly been in response to these perceived defects in agency process.

A. Institutional Theory

A key assumption underlying regulatory peer review proposals is that agencies often, perhaps systematically, use science poorly in their decisions. To be sure, some advocates of peer review support this assertion with no more than a basic distrust of government and regulation. But political science theory suggests why one might be concerned over agency use of science, quite apart from anti-regulatory agendas.

There is an immense literature on the institutional challenges inherent in agency operation, and many of these theories explain why agencies might selectively use scientific data in a biased or incomplete manner.⁷⁷ The theory of agency mission focus, for example, asserts that single-mission agencies tend zealously to further their statutory missions in a single-minded fashion.⁷⁸ This is a variant on the theories of agency capture and public choice, where the agency comes to view furthering the interests of the regulated community as more important to its mission than protecting the more amorphous public interest.⁷⁹

Personal bias can also play a role. Most biologist who work for the FWS or NOAA, one could reasonably imagine, care personally about conserving wildlife – that’s why they become wildlife biologists and have devoted their careers to working in an agency dedicated to wildlife conservation. There may be a set of “shared biases” for members of a discipline such as biology working in a mission-focused agency. If the neutrality of agency biologists is not to be trusted, this argument suggests—and this is clearly an underlying premise of the “sound science” movement—it is because they are *agency* biologists, not because they are simply biologists.⁸⁰

Finally, and perhaps most important, agencies work in an environment of serious resource and time constraints. The conclusion of the Klamath Committee, for example, was *not* that the agency decision makers dissembled or acted in bad faith. Rather, with decisions needing to be made within demanding time frames, often on the basis of uncertain and inconclusive data, the decision makers chose a course that experts at a later date, with more time and expertise to review the data, concluded was not supported by the available information. One need not adopt a cynical view of agency behavior to understand why the exigencies of making complicated decisions in a short time period based on uncertain or conflicting data can sometimes lead to decisions with no sound scientific basis.⁸¹ Nevertheless, time and resource constraints do appear

⁷⁷ Wendy Wagner’s comprehensive study of these institutional forces remains the classic study of the topic in the context of science and policy. See Wagner, *Science Charade*, *supra* note __, at 1650-72. In general, an understanding of these institutional theories is considered a foundation of administrative law in general. See RICHARD J. PIERCE, JR., ET AL., *ADMINISTRATIVE LAW AND PROCESS* § 1.7, 16-23 (3d ed. 1999).

⁷⁸ See PIERCE ET AL., *supra* note __, at 17-18.

⁷⁹ See PIERCE ET AL., *supra* note __, at 18-19.

⁸⁰ See PIERCE ET AL., *supra* note __, at 21-22.

⁸¹ The Klamath Committee recognized that “agencies may recommend practices for which the committee would find virtually no direct scientific support. The committee acknowledges the necessity of this

to be yet one more reason to believe that agencies may reach decisions with no sound scientific basis.

Arguing against the use of peer review in regulatory agencies, therefore, invites accusations of trying to hide the flaws of agency practice in the shadow of “agency expertise.” Advocates of peer review contend that it is the light that will expose those flaws, leading to improved quality of agency decisions and revealing the biases of agency decision makers. On the surface, therefore, peer review may have something to offer administrative law in general. Some veteran FWS field personnel believe, in fact, that “application of peer review to proposed listings and draft recovery plans has fallen short of its potential to promote scientifically sound decision making.”⁸²

At the same time, regulatory peer review clearly imposes costs on agencies that are already operating under tight resource constraints. One can agree with all of the theoretical explanations of why agencies might use science poorly. One can fully embrace the arguments explaining why peer review will improve agency decisions. But, taken singly or together, these alone do not provide compelling justifications for greater use of regulatory peer review for the simple reason, as already noted, that we just don’t know how many Klamaths are out there. Whether intentional or good faith mistake, what is the frequency of poor science-based decisions? Without a sense of how big a problem this poses, we cannot state with any confidence that the theoretical benefits of peer review outweigh the actual costs of implementation.

B. Faith, Perceptions, and Demand

We know of no comprehensive empirical study comparing regulatory decisions with and without peer review, or attempting to re-evaluate 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 make poor use of science.

Faith, however, is a powerful force when it is shared by a multitude. If enough of the public believes agencies make poor use of science, that this leads to policy failures, and that regulatory peer review is an effective check on the problem, arguments for imposing regulatory peer review will have traction. Even more compelling, if enough of the people who share these beliefs are experienced in administrative law and policy—can claim to have practical experience with agency regulatory practices—the public is less likely to demand empirical study of the issue before acting to put regulatory peer review in place. Indeed, this is precisely what we found to be the case in our survey.

We designed our survey to elicit respondents’ perceptions about the performance of regulatory agencies, the merits of regulatory peer review, and the design of regulatory peer review.⁸³ With respect to agency performance, we posed a general question and many detailed

practice in many situations where information is inadequate for development of scientifically rigorous decisions.” KLAMATH COMMITTEE FINAL REPORT, *supra* note __, at 119.

⁸² Anne Hecht and Mary J. Parkin, *Improving Peer Review of Listings and Recovery Plans under the Endangered Species Act*, 15 CONSERVATION BIOLOGY 1269, 1270 (2001) (article submitted September 2000—i.e., during the Clinton administration).

⁸³ 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.

questions relating to different attributes of agency use of science. 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 percent of respondents stated some level of agreement with the statement, 51 percent somewhat or strongly disagreed, suggesting a significant background level of concern over agency use of science among experienced practitioners. Indeed, in more detailed questions respondents revealed a deep mistrust of agency behavior. Figure 1 shows the percentage of respondents selecting different levels of agreement or disagreement with specific statements about components of agency use of science:

Figure 1. 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.

	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	41	13
d. Agencies generally place an adequate priority on searching for scientific data relevant to their decisions	9	31	11	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	11	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	12	48	8

We were not surprised to find (questions a through c) that so many respondents, consistent with institutional theory, believe that agencies face significant time and resource constraints in their use of science. We were more troubled (questions d through f) by the level of concern respondents revealed about how agencies prioritize their search for data and about how they select and rely data in support of their decisions, with almost half of respondents expressing negative perceptions of agency behavior. Most startling to us, however, were the responses to the final two questions in the series (questions g and h). Over 70 percent of respondents disagreed, 20 percent strongly so, with the statement that agencies generally give appropriate recognition to

scientifically reliable data that contradict their preferred decisions, and 56 percent 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 simply misuse science in their decision processes.

Of course, not all respondents felt this way, but what sharpens the difference of opinion even more so is the background of respondents with favorable views of agencies versus those with negative views. Not surprisingly, respondents who indicate federal or state agency government employment (combined in a regrouping designated as “G”) as their primary career experience, which made up 15 percent 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 industry (combined in a regrouping designated “I”), which accounted for 73 percent 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. Figure 2 shows how extensive this difference of opinion was for each of the specific questions about agency performance:

Figure 2. The second column shows which group, federal or state government career (G) or private firm or in-house industry career (I), was significantly more likely agree with the statement in the first column (i.e., answer “strongly agree” or “somewhat agree”), based on the breakdown between the two groups of who agreed (third and fourth column) and on the odds that a person selected randomly from the more likely group would agree compared to a person selected randomly from the less likely group (fifth column):

	More Likely to Agree	% agreeing that were G	% agreeing that were I	Odds
a. Agencies generally have sufficient time to conduct adequate searches for and analyses of scientific data relevant to their decisions	Neither			
b. Agencies generally have sufficient budgets to conduct adequate searches for and analyses of scientific data relevant to their decisions	G	70	30	5.7:1
c. Agencies generally have sufficient expertise to conduct adequate searches for and analyses of scientific data relevant to their decisions	G	64	36	3.3:1
d. Agencies generally place an adequate priority on searching for scientific data relevant to their decisions	G	63	37	2.9:1
e. Agencies usually select data that have adequate scientific reliability	G	60	40	2.2:1
f. Agencies generally place appropriate reliance on scientific data that support their preferred decisions	Neither			
g. Agencies generally give appropriate recognition to scientifically reliable data that contradict their preferred decisions	G	75	25	8.8:1
h. Agencies usually employ adequate scientific analysis when using the data they present as supporting their final decisions	G	71	29	6.3:1

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 fall 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 must be remarkably deep and broadly shared.

Our survey reveals a sharp difference of opinion between agency lawyers and lawyers representing industry about agency use of science. It is important to note, however, that interest groups associated with environmental causes also hold to the faith that agencies misuse science. Studies have shown that support for peer review under the ESA is strong in both the industry and the environmental camps, and is almost always limited to applying the review to the type of decisions each interest group finds the most troublesome. Dr. Deborah Brosnan has found, for example, that more than sixty prominent lobbying groups representing a diverse array of interests actively supported using peer review under the ESA, but that “each group favors review of actions that it finds unpalatable. Development groups want fewer species listings and therefore

demand review of listing decisions...Environmental groups are concerned about habitat loss under HCPs and want them independently reviewed.”⁸⁴

Indeed, in recent years some of the most vocal critics of agency use of science are scientists and environmental groups, who have made widespread allegations that political appointees in the Bush administration have forced agency scientists to manipulate, suppress, and distort scientific data. One group of prominent scientists endorsed a statement accusing the Bush Administration in general of misusing science.⁸⁵ Democrat members of Congress have produced reports accusing agencies of intentional suppression and distortion of scientific data,⁸⁶ and of practicing “weird science.”⁸⁷ Even scientists within NOAA have recently claimed that they have witnessed outright suppression and distortion of science within their agency.⁸⁸ In short, the perception that agencies misuse science has begun to transcend neat political boxes.

It does not surprise us that there are different denominations sharing the faith that agencies misuse science, so many, in fact, that it seems as if everyone except the agencies believes there is a significant problem. Regulatory agencies deal with so many issues affecting so many interest groups, it is likely that an agency will eventually offend every interest group with whom it deals a sufficient number of times to raise the concern in every interest group that science is being misused. Perhaps on each matter it depends on whose ox the agency gores, but over time if the agency gores everyone’s ox, the reliability of agency science is fair game for all.

But the breadth of this perception does not itself explain the extensive support for regulatory peer review. Here again, however, we found what appears to be a strong set of beliefs in the merit of regulatory peer review and what it could accomplish. Figure 3 shows the extent to which practitioners of environmental law turn to regulatory peer review as an answer to the perceived misuse of science by agencies:

⁸⁴ Deborah M. Brosnan, *Can Peer Review Help Resolve Natural Resource Conflicts?*, 16 ISSUES IN SCIENCE AND TECHNOLOGY 32, 33 (2000).

⁸⁵ See *Restoring Scientific Integrity Signatories*, available at http://www.ucsusa.org/global_environment/rsi/page.cfm?pageID+1335.

⁸⁶ See MINORITY STAFF OF COMM. ON GOV’T REFORM, POLITICS AND SCIENCE IN THE BUSH ADMINISTRATION, available at http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf (Nov. 13, 2004).

⁸⁷ See DEMOCRATIC STAFF OF COMM. ON RESOURCES, WEIRD SCIENCE: THE INTERIOR DEPARTMENT’S MANIPULATION OF SCIENCE FOR POLITICAL PURPOSES, available at <http://www.ourforests.org/wierdscience.pdf> (dec. 17, 2002).

⁸⁸ See *Officials, Scientists Spar over Whether Politics Trumps Science at NMFS*, Endangered Species & Wetlands Rep., June 2005, at 14-15.

Figure 3. We asked respondents to indicate the extent to which they agree or disagree with the following statements about the potential effects of applying Regulatory Peer Review to proposed regulatory decisions. Figures show percent of respondents in each category:

	Strongly Agree	Somewhat Agree	No Opinion	Somewhat Disagree	Strongly Disagree
a. It is likely to lead to substantial improvements in the quality of agency decisions	28	46	14	17	3
b. It is likely to reveal significant flaws in the ways agencies generally search for, select, or use scientific data	25	41	14	17	3
c. It is likely to improve public confidence in agency decisions	28	42	16	11	3

The perception that regulatory peer review is the answer to agency misuse of science appears to be overwhelming, with well over 65 percent 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 percent or less disagreeing that each of those expected benefits will accrue. Yet, given how little regulatory peer review is employed today in agency practice, what is the foundation for this set of beliefs? Once again, it appears to be little more than faith, for most of our respondents had never had direct contact with regulatory peer review. Over 60 percent of our respondents had neither represented a client in a matter undergoing regulatory peer review, nor advocated about whether to adopt regulatory peer review, nor even counseled a client generally about what regulatory peer review is. Indeed, as further support that views on regulatory peer review are largely based on faith, we were not surprised to find that government and industry attorneys differed about the effects of regulatory peer review, as shown in Figure 4, though we were no less than shocked by the degree of disagreement.

Figure 4. The second column shows which group, federal or state government career (G) or private firm/in-house industry career (I), was significantly more likely agree with the statement in the first column (i.e., answer “strongly agree” or “somewhat agree”), based on the breakdown between the two groups of who agreed (third and fourth column) and on the odds that a person selected randomly from the more likely group would agree compared to a person selected randomly from the less likely group (fifth column):

	More Likely to Agree	% agreeing that were G	% agreeing that were I	Odds
a. It is likely to lead to substantial improvements in the quality of agency decisions	I	16	84	33.3:1
b. It is likely to reveal significant flaws in the ways agencies generally search for, select, or use scientific data	I	22	78	12.5:1
c. It is likely to improve public confidence in agency decisions	I	19	81	20:1

Agency 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 counter-perception that appears to have taken hold among those who practice before them?

C. Meeting the Demand

Our survey results suggest that demand for regulatory peer review is strong among experienced practitioners of regulatory law. Responding to that demand, the Bush Administration has supported the policy that federal agencies broadly employ more rigorous peer review in their decision-making processes.⁸⁹ Indeed the centerpiece of the Bush Administration's "sound science" push has been OMB's peer review policy. Based ostensibly on authority granted in the Data Quality Act,⁹⁰ OMB's approach requires federal agencies to conduct "appropriate and scientifically rigorous peer review" of "influential scientific information" and "highly influential scientific assessments" an agency disseminates to the public.⁹¹ In its initial September 2003 proposal, OMB claimed this mandate will "improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public," because it will "provide a vital second opinion on the science that underlies federal regulation."⁹²

OMB responded to a wide range of comments on its initial proposal⁹³ and published a revised proposal in April, 2004.⁹⁴ Deleting its prior assertion that regulatory peer review is tantamount to a "second opinion," OMB then asserted that peer review would evaluate:

the clarity of hypotheses, the validity of the research design, the quality of the data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall project.⁹⁵

OMB received more comments on the revised policy,⁹⁶ though far fewer than on the original proposal, and adopted a final policy in December 2004 with relatively minor refinements.⁹⁷ Under the final policy, agency information subject to review would include data,

⁸⁹ See OMB Revised Bulletin, *supra* note __, 69 Fed. Reg. at 23,230 ("peer review improves both the quality of scientific information and the public's confidence in the integrity of science"), OMB Proposed Bulletin, *supra* note __, 68 Fed. Reg. at 54,024 ("Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses.").

⁹⁰ The Data Quality Act, also known as the Information Quality Act, is actually a set of provisions embedded in a 2001 appropriations bill, and requires, among other things, that OMB "issue guidelines...that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information...disseminated by Federal agencies"). Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153-54 (2001).

⁹¹ See OMB Revised Bulletin, *supra* note __, 69 Fed. Reg. at 23231; OMB Proposed Bulletin, *supra* note __, 68 Fed. Reg. at 54,027. Some observers have questioned OMB's authority to require peer review. See Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 34 *Envtl. L. Rep. (Envtl. L. Inst.)* 10064 (2004).

⁹² See OMB Proposed Bulletin, *supra* note __, at 54023-24.

⁹³ Public comments on the OMB Proposed Bulletin are posted at http://www.whitehouse.gov/omb/infocreg/2003iq/iq_list.html.

⁹⁴ See OMB Revised Bulletin, *supra* note __.

⁹⁵ OMB Revised Bulletin, *supra* note __, 69 Fed. Reg. at 23,231.

⁹⁶ Public comments on the OMB Revised Bulletin are posted at http://www.whitehouse.gov/omb/infocreg/peer2004/list_peer2004.html.

⁹⁷ See OMB Final Bulletin, *supra* note __, 70 Fed. Reg. 2664.

synthesis of facts, models, analyses, and assessments that will have a clear and substantial impact on public policies or private sector decisions. This could range from state of science reports, meta-analyses, and risk assessments to toxicity profiles and health and ecology assessments. Not all science underpinning decisions can be peer reviewed, of course, so the decision must have \$500 million of regulatory or private sector impact or have novel, precedent setting impact or significant inter-agency interest. If the data have already been subject to adequate peer review (e.g., journal review), no further review is needed. Otherwise, the agency must apply internal or external peer review by technical experts not associated with the work product and provide a summary or copy of comments to the public. The agency must publicly respond to the peer review report, and in some cases public comment and hearing on draft peer review report may be appropriate.

On the legislative side, a series of “sound science” reform bills have been proposed in Congress to amend the ESA. The “Sound Science for Endangered Species Act Planning Act of 2002,” introduced by Representative James Hansen (R-Utah), is the genesis of a line of such legislation that has followed since then in similar spirit.⁹⁸ In general, these proposals⁹⁹ would alter the procedures, standards of evidence, and burdens of proof under which federal agencies operate in carrying out ESA programs.¹⁰⁰ The legislation would stiffen ESA procedures in many respects, requiring FWS and NOAA to give preference to certain forms of evidence and apply more rigorous burdens of proof to a long list of specified decisions. In particular, the bills would require FWS and NOAA to give greater weight to field-tested and peer-reviewed data, accept data from affected landowners, solicit data on recovery plans, and, most important, subject every listing, critical habitat, recovery plan, and consultation decision to peer review by a three-expert panel. The resulting process would institute a much more formal and probing peer review process for many more ESA decisions than FWS imposed on itself under its internal 1994 peer review policy.

The proposed reforms have enjoyed strong support¹⁰¹ and engendered equally strident criticism.¹⁰² The Bush Administration generally has supported the reforms with only minor suggested changes.¹⁰³ The House Resources Committee held hearings on Representative Hansen’s bill in June 2002¹⁰⁴ and reported it favorably on July 10, 2002 in a 22-18 vote that followed party lines.¹⁰⁵ It remains a good indication of what to expect to be proposed in the

⁹⁸ H.R. 4840, 107th Cong. (2d Sess.) (2002).

⁹⁹ For a more recent version, see S. 369, 108th Cong. (1st Sess.) (2003), and H.R. 1662, 108th Cong. (1st Sess.) (2003). For a history of peer review provisions in ESA reform bills preceding H.R. 4840, see Brennan et al., *supra* note __, at 433-40.

¹⁰⁰ See Burke, *supra* note __, at 506-07.

¹⁰¹ See, e.g., NATIONAL ENDANGERED SPECIES ACT REFORM COALITION, H.R. 4840, THE SOUND SCIENCE FOR ENDANGERED SPECIES ACT PLANNING ACT OF 2002, at <http://www.nesarc.org/walden.htm> (last visited Jan. 19, 2004) (providing links to several relevant sites).

¹⁰² See, e.g., Press Release, Defenders of Wildlife, Statement by Rodger Schlickeisen, President of Defenders of Wildlife, on Committee Markup HR 4840, a Bill that Purports to Offer “Sound Science” for ESA (July 11, 2002), available at <http://www.defenders.org/releases/pr2002/pr071102.html> (calling the proposal “one more effort by the ‘development at any cost’ crowd to gut the ESA”).

¹⁰³ See DIVISION OF CONGRESSIONAL AND LEGISLATIVE AFFAIRS, U.S. FISH & WILDLIFE SERVICE, FISH AND WILDLIFE SERVICE TESTIMONY BEFORE THE 107TH CONGRESS, available at <http://laws.fws.gov/testimon/2001/main2001.html> (resonating that “sound science” has become a theme across many programs in the Bush Administration).

¹⁰⁴ Hearing of the House Resources Comm., Subcomm. On Fisheries Conservation, Wildlife and Oceans on H.R. 4781 The Marine Mammal Prot. Act Amendments of 2002, (2002) at <http://www.legendative.noaa.gov/Archives/2002/hogarthhearingreport061302.pdf>.

¹⁰⁵ E.g., Legislative Alert, Nat’l Endangered Species Act Reform Coalition, ESA Victory: Sound Science Legislation Passes House Resources Committee (July 11, 2002), available at <http://www.nesarc.org/4840alert.pdf> (last visited Nov. 7, 2003).

current Congress, and supported in the Bush Administration, in the way of efforts to make the ESA more “scientific” in method.¹⁰⁶

OMB and Congress offer no empirical evidence for their rush to meet the demand for regulatory peer review. But so what? The institutional theory supporting the case for peer review is practically a given in administrative law scholarship, and the perception that agencies misuse science appears to be widely held by attorneys and interest groups that appear before regulatory agencies. In politics, that’s usually more than enough. But even an objective analysis must acknowledge these bases for supporting regulatory peer review and ask of those who oppose it what case they have in response.

IV. THE CASE AGAINST PEER REVIEW

Critics of mandating regulatory peer review have advanced two positions. The first is that there is insufficient evidence suggesting agencies make improper use of science. Failing that, they argue that peer review is by no means a solution to the alleged problem of poor use of science by agencies, but rather a practice to be avoided at all costs. Not only will it fail to provide the promised benefits, they argue, it will further politicize the decision making process and slow down agency process to the point of frustrating agencies’ missions to protect the public welfare. Alas, when examined closely, these arguments rest on simply a different faith than the one held by the supporters of regulatory peer review.

A. There’s not a Problem

Our survey revealed that attorneys representing agencies as the primary focus of their careers generally believe that regulatory agencies do not misuse science. This is a theme of most critiques of regulatory peer review. For example, Wendy Wagner asserts that “there are surprisingly few examples of EPA using unreliable science or using science inappropriately to support a final regulation” and that “the examples of regulatory bad science are winnowed down to a few, virtually all of which are contested.”¹⁰⁷ Upon closer examination, however, her assertion is without affirmative empirical foundation. She points to evidence such as testimony from an EPA official, who merely denies the agency misuses science, testimony of one independent scientist who makes the same assertion, and a law review article observing not that empirical evidence supports her view, but rather that although “there is widespread belief that many of the problems surrounding the law-science interactions are attributable to junk science[,] [t]his hypothesis is largely unexamined...[,] [and] there is no empirical evidence to support this conclusion.”¹⁰⁸ She also discusses several expert studies of EPA’s use of science, some of which suggest the agency could do better in its scientific methodology, and others of which are silent on the issue of misuse of science.¹⁰⁹ She also excludes from here assertion, as do all the other sources she references, “the larger universe of regulatory decisions involving the grant of permits and licenses,”¹¹⁰ which is, of course, a principal target of many proposals for regulatory peer review. In short, neither she nor anyone else critiquing regulatory peer review has presented evidence based on systematic, objective

¹⁰⁶ [Update at publication with current state of play in Congress]

¹⁰⁷ See Wagner, *Bad Science*, *supra* note ___, at 72-73.

¹⁰⁸ See *id.* at 72 n.38.

¹⁰⁹ See *id.* at 73-77.

¹¹⁰ See *id.* at 73.

analysis of any meaningful set of agencies' *regulatory* decisions. Nevertheless, her assertion is repeated in critiques of regulatory peer review as if it is an empirical fact.¹¹¹

To be sure, if the argument is simply that there has been no comprehensive examination of the prevalence of agency misuse of science, or that there is no reliable empirical study showing agencies widely misuse science, we agree. As we explained in the previous section, however, we do not believe such an assertion is adequate rebuttal of the case for regulatory peer review. One might argue that the burden is on advocates of regulatory peer review to produce empirical proof that agencies misuse science, in which case that burden unquestionably has not been met.¹¹² But why place the empirical proof burden on the side that wishes to employ, for agencies that base regulatory decisions in whole or in part on science, a procedure that has been the bedrock of science for over 300 years? Given how crucial peer review is to the scientific method, and given the institutional forces that suggest agencies may misuse science and the belief held by many industry and environmental interests alike that in fact they do, it is not unreasonable to expect critics of regulatory peer review to demonstrate that what is good for science is unnecessary for regulation. Observing that a data vacuum exists, therefore, does little to advance their cause.

B. If there is a Problem, Peer Review is not the Solution

Our survey revealed that attorneys representing agencies as the primary focus of their careers generally believe that agencies do not misuse science. This is the fallback theme of most critiques of regulatory peer review. For example, in response to OMB's initial proposal for regulatory peer review, the American Association for the Advancement of Science issued a resolution condemning the proposal on several grounds, including that "there is no evidence that proposed new procedures are likely to improve the quality of science used in the regulatory process."¹¹³ Of course, there is no evidence regulatory peer review is unlikely to improve the quality of science used in the regulatory process either. Putting aside the issue of which side bears the burden of proof in this regard, on this score the critics of regulatory peer review have some strong institutional reasons for suggesting caution in its use.

One concern is that advocates of regulatory peer review promise too much and thus distort the public's expectations of agency practices. Recall that Representative Walden and the OMB's initial peer review proposal both portrayed regulatory peer review as a "second opinion." That sounds pretty attractive—after all, who wouldn't want a second opinion before amputating a limb? But peer review does *not* provide a second opinion in the conventional sense. Medical doctors providing a second opinion examine the patient, not just the other doctor's written opinion; whereas scientists providing peer review for professional journals do not "examine the patient" in the form of conducting independent experimentation or data analysis. As Lars Noah has described, "policymakers often seem to conflate peer review with science itself, which in turn may lead them to exaggerate the possible utility of independent expert scrutiny of decisions based on science."¹¹⁴

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

¹¹¹ See Sidney Shapiro, *The Case Against the IQA*, THE ENVTL. F., July-Aug. 2005, at 26, ___.

¹¹² See Wagner, *Bad Science*, *supra* note ___, at 76-78 (demonstrating "the failure of the reformers themselves to document a problem").

¹¹³ American Association for the Advancement of Science, *On the PMB Proposed Peer Review Bulletin*, available at http://archives.aaas.org/docs/documents.php?doc_id+434.

¹¹⁴ Noah, *supra* note ___, at 1046.

interpret the data and then, where permitted or required, to employ other policy considerations to reach a final decision. Regulatory peer review will not close the data gaps or ensure that every agency decision is fully supported by science.¹¹⁵ If advocates of regulatory peer review suggest otherwise, they risk overselling to the public what regulatory peer review really offers.

This leads to another concern—that, far from advocates’ claims that peer review will eliminate bias from agency decisions, it will actually exacerbate these concerns by allowing agencies to hide cover up their biases in the veneer of science. Agencies, themselves, can misuse peer review. The ESA provides a particularly illustrative example. FWS and NOAA have long been criticized for operating a “black box” style of decision-making—relatively closed to the public, relying on informal channels of scientific communication, and generally unwilling to communicate their data and scientific reasoning in a manner that facilitated review by the public and the courts.¹¹⁶ The 1994 peer review policy, described earlier, was intended to fix that—to instill greater confidence in the public and the courts. These agencies pledged to “incorporate independent peer review in listing and recovery activities.”¹¹⁷ This step would involve “[s]olicit[ing] the expert opinions of three appropriate and independent specialists regarding pertinent scientific or commercial data and assumptions relating to the taxonomy, population models, and supportive biological and ecological information for species under consideration for listing.”¹¹⁸ Sounds like regulatory peer review.

In 2003, however, the General Accounting Office (GAO) conducted a study of how FWS had implemented the peer review policy. Its findings were disturbing. Perhaps most important, the process was informal and actually seemed to invite bias. The report noted that “Service officials told us that they have not adopted a formal procedure to assess peer reviewers’ independence, and the Service does not publicly disclose . . . potential conflicts or prior involvement by its peer reviewers.”¹¹⁹ Although the agency guidelines explained that “[i]ndependent peer reviewers should be selected from the academic and scientific community, Tribal and other native American groups, Federal and State agencies, and the private sector,”¹²⁰ and that “those selected have demonstrated expertise and specialized knowledge related to the scientific area under consideration,”¹²¹ it was the agencies who selected their peer reviewers, reviewed the peer reviews, and reported the results of the peer reviews.¹²² The GAO found that FWS “peer reviewers are selected at the discretion of the field office scientists responsible for developing listing and critical habitat decisions.”¹²³ Not surprisingly, the study noted that the

¹¹⁵ Indeed, as we point out in Part V of the Article, 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.

¹¹⁶ See Doremus, *Listing Decisions*, *supra* note __, at 1082-87.

¹¹⁷ See PEER REVIEW IN ENVIRONMENTAL TECHNOLOGY DEVELOPMENT PROGRAMS, *supra* note __, at 2.

¹¹⁸ *Id.*

¹¹⁹ U.S. GENERAL ACCOUNTING OFFICE, GAO-03-803, ENDANGERED SPECIES: FISH AND WILDLIFE SERVICE USES BEST AVAILABLE SCIENCE TO MAKE LISTING DECISIONS, BUT ADDITIONAL GUIDANCE NEEDED FOR CRITICAL HABITAT DESIGNATIONS 15–16 (2003), *available at* <http://www.gao.gov/new.items/d03803.pdf>.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² See, e.g., Endangered and Threatened Wildlife and Plants; Final Rule to Reclassify and Remove the Grey Wolf from the Endangered and Threatened Wildlife in Portions of the Conterminous United States; Establishment of Two Special Regulations for Threatened Grey Wolves, 68 Fed. Reg. 15,804, 15,819–20 (Apr. 1, 2003) (to be codified at 50 C.F.R. pt. 17) (discussing FWS’s use of the peer review process in connection with a decision about the status of gray wolves (*Canis lupus*)).

¹²³ *Id.* at 15. By contrast, the NRC peer review policy, under which the Klamath Committee was formed, provides:

people FWS chose to serve as peer reviewers usually agreed with the agencies' positions.¹²⁴ Without independence of the reviewers ensured, however, this process and its results simply invite charges of manipulation.

Similarly, while OMB justified its proposal in part on the flaws in current federal agency peer review practices such as those used by FWS, OMB does not provide an encouraging example in its own actions. OMB has been required since 1997 to provide Congress an accounting statement and a report on its guidelines issued to agencies.¹²⁵ The *Accounting Statement and Report* would estimate the total annual costs and benefits of agency regulation and an analysis of the impacts of regulation on small businesses, local, state and tribal governments, and economic growth. In 2000, Congress required OMB to ensure an "independent, external peer review of the guidelines and each accounting statement and associated report." Research by Joanna Goger of OMB's peer review practice has revealed that the process has no internal guidelines, no conflict of interest disclosure requirements, repeatedly uses the same reviewers, and has no requirement of balance.¹²⁶ As one reviewer wrote to OMB following his review of the 2001 report, "At this point, you are likely getting tired of my comments so that next year you might want to bring on a new reviewer in my place."¹²⁷ Beyond the problem of hypocrisy—this process clearly fails to satisfy the procedures called for in OMB's proposal that other agencies must follow—is the institutional concern that OMB seems to have followed the example of FWS. 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.

The final major institutional critique against regulatory peer review is that, even if the preceding concerns are mistaken—that peer review will improve agency decisions and not be politically manipulated—the resources needed to carry out reviews will significantly delay regulatory decisions. This is the "paralysis by analysis" charge leveled against other broad, mandatory regulatory procedures such as cost-benefit analysis and risk assessments, criticized as "offering regulatory relief for industry in the guise of more rational procedures."¹²⁸ Inflexibly mandating rigorous peer review adds substantial demands on agency resources, potentially draining resources from other decision-making components and, in many cases, impeding decision-making altogether.¹²⁹

Indeed, the deadlines Congress has frequently placed on agency decision-making acknowledge the pressing need in many cases to intervene on policy problems. Agencies already have a difficult time meeting those deadlines,¹³⁰ and adding peer review steps to the process is unlikely to improve that experience. If regulatory peer review were to lengthen the decision process, it is possible in some cases that an agency will be unable to act before it is too late, as in,

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.

NAT'L RESEARCH COUNCIL, THE NATIONAL RESEARCH COUNCIL PROCESS, at <http://www.nationalacademies.org/about/faq4.html> (last visited July 10, 2003).

¹²⁴ *Id.* at 21–22.

¹²⁵ The OMB example is based on the presentation of Joanna B. Goger, *Peer Review of OMB's Cost-Benefit Reports to Congress*, Center for Progressive Regulation workshop, Baltimore, MD (Apr. 16, 2004) (presentation slides on file with authors).

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for example, an endangered species moving ever closer to extinction while the agencies engage in further process. In the context of regulatory regimes where decision time matters, mandatory regulatory peer review may well cause as many or more errors of omission than of commission.¹³¹

Just as the institutional theories for why agencies may misuse science make intuitive sense, so too do these institutional theories for why peer review may not be as good for regulation as it is for science. We found through our survey that many practitioners do in fact believe that one or more of these three major concerns about regulatory peer review are likely to occur, as shown in Figure 5.

Figure 5. We asked respondents to indicate the extent to which they agree or disagree with the following statements about the potential effects of applying Regulatory Peer Review to proposed regulatory decisions. Figures show percent of respondents in each category:

	Strongly Agree	Somewhat Agree	No Opinion	Somewhat Disagree	Strongly Disagree
a. It is likely substantially to slow down agency decision making processes	17	47	15	18	3
b. It is likely to add substantially to the costs of agency decision making	10	47	16	23	4
c. It is likely to add substantially to the incidence of litigation over agency decisions	7	19	17	45	12
d. It is likely to lead to erosion of agency personnel morale	3	17	29	40	10
e. It is likely to deter agencies from making the kinds of decisions that are subject to Regulatory Peer Review	9	31	30	23	7
f. It is likely to be subject to manipulation by agencies to serve their interests	8	40	27	19	5
g. It is likely to be subject to manipulation by interest groups to serve their interests	24	37	19	16	3

¹²⁸ Noah, *supra* note __, at 1068. See also Randolph J. May, *OMB's Peer Review Proposal—Swamped By Science?*, ADMIN. & REG. L. NEWS, Spring 2004, at 4, 4-5 (describing mandatory peer review as “an invitation for regulatory ossification”).

¹²⁹ Thus twenty former high-level agency officials, including former EPA directors Carol Browner and Russell Train, signed a letter to OMB stating that implementation of the OMB “proposal would lead to increased costs and delays in disseminating information to the public and in promulgating health, safety, and environmental and other regulations.” http://www.progressiveregulation.org/articles/Letter_Bolten_Sig.pdf.

¹³⁰ See U.S. GENERAL ACCOUNTING OFFICE, GAO-04-93, ENDANGERED SPECIES: MORE FEDERAL MANAGEMENT PROTECTION IS NEEDED TO IMPROVE THE CONSULTATION PROCESS (2003), (explaining how frequently the agencies exceed deadlines applicable to consultation under Section 7(a)(1) of the ESA).

¹³¹ See McGarvey & Marshall, *supra* note __, at 108-09 (suggesting this to be a serious concern under the ESA).

We did not find any surprising differences of opinion on these issues between government and industry attorneys. As shown in Figure 6, industry attorneys are more likely to believe regulatory peer review will slow down agency work and be subject to manipulation, government attorneys are more likely to believe it will add to litigation and erode agency morale, and the two groups agreed that it will add to agency costs and in their mixed feelings about whether it will steer agencies away from making decisions subject to peer review.

Figure 6: The second column shows which group, federal or state government career (G) or private firm/in-house industry career (I), was significantly more likely agree with the statement in the first column (i.e., answer “strongly agree” or “somewhat agree”), based on the breakdown between the two groups of who agreed (third and fourth column) and on the odds that a person selected randomly from the more likely group would agree compared to a person selected randomly from the less likely group (fifth column):

	More Likely to Agree	% agreeing that were G	% agreeing that were I	Odds
a. It is likely substantially to slow down agency decision making processes	I	37	63	3:1
b. It is likely to add substantially to the costs of agency decision making	Neither			
c. It is likely to add substantially to the incidence of litigation over agency decisions	G	71	29	6.2:1
d. It is likely to lead to erosion of agency personnel morale	G	70	30	5.5:1
e. It is likely to deter agencies from making the kinds of decisions that are subject to Regulatory Peer Review	Neither			
f. It is likely to be subject to manipulation by agencies to serve their interests	I	35	65	3.6:1
g. It is likely to be subject to manipulation by interest groups to serve their interests	I	37	63	2.9:1

Overall, therefore, the case against regulatory peer review, while not based on persuasive empirical evidence, does find support in basic institutional theory and in perceptions that are fairly widely held among experienced practitioners of regulatory law. Hence, while case for regulatory peer review seems to deserve serious consideration, so too does the case for proceeding with caution. Indeed, most of our respondents agreed that, on balance, the costs of regulatory peer review would not significantly outweigh the benefits.¹³² Rather than never employing regulatory peer review, or employing it all the time, a balanced approach thus seems called for.

Yet peer review has become a pawn in a much larger debate over the appropriate roles of science and policy in our society. As such, its supporters and its opponents alike overstate its advantages and disadvantages. There is little question that increased use of regulatory peer review would detect some cases of agency failure, but that it could also place some drag on agency process. The Klamath Committee, after all, did confidently conclude that the federal agencies acted without scientific foundation, but it took time and money to reach that conclusion. Most of the asserted promises and pitfalls of regulatory peer review, however, are posited in an empirical vacuum. In short, we really do not know how much benefit or burden to expect from wholesale or strategic application of regulatory peer review to administrative decisions.

V. RECONCEIVING THE ROLE OF REGULATORY PEER REVIEW

Since any discussion of regulatory peer review must operate, for now, based on theory and perception rather than empirical evidence, it is important to think clearly about how it might be implemented to balance the countervailing concerns. Before entertaining any specific proposal for its use, therefore, three overarching questions about regulatory peer review in general ought to be addressed: (1) what are its most important potential benefits; (2) where in the regulatory process could it be applied to maximize these benefits; and (3) under what conditions would it most likely substantially ossify 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 NRC report on the Klamath was issued, for example, one 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.”¹³³ In science, of course, that’s enough—one generally doesn’t 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 fact that the peer review found a lack of scientific support for the agency’s position rather than finding that scientific support refuted the agency’s position.

The difference, for regulatory decisions at least, is grounded in the policy component of administrative decision. In fact, Congress has quite infrequently commanded that an agency decision be based solely on scientific evidence conclusively proving the decision correct. In the Klamath setting, for example, the decision FWS was required to make involved an evaluation of whether the Bureau’s proposed water diversions would jeopardize the continued existence of the

¹³² Fifty-four percent of our survey respondents disagreed with the statement that “the likely costs (such as slowing down agency decisions) would significantly outweigh the likely benefits (such as improving the quality of agency data selection), whereas only 29 percent agreed and 16 percent had no opinion. Government attorneys were almost three times more likely to agree with the statement than were industry attorneys.

¹³³ Michael Grunwald, *Scientific Report Roils a Salmon War*, WASH. POST, Feb. 4, 2002, at A1.

protected fish species,¹³⁴ and Congress has commanded that FWS use the “best scientific data available” to make that decision.¹³⁵ This standard’s “obvious purpose . . . is to ensure that the ESA not be implemented haphazardly, on the basis of speculation or surmise.”¹³⁶ It is, in other words, a check on the uninformed use of science. But it does not handcuff the agency’s use of professional judgment in the face of incomplete scientific evidence. Rather, the courts have interpreted the standard to impose several practical guidelines for the agencies’ use of science:¹³⁷

- The agencies may not manipulate their decisions by “unreasonably relying on certain sources to the exclusion of others.”¹³⁸
- The agencies may not disregard “scientifically superior evidence.”¹³⁹
- Relatively minor flaws in scientific data do not render that information unreliable.¹⁴⁰
- The agencies must use the best data available, not the best data possible.¹⁴¹
- The agencies may not insist on conclusive data in order to make a decision.¹⁴²
- The agencies are not required to conduct independent research to improve the pool of available data.¹⁴³
- The agencies thus “must rely on even inconclusive or uncertain information if that is the best available at the time” of the decision.¹⁴⁴
- The agencies must manage and consider the data in a transparent administrative process.¹⁴⁵

Some of these are, quite clearly, *not* guidelines a scientist uses in the laboratory or the field. So it frequently will be the case that it is necessary for FWS to use some basis in addition to the best scientific data available for reaching a jeopardy decision. In some regulatory settings Congress prescribes additional policy-based factors, such as cost-benefit analysis, that an agency must meld with its scientific analysis to reach a final regulatory decision. In other cases, such as the ESA jeopardy analysis, it may come down to simply the agency’s exercise of professional judgment about which way to lean when the science is not definitive in either direction, jeopardy or nonjeopardy. Indeed, FWS and NOAA frequently have stated that they will “err on the side of

¹³⁴ 16 U.S.C. 1536(a)(2).

¹³⁵ *Id.* § 1536(c); 50 C.F.R. 402.14(g)(8) (2003). Neither the ESA nor the FWS regulations defines the standard. Although several other environmental statutes use the phrase or something close to it, all leave it undefined. *See* Doremus, *supra* note --, at 1034 n.9 (collecting statutes); Brennan et al., *supra* note --, at 402 n.81 (collecting statutes).

¹³⁶ *Bennett v. Spear*, 520 U.S. 154, 176 (1997).

¹³⁷ *See* *Southwest Ctr. for Biological Diversity v. Norton*, 2002 WL 1733618, at *8 (D.D.C. 2002) (summarizing the existing body of case law). For further discussion of these guidelines see generally Brennan et al., *supra* note 79, at 396–430; Doremus, *supra* note 15, at 1051–85; John Earl Duke, *Giving Species the Benefit of the Doubt*, 83 B.U. L. REV. 209 (2003); Laurence Michael Bogert, *That’s My Story and I’m Sticking To It: Is the “Best Available” Science Any Available Science Under the Endangered Species Act?*, 31 IDAHO L. REV. 85 (1994).

¹³⁸ *Southwest Ctr. for Biological Diversity*, 2002 WL 1733618 at *8.

¹³⁹ *Id.* (quoting *Las Vegas v. Lujan*, 891 F.2d 927, 933 (D.C. Cir. 1989), and citing *Southwest Ctr. for Biological Diversity v. Babbitt*, 926 F. Supp. 920, 927 (D. Ariz. 1996)).

¹⁴⁰ *Id.* (citing *Bldg. Indus. Ass’n of Superior Cal. v. Norton*, 247 F.3d 1241, 1246–47 (D.C. Cir. 2001)).

¹⁴¹ *Id.* (citing *Bldg. Indus. Ass’n of Superior Cal.*, 247 F.3d at 1246).

¹⁴² *Id.* at *9 (citing *Defenders of Wildlife v. Babbitt*, 958 F. Supp. 670, 680 (D.D.C. 1997)).

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ For a discussion of some of the case law that imposes this requirement, see Doremus, *supra* note 15, at 1084–87.

the species” in such cases.¹⁴⁶ This may be a perfectly appropriate policy decision, but it is not one the agency can use science to prove right in particular cases.

The problem is that agencies might not make the policy-based preferences or findings underlying their decisions explicit in their justifications. In the Klamath experience, for example, neither FWS nor NOAA presented any basis other than science for their respective decisions. In other words, once the Klamath Committee “said there wasn’t enough science to prove us right,” the agencies were left speechless—they had articulated no reasoned alternative basis to justify their decisions that led directly to the termination of irrigation water. It is not clear whether the agencies believed their scientific explanation was airtight, and thus no professional judgment was needed, or whether they simply believed enough science was presented so that nobody would ask for additional justification. Had the Klamath Committee not conducted its peer review, nobody would have asked, at least not in any way that would have been likely to succeed in demonstrating the lack of scientific support for the agencies’ positions.

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. Agencies should be loathe to have science prove their decisions wrong, but should take no pride when science does not prove their decisions right and no other supporting basis exists in the decision record. This is not to say that science alone must ever conclusively prove an agency right in order for its decision to be consistent with statutory expectations. Rather, 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. In short, the public ought to know how far science takes the agency in support of its decision, and what beyond science fills any gaps.

It is not just the potentially biased industry attorneys of our survey who believe this is an important goal of administrative law. Another National Research Council committee of experts, this one convened to review the scientific support for federal agency management decisions in the Platte River Basin, explained the difficulty agencies save in integrating incomplete and inconclusive science into regulatory decisions that involve value judgments.¹⁴⁷ The committee observed that the policy aspects of such decisions

are not scientific in the sense that they could, even in theory, be decided solely through evaluation of empirical, objectively gathered data. They require social or political value judgments that are inevitably subjective. The committee believes that these judgments should be made transparent; that is, [an agency] should clearly explain in a decision document both its evaluation of the scientific data and its use on nonscientific factors to reach a final decision.¹⁴⁸

Similarly, Cary Coglianese and Gary Marchant recently observed that

Embedded within any bare claim that a policy decision is “based on” science, or that science “leads to” a particular policy choice, will be some underlying normative position. If the core normative dimension to any policy decision is camouflaged in science, the

¹⁴⁶ See Interagency Cooperation—Endangered Species Act of 1973, As Amended; Final Rule, 51 Fed. Reg. 19,926, 19,952 (June 3, 1986) (“[T]he Service must provide the ‘benefit of the doubt’ to the species concerned.”); U.S. FISH & WILDLIFE SERVICE & NAT’L MARINE FISHERIES SERVICE, ENDANGERED SPECIES CONSULTATION HANDBOOK: PROCEDURES FOR CONDUCTING CONSULTATION AND CONFERENCE ACTIVITIES UNDER SECTION 7 OF THE ENDANGERED SPECIES ACT 1–6 (1998), available at <http://endangered.fws.gov/consultations/s7hndbk/s7hndbk.htm>.

¹⁴⁷ See NATIONAL RESEARCH COUNCIL, ENDANGERED AND THREATENED SPECIES OF THE PLATTE RIVER (2005).

¹⁴⁸ See *id.* at 99-100.

resulting policy outcomes, as well as any explanations or rationalizations offered in their defense, will likely be inconsistent if not unreasonable.¹⁴⁹

If this sharper delineation between science-based and policy-based support for decisions is seen as a benefit in the regulatory context, one would be hard-pressed to identify a better method for producing the effect than regulatory peer review. 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. Any question that peer review falls short of meeting this purpose ought to be dispelled by the fact that it has been in use for centuries and remains the essential ingredient of the scientific method in the opinion of most scientists.

Nevertheless, some have argued that regulatory peer review may actually *help* agencies camouflage misuse of science by giving policy decisions the appearance of a scientific exercise.¹⁵⁰ To be sure, peer review can be misused as easily as science can be misused, and thus its design matters. As yet another National Research Council committee recently concluded, however, peer review when properly conducted is a critical component of the transparency and openness desired of regulatory decisions.¹⁵¹ If peer reviewers, in their charge, are asked to identify aspects of a regulatory decision not supported by science, they have performed this service, and it would be left to the agency to explain what nonscientific factors went into filling the gap.

Moreover, as the *only* basis for supporting the conclusions of scientific research is science, the principal benefits of peer review in science are that researchers have an incentive to produce better research—research that will withstand the rigors of peer review—and the scientific community at large has greater confidence in the overall quality of published, peer-reviewed research. This same effect ought to be expected in the regulatory context as well—once agencies realize that peer review will weed out cases of oversold science and thereby focus attention on the quality of the agencies' use of science, agencies are more likely to be careful about their use of science. The result is that regulatory peer review ought to produce not only clearer delineations by agencies of their decision bases, but also better practices in their use of science to the extent it is offered as one or the principal basis of decision justification. The question is, since regulation is not science, where in the regulatory process can peer review best be applied so as to maximize these potential benefits?

B. Mapping Peer Review Onto Regulation

Opponents of the “sound science” movement frequently (and 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.¹⁵² Some agencies, of course, engage in pure research, and we assume nobody is opposed to having them undergo *scientific* peer review. Most regulatory agencies, such as FWS conducting a jeopardy evaluation, are neither expected by law nor equipped by budget to conduct the original research necessary to evaluate a decision. In the general sense, therefore, the “sound science” movement is truly off the mark.

¹⁴⁹ Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 PENN. L. REV. 1255, 1360 (2004).

¹⁵⁰ See Wagner, *Science Charade*, *supra* note __, at 1700.

¹⁵¹ See NATIONAL RESEARCH COUNCIL, IMPROVING THE USE OF THE “BEST SCIENTIFIC INFORMATION AVAILABLE” STANDARD IN FISHERIES MANGEMENT 56-57 (2004).

¹⁵² See Wagner, *Bad Science*, *supra* note __, at 109-32; Burke, *supra* note __, at 512-14.

But peer review is simply one component of the practice of competent science, and it imposes nothing directly in the way of requiring a researcher to do more science. It is quality control, not quantity control. To be sure, the result of peer review may be to fault a researcher for shortcutting some aspect of research—not enough test runs, too few data points, insufficient control procedures, and so on—which may translate into a finding that the research design was inadequate. But peer review does not impose arbitrary minimum quantities of procedures on researchers.

Seen in this light, once peer review is severed from the larger “sound science” movement, its use in regulatory contexts does not fall prey to the criticism that it is about quantity rather than quality. Indeed, it is all about the quality of the agency’s use of science, not the quantity of the agency’s conduct of science.

On the other hand, that is all that regulatory peer review is about—the agency’s use of science. To the extent that an agency is candid about the relative contribution of science and policy bases in support of a regulatory decision, therefore, regulatory peer review focuses exclusively on the science component. Anyone who has in mind going further—that is, subjecting the agency’s policy rationales to evaluation—is not talking about importing scientific peer review into the regulatory process.

Defined as such, peer review actually maps onto the regulatory process in a rather straightforward manner. Using the components of scientific peer review introduced earlier in the article, the following model compares scientific peer review to the four stages of the use of science in regulatory decision making: (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.

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 it 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

To illustrate more concretely how this model operates, consider the decision FWS and NOAA must make, once they have listed a species, whether or not to designate “critical habitat” for the species. Section 4(a)(3) requires the agencies, within certain time frames, and only “to the maximum extent prudent and determinable,” to “designate any habitat of such species which

is...considered to be critical habitat.”¹⁵³ Section 3(5)(A)(i) defines critical habitat as “specific areas within the geographic area occupied by the species, at the time it is listed..., on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management consideration or protection.”¹⁵⁴ Areas outside the species’ geographic range may be designated if they are “essential for the conservation of the species.”¹⁵⁵ These determinations must be made “on the basis of the best scientific data available.”¹⁵⁶ In either case, however, the agency must “tak[e] into consideration the economic impact, the impact on national security, and any other relevant impact, of specifying a particular area as critical habitat.”¹⁵⁷ Taking those impacts into consideration, the agency “may exclude any area from critical habitat if...the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat.”¹⁵⁸ However, this impact analysis may not be used to exclude an area if the agency “determines, based on the best scientific and commercial data available, that the failure to designate such area as critical habitat will result in the extinction of the species concerned.”¹⁵⁹

This snarl of science and policy decisions can be unpacked into its discrete components as follows:

- Step One—Science: What is the geographic range of the species and which areas within and outside that range contain biological or physical features essential to the conservation of the species?
- Step Two—Policy: Which areas identified in Step One that are within the geographic range require special management consideration or protection?
- Step Three—Policy: What are the economic and other impacts of designating areas that are candidates for designation after conclusion of Step One and Step Two?
- Step Four—Policy: Does the impact analysis from Step Three provide a basis for excluding candidate areas from designation, on the ground that the social and economic benefits of exclusion outweigh the benefits to the species of designation?
- Step Five—Science: Would exclusion of any areas based on Step Four lead to the extinction of the species?
- Step Six—Policy: Is there any other reason why designation would not be prudent?

Regulatory peer review, as we suggest it should be constructed, would not apply to any step designated as a policy question. Rather, only Step One and Step Five in our configuration of the critical habitat decision tree require the agency to search for, select, and interpret scientific data and research. Regulatory peer review applied to those two stages of the decision making process would engage in the following kinds of inquiry:

¹⁵³ 16 U.S.C. § 1533(a)(3).

¹⁵⁴ 16 U.S.C. § 1532(5)(a)(i).

¹⁵⁵ 16 U.S.C. § 1532(A)(ii).

¹⁵⁶ 16 U.S.C. § 1533(b)(2)).

¹⁵⁷ 16 U.S.C. § 1533(b)(2)).

¹⁵⁸ 16 U.S.C. § 1533(b)(2)).

¹⁵⁹ 16 U.S.C. § 1533(b)(2)). FWS has an unmistakable policy aversion to designating critical habitat, arguing on many occasions that it “provides little or no conservation benefit despite the great cost to put it in place.” Endangered and Threatened Wildlife and Plants; Final Determination of Critical Habitat for the Southwestern Willow Flycatcher, 62 Fed. Reg. 39,129, 31,130 (July 22, 1997). In addition, because few people understand its implications, FWS believes that the critical habitat process “can arouse concern and resentment on the part of private landowners and other interested parties.” Endangered and Threatened Wildlife and Plants; Proposed Rule to List Three Aquatic Snails as Endangered, and Three Aquatic Snails as Threatened in the Mobile River Basin of Alabama, 62 Fed. Reg. 54,020, 52,024 (Oct. 17, 1997).]

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 the species in question is limited, did the agency search for data and research about similar species?
Agency's selection of data and research identified in its search	How did the agency evaluate the quality of available data to select the "best available" as required by the statute? 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 appropriate reasons? Did the agency rely on data or research of questionable reliability?
Agency's interpretation of data and research selected	Are the agency's conclusions about the geographic range of the species, biological and physical features essential to the conservation of the species, and the threat of extinction were specific areas excluded from designation all 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 "maximum determinable" aspects of each of these inquiries?

None of these questions strikes us as inconsistent with the type of inquiry conducted in scientific peer review. Nor do they strike us as inappropriate questions to ask of an agency purporting to base its regulatory decision in any significant part on science. 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 of, 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

The core issue for regulatory peer review as we outline it above is straight forward: did the agency have a valid basis in the relevant scientific data and research for concluding what it did about the extent to which science supports the agency's decision? As such, it avoids the concerns opponents of the "sound science" movement have lodged regarding the potential of peer review to ossify administrative processes.

As to the concern regarding 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. As previously noted, achieving quality in the use of science may require some agencies to do more work than they have in the past—conduct broader literature searches, deliberate more over relative quality of data, spend more time analyzing the data and research—but 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 claims of science ought not strike anyone as repugnant to appropriate administrative procedures, even if it does demand more of an agency that heretofore has not been careful about doing so.

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. Regulatory peer review does not import the default scientific standard that the data support the conclusion within a 95 percent level of confidence. Rather, regulatory peer review imports the standards of proof prescribed in the relevant statutory program. In the critical habitat designation procedure, for example, regulatory peer review would be conducted within the statutory directives that the agency consider only the “best scientific data available” and reach conclusions based on what is the “maximum determinable” from that body of information.

Finally, as to the concern that regulatory peer review will somehow unduly impede and interfere with agencies’ policy deliberations, that is the least likely effect under the formulation we propose. The unyielding boundary of regulatory peer review stops at the line between agency interpretation of available data and research and agency integration of its scientific conclusions with other factors in the decision making procedure. 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.

Nevertheless, we do recognize that regulatory peer review will take time and money to conduct properly, and it must be conducted properly if it is to be conducted at all. Accordingly, in the next section we outline a proposal for implementing regulatory peer review which we believe would yield its major benefits without imposing significant time or budget constraints on regulatory processes.

VI. A PROPOSED MODEL OF RANDOMIZED PEER REVIEW

We have set out the main arguments in favor and opposed to regulatory peer review, described the major peer review initiatives in Congress and OMB, and considered how we should think about peer review, all leading to three key points. First, peer review *can* improve agency decision making based on the use and interpretation of scientific data but, second, we do not know how many agency decisions actually would be improved by peer review. And this matters because, third, the practice of peer review imposes costs. The policy question then becomes how we can capture the benefits of regulatory peer review at lowest cost to improve overall agency decision quality. In our view, none of the major peer review proposals provides an adequate answer.

The ESA legislation assumes that virtually *all* agency decisions increasing species protection warrant regulatory peer review. This approach is senselessly over-inclusive (imposing peer review on all ESA protection measures would significantly weaken the statute’s ability to conserve biodiversity) and under-inclusive (de-listing decisions and incidental take permits also rely on scientific data but would not be subject to peer review). Indeed, even though most of our survey respondents favored regulatory peer review, over two-thirds of respondents opposed applying it to all regulatory decisions of an agency.

The OMB proposal, which became effective in December, 2004, understands that subjecting all agency information products to peer review imposes too many costs. Thus it mandates peer review for data that could have a substantial impact on important public policies, impose private sector impact of over \$500 million impact, or which involve precedent-setting, novel and complex approaches. A slim majority of our survey respondents favored this approach. Nevertheless, while these thresholds do provide cut-off points, they also screen out most regulatory actions from consideration. For example, in the ESA context, most habitat conservation plans and jeopardy consultations would be immune from peer review. The OMB proposal either assumes that these actions would not benefit from peer review (which seems questionable) or that it would be too expensive. It is also worth noting that OMB’s guidelines

assume that if an agency relies on peer-reviewed research, the need for peer reviews is eliminated. This points directly into the ultimate shortcoming of the OMB guidelines—peer review is required only for “information products,” not how the agencies use the “information products” in their regulatory decisions. If OMB cares about improving the quality of regulatory decisions and not just the information products, which seems to be the case given the threshold standards, its guidelines do so in an indirect manner. The net result of focusing on information products and excluding peer-reviewed research is that the key steps of search, selection, and interpretation set out in Section V are missed, as well. By focusing only on the quality of the information agencies use, it is not at all clear that the OMB Guidelines will, or can, effectively address whether the agency appropriately interpreted and applied the information.

The peer review critics’ counter-proposals are unsatisfying, as well. Groups calling for no peer review at all either deny that *any* agency decisions would benefit from peer review or claim that, in any case, the medicine will prove worse than the disease. Sid Shapiro takes a more nuanced approach, recommending that agencies be allowed to employ ad hoc procedures for deciding when peer review is appropriate.¹⁶⁰ Given the self-serving experiences of FWS, NOAA, and OMB with peer review, however, there is little reason to be optimistic that the quality-control benefits of peer review would endure. If these agencies’ experiences provide any guide, the legitimacy of peer review would be undermined by agency discretion and self-interest in its application. In his comment letter on behalf of the Center for Progressive Regulation, Shapiro offers a different proposal, that “OMB should limit peer review to circumstances in which the information to be disseminated sets a new precedent or is reasonably controvertible.”¹⁶¹ This proposal was largely adopted in the revised OMB proposal described above, but it focuses more on the nature of the data than the nature of the decision, which is clearly where the interest lies in peer review.

If all of these proposals have serious shortcomings, is there a better approach? We believe there is, but to explain why one needs to return to first principles. In order to craft a peer review policy, we need to be clear what the most significant benefits of peer review are. Debate and scholarship to date have largely focused on four types of benefits. The most obvious is *quality control*. Hence the descriptions of peer review as a “second opinion” that catches mistakes in the original decision’s use of science or as an expert filter that catches bias or theory protection in the original decision.¹⁶² This is closely linked to the *legitimizing function* of peer review. As OMB has argued, peer review can promote greater public confidence in agency use of science. This clearly is the reason most scientists believe that peer review is “essential to the integrity of scientific and scholarly communication.”¹⁶³ Peer review also serves a *deliberative function*, providing for give and take between proponent and reviewers.¹⁶⁴

There is serious debate over how significant these potential benefits are, however, because there is significant uncertainty over how often agencies misuse good science or use poor science in making decisions. Implicit in the arguments of Representative Walden and OMB is the assumption that agency mistakes are common enough to justify making peer review commonplace. Otherwise their proposals would be pointless, requiring extensive reviews to address a negligible problem. Critics of their proposals similarly argue that the problems

¹⁶⁰ See, e.g., Shapiro, *supra* note __, at __.

¹⁶¹

¹⁶² Quality control is equally important in the context of journal peer review. Rowland’s study of scientists’ perceptions of peer review found that “it is widely agreed that this improving function by referees is of value in maintaining the overall quality of the scholarly literature.” Rowland, *supra* note __, at 1.

¹⁶³ WELLER, *supra* note __, at 322.

¹⁶⁴ This is particularly evident in journal peer review, where approximately 80 percent of submitted papers are in the “publish with changes” category. Rowland, *supra* note __, at 1.

surrounding agencies' use of science have been exaggerated. As we noted in the Introduction, though, the fact is that we simply don't know how many Klamaths are out there. And this ignorance forms the basis for our proposal, for regulatory peer review offers a potential benefit that no one has talked about – its *diagnostic function*. We cannot intelligently assess the merits of requiring regulatory peer review, whether restricted to major decisions, decisions that create precedent, or decisions that protect species, unless we have a clear sense of whether none, a few, or many of these decisions would benefit from peer review. Yet this critically important issue has received little consideration in the current debate.¹⁶⁵ The greatest benefit of peer review may lie in providing empirical data on the scope of the problem and telling us whether broader or reduced use of peer review is warranted.

To capture all 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 (similar to the chart of ESA decisions set out in Section II). Within this broad class of decisions, randomly select a subset of specific regulatory decisions within a six month period.¹⁶⁶ To commence, we would suggest following the IRS audit practice of selecting roughly 1-2% of the eligible decisions.¹⁶⁷

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 improve timely performance, vetted for potential bias by the NRC through its standard practice described in Section II, 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 interviews precludes anonymity. 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.¹⁶⁸ Where

¹⁶⁵ The Natural Resources Defense Council, it should be noted, asked OMB to shelve its proposal and assemble a panel of experts on peer review to assess whether existing practices are a problem.

¹⁶⁶ The OMB proposal also focuses on information that will have an important impact on public policies or an impact of more than \$500 million per year. We believe that focusing on science underpinning discrete regulatory decisions is more appropriate because, at its core, this is really what parties on both sides of the sound science debate care about—whether the science underpinning agency decisions accurate and properly interpreted.

¹⁶⁷ Add cites on IRS audit rates. As regulators well know, deterrent effects can be realized even when compliance inspections are conducted less than 100 percent of the time for fewer than 100 percent of the regulated facilities. The number of reviews, of course, could not exceed the review budget, which would ultimately determine the percent used.

¹⁶⁸ There is an ongoing effort among many ecologists, economists, and policy thinkers to describe this threshold with more precision. See S.W. Pacala et al., *False Alarm over Environmental False Alarms*, 301 SCI. 1187 (Aug. 29, 2003) (proposing a marginal cost-benefit analysis basis for measuring “sensitivity” to Type II error); Gordon K. Durmil, *How Much Information Do We Need Before Exercising Precaution*, in IMPLEMENTING THE PRECAUTIONARY PRINCIPLE, *supra* note 21, at 266; See generally Stephen Charest,

necessary, the peer reviewers could request important data compilations or research reports the agency relied upon in order to make these evaluations. The peer review would be completed in no more than 90 days deliberations and would not be subject to the Federal Advisory Committee Act.

Stage Three: Disseminate and Analyze Reviews

The results of the peer review would be released to the agency and the public prior to 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 regulatory program (e.g., designations of critical habitat) would be assessed to determine whether the audit rate is appropriate and, more generally, whether 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? For those decisions that are reviewed, the proposal ensures quality control in particular cases. Based on the IRS experience, the randomized aspect of the proposal is intended 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 rather 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. Such a regulatory peer review framework ultimately may not substantially change the outcome of many regulatory decisions, but will beneficially influence the way in which most regulatory decisions are carried out. The proposal also helps further legitimize agency decisions, ensuring in a transparent process, independent of agency influence, that the use of science was appropriate. It promotes the deliberative function of peer review, furnishing an independent, expert review of an agency decision that the agency can consider in its final determination. And, perhaps most important, it provides a way for us to empirically assess 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 we 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 decision-making process that the policy effectiveness of the decision is impeded. What a hollow victory it would be, for example, to spend so much time ensuring the reliability of the data proving a species is endangered, that the species is already extinct by the time the decision to protect it is made. Adding time and budget constraints to the picture amplifies the prospect and potential intensity of these conflicting constraints. Optimal decision-making, in other words, requires that we intentionally operate at an "optimal level of ignorance," understanding that comprehensive peer review would be counter-productive.¹⁶⁹

Bayesian Approaches to the Precautionary Principle, 12 DUKE ENVTL. L. & POL'Y F. 265 (proposing a method based on Bayesian rather than frequentist statistical analysis); see also SCIENCE AND THE ESA, *supra* note 12, at 157–74 (emphasizing the need to use structured approaches in ESA decision making and exploring frameworks used and tradeoffs made between competing objectives). This is the kind of issue that would be appropriate for an entity like NRC to examine as a general matter.

¹⁶⁹ For discussion of the conflicting constraints property of complex systems, and of regulatory systems in particular, see J.B. Ruhl & James Salzman, *Mozart and the Red Queen: The Problem of Regulatory Accretion in the Administrative State*, 91 GEO. L.J. 757, 806–12 (2003).

Our proposal has its costs, to be sure, but they are significantly less than the 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.¹⁷⁰ 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 to use it and how to conduct it outside of the agencies' hands and into the hands of a generally-respected neutral player. Although many stakeholders disagreed with the Klamath Committee's conclusions and how the Departments of Interior and Commerce incorporated them into policy, no allegations were heard that the committee somehow was influenced by bias. The same cannot be said of peer reviews that have been carried out under the peer review policy FWS and NOAA have used for their ESA decisions.

Our model of Randomized Peer Review also raises a series of important administrative law questions. The first is how the agency should use the reviews. This could range from treating the review no different than a comment letter from the general public to requiring an agency response explaining why it has or has not revised its decision consistent with the peer review results.¹⁷¹ In either case, the review would become part of the administrative record for purposes of any judicial challenge. The more difficult question turns on what role the peer review should play if the agency decision is later challenged as arbitrary and capricious. Here again, the court's treatment of the review could range from giving it no special status, to the heightened deference accorded to views expressed by sister agencies.¹⁷²

In our view, the peer review report should be treated no differently than public submissions through the notice and comment process of informal rulemaking. Given the intense light and heat surrounding the sound science debate, simple political expediency would likely force the agency's hand. It would be a secure agency director, indeed, who simply ignored a critical peer review finding (and likely a director who did not mind traveling up to Capital Hill to explain to skeptical senators why the agency's actions were contrary to the peer review). Similarly, we see no need for the court to grant special deference to the review. In many cases involving peer review, the agency will be making decisions in the face of scientific uncertainty. Upsetting the tendency of courts to defer to the agency's choice in close-call cases, where some record evidence exists to support a decision in either direction and the statute imposes no default position, strikes us as unwarranted.¹⁷³ Fundamentally, it must be remembered, the purpose of peer review is to improve agency decision quality, not to arm litigants or undermine agency discretion.

¹⁷⁰ In order to make these decisions, we obviously would need more information 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.

¹⁷¹ The agencies' existing peer review policy does not require this, and the agencies often are not forthcoming about why they agree or disagree with their (hand-picked) peer reviewers. *See, e.g.*, Endangered and Threatened Wildlife and Plants; Withdrawal of the Proposed rule to List the Mountain Plover as Threatened, 68 Fed. Reg. 53,083 (Sept. 9, 2003) (to be codified at 50 C.F.R. pt. 17) (after confirming the merits of a proposed rule to list the mountain plover that was supported in two rounds of peer review, FWS later withdrew the rule based ostensibly on new information, but without additional peer review). *Discuss OMB requirements for agency explanation if its regs fail a CBA test.*

¹⁷² Cite NEPA case where FWS tells agency there are serious ESA issues and the agency ignores

¹⁷³ *See supra* notes ___-___ and accompanying text.

V. CONCLUSION

Agency use of peer review processes is neither new nor, until recently, particularly controversial, but neither has it been widely used in regulatory settings. The Klamath saga, the OMB mandate for peer review of “information products” across the federal government, and the obvious legislative attempts to smother the regulatory arms of the ESA through peer review, have fundamentally changed the landscape. The ensuing debate has generated inflated claims over the use of peer review in regulatory settings as either a golden virtue or a sinister evil.

We have sought to show that regulatory peer review can meaningfully improve agency decisions that rely on the use or interpretation of scientific information, but that this alone tells us nothing about whether peer review should therefore become part and parcel of agency decision processes. We believe it is unwarranted and may well prove unwise to mandate peer review across the board for agency actions, such as the preparation of “information products” or the promulgation of rules or decisions based on such information, without a clear understanding of the real extent of the problem peer review is supposed to address. In proposing an approach of randomized peer review, we hope to shift the debate away from whether regulatory peer review is good or bad, or whether agencies are biased or not, and on to a more productive, empirically-grounded vantage from which we can more intelligently assess the proper role for this process in agency settings.