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IN DEFENSE OF REGULATORY PEER REVIEW

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I. INTRODUCTION

On June 29, 2001, just outside Klamath Falls, Oregon, an angry mob of farmers took actions into their own hands. Massing around the closed headgates of a federally operated irrigation ditch, the crowd defied federal government orders, burst open the headgate locks, and returned the flow of water to the thirsty soils of their croplands.[1] The mob stayed put and made camp for the next few days, challenging federal officials time after time by unlocking the gates as soon as they had been closed. The crowd finally was dispersed under the stern direction of United States Marshals. The battle lines could not have been more clearly drawn. The farmers cried for relief from dry irrigation ditches and the specter of failed crops. The federal government stood firm: the gates had to stay shut and farmlands go dry in order to save endangered fish dependent on the water stored in Upper Klamath Lake and flowing in the Klamath River. The following March, however, amidst the flash of news cameras, the Secretary of Agriculture and Secretary of the Interior quite publicly opened the very same headgates.[2] What made the first liberation of water an act of civil disobedience and the latter a high-profile case of wise federal governance? Improbably, the answer came from a room full of scientists and a practice called peer review.

This saga, popularly known as "the Klamath," made headlines around the nation and served as a rallying call for many communities in the Western United States concerned about the future in the face of "their water" being dedicated to endangered species protection.[3] The standoff had been building ever since two local species of sucker fish found in the lake and a population of coho salmon found in the river below the dam had been listed for protection under the Endangered Species Act (ESA).[4] This placed the fish under the watchful protection of the federal government.[5] When the government declared that the fish could no longer

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1. For an account of the events described in this paragraph, see Ted Williams, *Salmon Stakes*, 105 AUDUBON 42 (2003), *available at* http://magazine.audubon.org/incite/incite0303.html. For a comprehensive history of the Klamath River Basin and the events involving the "crisis of 2001," see Holly Doremus & A. Dan Tarlock, *Fish, Farms, and the Clash of Cultures in the Klamath Basin*, 30 ECOLOGY L.Q. 279 (2003).

2. *See* Doremus & Tarlock, *supra* note 11, at 334–35.

3. *See id*. at 321–24.

4. Endangered Species Act of 1973, Pub. L. No. 93-205, 87 Stat. 884 (codified as amended at 7 U.S.C. § 136, 16 U.S.C. §§ 1531–44, and in other scattered sections of 16 U.S.C.).

5. The United States Fish and Wildlife Service (FWS) is responsible for the suckers, and the National Oceanic and Atmospheric Administration (NOAA) for the salmon. For a description of the regulatory and other authorities FWS and NOAA administer under the ESA, see *infra* notes 48–65 and

tolerate the release of water from the lake for irrigation,[6] angry farmers around the Klamath took charge, transforming the conflict into "Exhibit Number One" for critics of the ESA and their charge that agencies work on the basis of so-called "junk science."[7] As closely as the popular press followed both these developments, however, it completely missed the other consequence of the Klamath story, one that we believe has proven far more significant—the rise of regulatory peer review.

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, and the federal government turned to peer review to break the tie. Following the public outcry over the "fish-versus-humans" decision and the standoff between farmers and federal officials at the floodgates, the National Research Council (NRC), an arm of the National Academy of Science, was requested to convene a committee of experts, known as the Klamath Committee, to conduct a peer review of the agencies' decisions—the first ever conducted of an agency decision of this magnitude under the ESA.[8]

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accompanying text.

6. Specifically, according to FWS and NOAA, further releases would have 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(a)(2) (2000). *See* Doremus & Tarlock, *supra* note 1, at 316–20.

7. *See* 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, 79–80 (2005). The National Research Council's Committee on Endangered and Threatened Fishes in the Klamath River Basin (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*, SCIENCE, Apr. 2003, at 36, 36. The lack of established structure for carrying out the peer review probably contributed to the ways in which the findings were used and abused—one reason for our proposal, *infra* Part VI.

8. J.B. Ruhl was a member of the Klamath Committee. The Klamath Committee provided a report thoroughly studying the area's land use and water management history. *See* COMM. ON ENDANGERED & THREATENED FISHES IN THE KLAMATH RIVER BASIN, NAT'L 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]. The Klamath Committee also provided detail in an interim report. *See* COMM. ON ENDANGERED & THREATENED FISHES IN THE KLAMATH RIVER BASIN, NAT'L 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 Reed D. Benson, *Giving Suckers (and Salmon) an Even Break: Klamath Basin Water and the Endangered Species Act*, 15 TUL. ENVTL. L.J. 197 (2002); Marcilynn A. Burke, *Klamath Farmers and Cappuccino Cowboys: The Rhetoric of the Endangered Species Act and Why It (Still) Matters*, 14 DUKE ENVTL. L. & POL'Y F. 441 (2004); Doremus & Tarlock, *supra* note 1; McGarvey & Marshall, *supra* note 7; Julia Muedeking, Note, *Taking the Heart of the Klamath Basin: Is It Free?*, 8 DRAKE J. AGRIC. L. 217

The initial results of the Klamath Committee's peer review sparked a firestorm of controversy.[9] Reviewing the information available to the federal agencies responsible for managing the fish at the time of their respective decisions, the experts found that "no substantial scientific foundation" existed for the agencies' conclusions.[10] In other words, the conclusions that further reducing lake levels would jeopardize the suckers and that reducing river flows would harm the salmon could not be justified based on the available data. Releasing irrigation waters might harm the endangered fish, or it might not—the science was too uncertain to say. Simply put, the agencies said that the science got them from point A to point B, but the Klamath Committee concluded it did not. Soon after, the floodgates were dramatically re-opened.

After the Klamath Committee issued its opinion, many observers began to ask whether peer review should guide decisions in *other* regulatory settings. Indeed, since the Klamath controversy, strong, insistent calls for improving agency decisions based on science have been heard from the White House[11] and from Congress.[12] This self-proclaimed "sound science" movement argues that procedural safeguards to ensure better use of scientific data will improve agency decisions.[13] Ensuring the proper

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(2003); Cori S. Parobek, Note, *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).

9. *See* Doremus and Tarlock, *supra* note 1, at 326.

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

11. The Bush Administration has aggressively advanced this agenda through means such as prescribing standards for agency data quality control. *See, e.g.*, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002); *see generally* ENVIRONMENTAL PROTECTION AGENCY, SUMMARY OF FISCAL YEAR 2004 BUDGET REQUEST, 34 Env't Rep. (BNA) S-17, S-112 to S-121 (Feb. 3, 2003) (including "Goal 8," which the agency described as "Sound Science, Improved Understanding of Environmental Risk, and Greater Innovation to Address Environmental Problems").

12. Legislative proposals routinely use the "sound science" label to gain support. *See, e.g.*, Sound Science for Endangered Species Act Planning Act of 2003, H.R. 1662, 108th Cong. (2003); Sound Science for Endangered Species Act Planning Act of 2002, H.R. 4840, 107th Cong. (2002).

13. *See* David E. Adelman, *Scientific Activism and Restraint: The Interplay of Statistics, Judgment, and Procedure in Environmental Law*, 79 NOTRE DAME L. REV. 497, 498 (2004) ("[S]chisms exist over how science is used in setting environmental policy. For most critics of environmental regulation, broad reliance on science is viewed as progress towards increased rationality and objectivity."). A comprehensive overview of the sound science debate is found in Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897 (2004). A more entertaining, though studiously documented account is available in CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE (2005). The discussion and debate regarding the use of "sound science" in environmental law is pervasive—we found over 39,000 web sites through a Google search of "'sound science' AND 'environmental law.'" For a historical perspective on the use

basis for agency decisions has, of course, been a concern of administrative procedures since the New Deal.[14] But the focus of administrative law for agencies' use of science has been the prevention of abusive practices, such as suppression or manipulation of data, not the quality of the data themselves. The focus of interested parties has been to expose these practices, and that of judges has been to halt them when they amount to arbitrary and capricious actions or an abuse of discretion.[15] Yet the sound science movement seeks more than the traditional protections afforded by these conventions of administrative law. Its claim is that agencies will use better science when they are required to employ the scientific method as their decision making protocol.[16] More specifically, just as peer review is one of the principal components of the scientific method, it has become one of the principal demands of the "sound science" agenda.[17]

Scientific peer review is generally described as a rigorous review and critique of a study's methods, results, and findings that is conducted by others in the relevant field who have the requisite training and expertise, who have no pecuniary or other disqualifying bias with respect to the topic, and who are independent of the persons who performed the study.[18]

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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, 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, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181 (1999); Wendy E. Wagner, *The 'Bad Science' Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, LAW & CONTEMP. PROBS., Autumn 2003, at 63 [hereinafter Wagner, *Bad Science*]; Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995) [hereinafter Wagner, *Science Charade*].

14. *See* JAMES O. FREEDMAN, CRISIS AND LEGITIMACY: THE ADMINISTRATIVE PROCESS AND AMERICAN GOVERNMENT (1978); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669 (1975). For a more recent discussion, see David Markell, *"Slack" in the Administrative State and Its Implications for Governance: The Issue of Accountability*, 84 OR. L. REV. 1 (2005).

15. For a more complete description of administrative law protections against agency misuse of science, see *infra* notes 75–83 and accompanying text.

16. For discussions of how demanding that agencies employ the scientific method would affect agency decisions, see Holly Doremus & A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resources Regulation*, 26 PUB. LAND & RESOURCES L. REV. 1, 17–20 (2005); J.B. Ruhl, *The Battle over Endangered Species Act Methodology*, 34 ENVTL. L. 555, 584–91 (2004).

17. *See* MOONEY, *supra* note 13, at 116–19. A counter-movement also has emerged. For example, a group of legal scholars openly skeptical of the movement's motives has formed to, among other things, monitor and challenge initiatives of the "sound science" movement such as proposals for requiring agencies to subject their proposed decisions to regulatory peer review. *See* Center for Progressive Reform Issues; Clean Science, http://www.progressiveregulation.org/issue_science.cfm (last visited Mar. 29, 2006).

18. THE DEP'T OF ENERGY'S OFFICE OF SCI. & TECH. ET AL., PEER REVIEW IN ENVIRONMENTAL TECHNOLOGY DEVELOPMENT PROGRAMS 2 (1998). A peer is "a person having technical expertise in

Peer review is commonplace, indeed, fundamental, to the practice of science. It is the gold standard for determining publication and general acceptance of scientific research.

Just as scientific peer review involves independent evaluation of scientific research, regulatory peer review refers to the outside evaluation of an administrative agency's compilation, selection, or use of scientific data to support a proposed regulatory decision such as a rule, standard, permit, or other policy. Like scientific peer review, the review and critique would be conducted prior to the agency's final decision by qualified, independent experts who have no pecuniary or other conflict of interest in the outcome of the agency's decision. If peer review works for science, goes the argument, it should work for agency decisions that purport to rely on science as well.

This seemingly straightforward logic has not, however, met with easy acceptance. The 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. To Congressman Greg Walden (R-Or.), for example, the case for peer review is obvious.

> If you went to a doctor and he said to you, "we are going to have to take 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.[19]

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

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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.*

19. Greg Walden, Statement Before the Subcomm. on Energy and Minerals of the H. Comm. on Resources on H.R. 1662, 3 (Feb. 4, 2004), http://walden.house.gov/issues/esa/108thcongress/ESA statement.pdf (Rep. Walden (R-OR) was the Sponsor of H.R. 1662).

public health, environmental and other information on a timely basis.[20]

The increasing temperature of this debate reflects action heating up in Washington as well. A series of bills requiring regulatory peer review has been proposed in Congress,[21] and the Office of Management and Budget (OMB) has finalized peer review requirements for the "information products" regulatory agencies use in classes of regulatory decisions likely to have significant economic or other impacts.[22] That regulatory peer review has moved so quickly from the newspapers to the Federal Register signals the potentially significant ramifications it could have. Regulatory peer review is being added to the administrative law toolbox, and it is important to understand what this means for agency practice in the future.

To make sense of the competing claims over regulatory peer review, three fundamental questions need to be answered: The first is *how many Klamaths are there?* Regulatory peer review can be justified only if many agency policy decisions that should be based at least in part on science actually have no or insufficient scientific basis. Increased use of peer review will undeniably impose costs on agencies, and unless there is first a firm sense of how often agencies reach decisions without sufficient scientific support, we may end up overreacting—using a sledgehammer to crack an acorn. Second, even if the Klamath experience is widespread—even if agencies frequently fail to adequately justify policy decisions on scientific grounds—*are these actually poor policy decisions*? The Klamath Committee, it is worth noting, never condemned the federal government's decision to close the floodgates, acknowledging that the decision may or may not have been justified on policy grounds.[23] It just was not justified on scientific grounds alone.[24] If the policy decision is on target, does it really matter that it was not justified by the available data, or does the lack of a firm scientific basis inherently call into question the risk of policy

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20. Letter from Joan Claybrook, President, Public Citizen to D. Margo Schwab, Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, 1–2 (Dec. 15, 2003), http://www.progressive regulation.org/articles/peer/Public_Citizen_PR_Comments.pdf.

21. *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 120–31 and accompanying text.

22. *See* Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005). OMB's policy unfolded through several iterations. *See* Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23,230 (Apr. 28, 2004); Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023 (Sept. 15, 2003). The history and details of OMB's policy are discussed *infra* at notes 103–11 and accompanying text.

23. *See infra* note 92 and accompanying text.

24. *See* KLAMATH COMMITTEE FINAL REPORT, *supra* note 8, at 34–35.

failure? Finally, even if there necessarily is cause for concern when agencies explicitly base their policy decisions on inadequate scientific foundations, *does regulatory peer review provide an effective safeguard?* Put differently, if instances such as the Klamath do pose a significant risk of policy failure, is regulatory peer review the answer? Will it avoid more Klamaths in the future?

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 various interest group combatants. Most legal scholarship on the issue has opposed the use of regulatory peer review, but, as useful and insightful as some of this work has proven to be, we believe the issue is far from put to rest.[25] Indeed, most of the academic commentary has focused on whether agencies produce or rely on flawed scientific evidence or so-called "bad science." Largely overlooked, but pertinent to the question of what role peer review could play, is the potential that agencies might misuse perfectly credible science, or so-called "good science," by overstating the extent to which it supports their policy and regulatory decisions. No study has ever demonstrated whether use of regulatory peer review would have detected other instances, like the Klamath, in which the concern is that the agency has stretched credible science too far in an effort to justify its policy decision, or whether the benefits of detecting those instances would have justified the costs of the peer review programs, or whether it would have even mattered from the standpoint of reaching sound policy decisions.[26] This Article addresses these questions directly, grounding the

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25. 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 (2000). The Klamath saga prompted several scholars to examine the use of peer review in the context of endangered species protection. *See* Burke, *supra* note 8, at 506–14; Doremus & Tarlock, *supra* note 1, at 324–31; McGarvey & Marshall, *supra* note 7, at 107–11. 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. Wagner, *Bad Science*, *supra* note 13, at 67–84; Wagner, *Science Charade*, *supra* note 13, at 1699–1701. 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, Recent Development, *Public Controversy over Peer Review*, 57 ADMIN. L. REV. 275 (2005); Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 34 Envtl. L. Rep. (Envtl. Law Inst.) 10,064 (2004).

26. Wendy Wagner has pointed out that the debate over regulatory peer review has focused primarily on agencies that establish science-based standards and perform scientific functions directly, such as the Environmental Protection Agency's (EPA) setting of toxicity levels or the Food and Drug Administration's review of drug health effects, and thus has largely ignored "the larger universe of

debate over the use of regulatory peer review in agency decision making and charting a productive route forward.

Part II of the Article describes scientific peer review and its practical application in journal publication, grant-award, and agency settings, illustrating the distinction between those applications and regulatory peer review. The obvious difference between the use of peer review in scientific research settings and in agency regulatory settings is that science does not purport to involve normative policy decisions, whereas regulation explicitly does. This section thus explores how peer review would operate in that different context.

The next two sections of the Article address the current debate over regulatory peer review, setting out the arguments in favor of its use in Part III and their critiques in Part IV. Ironically, claims pro and con about regulatory peer review rely on very few data points—any rigorous peer review of their merits would fault them for this. In order to provide an empirical basis for our evaluation, therefore, we conducted a nationwide survey of environmental lawyers to reveal the perceptions of practitioners whose clients are or would be affected by regulatory peer review. As reported *infra*, we found a remarkably intense divergence of opinion between private and public sector attorneys over the prevalence of poor use of science by regulatory agencies, the need for regulatory peer review in response, and its likely effectiveness. Generally, representatives of industry, and also, increasingly, of environmental groups, believe agencies frequently base policy decisions on inadequate scientific foundations, whereas agency representatives defend their performance. The debate raging in the White House and Congress, in other words, is not merely political rhetoric. It reflects a sharp, deep division of opinion among the front line practitioners of administrative law who have the experience to evaluate the prospects of regulatory peer review. Put simply, regulatory peer review has become a polarizing and deeply felt issue.

In Part V of the Article we step back from the intensity of the debate to reassess the role of peer review in the regulatory process, suggesting a different way to think about its potential costs, benefits, and appropriate

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regulatory decisions involving the grant of permits and licenses." *See* Wagner, *Bad Science*, *supra* note 13, at 72–73. OMB, for example, excludes from its peer review policy for federal agencies any data "[d]isseminated in the course of an individual agency adjudication or permit proceeding." Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. at 2677. Wagner also observes that "these decisions rest in large part on unvalidated industry science," Wagner, *Bad Science*, *supra* note 13, at 73, which, if true, would make the case for applying regulatory peer review to them even *stronger*. It is, therefore, this larger, but largely ignored universe of regulatory decisions that is the focus of this Article.

applications. Contrary to most scholarship on the topic, we argue that the unavoidable confluence of science and policy that agencies confront does not pose an insurmountable barrier to effective use of regulatory peer review. Most of the debate over regulatory peer review centers on whether agencies adequately *practice* science and, if not, whether peer review could improve the quality of agency practices. But this reflects just one side of the two-sided problem of how to meld science and policy, and we agree that it is likely not where peer review would produce much gain. Rather, we believe regulatory peer review is most effective when focusing on how agencies *apply* science in support of their regulatory decisions. The Klamath experience illustrates the difference: the Klamath Committee did not criticize the way in which the agencies compiled data or the merits of the final policy decision to close the floodgates; rather, the Klamath Committee faulted the agencies for arguing that the data alone were sufficient to support the decision without reliance on normative policy judgments to fill any gaps.[27]

When focused on the latter inquiry—the question of whether the agency's claims of scientific support for its decision are justified—regulatory peer review can help inform the public about where an agency's use of science in support of a proposed decision ends and where its use of professional judgment and normative policy choices begins. The standard 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. Designed wisely, regulatory peer review can help reveal how much scientific uncertainty underlies an agency decision and can thus demand that the agency *explain how the gap was filled*. This function, we argue, can lead to greater transparency in agency decision processes and greater legitimacy of agency decisions in the eyes of the public, legislatures, and the courts.

Finally, in Part VI of the Article we move the debate forward by evaluating different proposals currently under consideration for the design of regulatory peer review and propose a way to take advantage of what peer review has to offer without imposing undue demands on agency resources. Regulatory peer review is a hot topic at the moment, with agencies moving to implement OMB's recently promulgated policy and Congress proposing yet more peer review requirements. These proposals, however, are either over-inclusive, as are proposals in Congress to subject virtually all ESA decisions to regulatory peer review, or under-inclusive,

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27. *See supra* note 24 and accompanying text.

as is 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 serve salutary purposes in administrative law, the scope of the problem is not competently addressed. There is no evidence that *all* agency decisions suffer from the Klamath syndrome, or that only the "big" ones are suspect.

Ironically, the scope of the problem cannot be assessed meaningfully *without* peer review. Without conducting regulatory peer review one cannot reasonably conclude whether agencies ought to be required to conduct regulatory peer review, because no one knows how big a problem agency misuse of science is. To a scientist, this dilemma has an easy solution—the practice of random sampling. At present there is no institutional structure in place for systematically reviewing the scientific basis of regulatory decisions—i.e., for evaluating whether an agency's claim that science gets it from point A to point B has a legitimate basis. Hence, in order to assist policymakers in assessing the problem of agencies' reliance on science in regulatory decisions, if there is one, we propose the use of mandatory "randomized peer review" by agencies. 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 for the agency as a whole is justified. This diagnostic, adaptive approach has not been considered to date and, we argue, delivers the greatest benefits of regulatory peer review while minimizing the costs.

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

The underlying premise for regulatory peer review boils down to "what's good for science is good for regulation that relies on science." This is an attractive turn of phrase, but it compares apples and oranges. Promulgating a regulation for exposure to carcinogens, it goes without saying, is not the same thing as finding the cure for cancer. *Using* science, in other words, is not the same thing as *doing* science. In order to assess whether the practice of peer review makes sense in regulatory settings, then, we must first understand clearly the use and benefits of peer review in science and how transferable these are.

A. Conventional Applications of Scientific Peer Review[28]

Peer review is most strongly associated with scientific journal publication decisions, in which 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.[29] Within science, peer review is widely considered "essential to the integrity of scientific and scholarly communication."[30] Indeed, for many scientists, peer review "does not merely reflect the scientific method; it *is* the scientific method."[31]

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

> [a]n 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.[32]

Grant-funding peer review follows a similar process.[33] In both cases, the procedures seek to ensure "a documented, critical review performed by

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28. This discussion of the use and perception of peer review in science also appears in substantially the same form in Ruhl, *supra* note 25, at 407–09.

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

30. *Id*. at 322.

31. Noah, *supra* note 25, at 1045.

32. WELLER, *supra* note 29, at 1; *see also* FYTTON ROWLAND, THE PEER REVIEW PROCESS: A REPORT TO THE JISC SCHOLARLY COMMUNICATIONS GROUP 1 (2002), http://www.jisc.ac.uk/uploaded_documents/rowland.pdf (JISC is the Joint Information Systems Committee, the UK's higher education support agency). Rowland states:

> [w]hen 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.

Id.

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

peers . . . who are independent of the work being reviewed."[34] 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.[35]

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.[36] Yet 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 and analyses of the paper, but the instructions do not include engaging in independent data authentication.[37]

> [p]roposals 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.

NAT'L SCIENCE FOUNDATION, GRANT PROPOSAL GUIDE 35 (2003), *available at* http://www.nsf.gov/pubs/2003/nsf03041/nsf03_04.pdf. 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 29, at 2.

34. THE DEP'T OF ENERGY'S OFFICE OF SCI. & TECH ET AL., *supra* note 18, at 2; *see supra* note 18 and accompanying text.

35. WELLER, *supra* note 29, at 207. Of course, even reviewers who meet these criteria may have personal biases about approaches to or disputes in the particular scientific discipline, and there is no objective way of de-biasing review panels from this effect. *See* Robert J. MacCoun, *Biases in the Interpretation and Use of Research Results*, 49 ANN. REV. PSYCHOL. 259, 277 (1998).

36. Ecological Soc'y of Am. Publ'ns Office, Guidelines for Reviewers (Dec. 9, 2005), http://www.esapubs.org/esapubs/reviewers.htm. These criteria are representative of the scientific journal industry in general. *See* WELLER, *supra* note 29, at 160–66.

37. Ecological Soc'y of Am. Publ'ns Office, *supra* note 36. 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." Holly Doremus,

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.

While not nearly as probing as a de novo analysis, it is widely believed that this "appellate style" peer review provides tremendous benefits.[38] First, peer review serves as a filter, ensuring quality control. Knowing their articles will be evaluated by peers, submitting authors have a strong incentive to ensure their conclusions are supported by the data. Second, peer review prioritizes, allowing editors and grant makers to rank articles and proposals. In the face of more articles or grant proposals submitted than can be published or funded, peer review provides an effective means of winnowing the competition.

While less widespread than in scientific publications or grant making, peer review is also employed by a number of federal agencies that have primarily science-based missions. A 1999 study by the General Accounting Office (GAO), for example, found widespread peer review employed by science agencies such as the National Aeronautics and Space Administration and the National Institutes of Health.[39] 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.[40] These procedures were ad hoc, with no uniform definitions or procedures, and ranged from outside mail reviewers and workshops to internal and external standing panels.[41] Similar studies have documented how agencies use (or do not use) peer review to fulfill science-based missions.[42]

Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy, 75 WASH. U. L.Q. 1029, 1147 (1997).

38. There is some empirical evidence in support of this belief. *See* WELLER, *supra* note 29, at 51, 53.

39. GEN. ACCOUNTING OFFICE, GAO/RCED-99-99, FEDERAL RESEARCH: PEER REVIEW PRACTICES AT FEDERAL SCIENCE AGENCIES VARY 1–10 (1999).

40. Some specific examples of agency uses of peer review include NOAA competitive research proposals, Agricultural Research Service project plans, and National Institutes of Health reviews of intramural research. *Id*. at 18, 39, 53.

41. *Id*. at 4–7.

42. *See* PANEL ON PEER REVIEW, NAT'L RESEARCH COUNCIL, REVIEW PROCEDURES FOR WATER RESOURCES PROJECT PLANNING 19–31, app. D (2002), *available at* http://www.nap.edu/openbook/030908508X/html (describing procedures used by the Army Corps of Engineers, EPA, the Department of Agriculture, and the Department of Transportation); Subcomm. on Water Res. and Env. of the H. Comm. on Transp. and Infrastructure, Independent Peer Review of Products that Support Agency Decision-Making, http://www.house.gov/transportation/water/03-05-03/03-05-03memo. html (last visited Mar. 31, 2006) (describing peer review practices of EPA, the Fish and Wildlife Service, and the Army Corps of Engineers).

B. Extending Peer Review to Regulation

The use of peer review is far more limited and variable by agencies when exercising *regulatory* responsibilities. There is a strong tradition of expert advisory panels advising agencies on specific policy topics, ranging from the Environmental Protection Agency's Science Advisory Boards to the Food and Drug Administration's Technical Advisory Committees.[43] Peer review is used much less frequently for discrete regulatory decisions such as standard setting, and almost never in permitting and licensing.[44] 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.

Using peer review in a regulatory context would thus require 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 available through other scientific research efforts. Thus, regulatory peer review will need to address how the agency incorporated pre-existing scientific knowledge into its own decision processes. Second, it will not always be the case that the data upon which the agency relies are the result of peer-reviewed studies.[45] Regulatory peer review, therefore, will need to provide some assessment of those studies in the form of an evaluation of the agency's choices over 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. Regulatory peer review thus would have to be mindful that, in getting from point A to point B, an agency may have the discretion or the mandate to rely on an integration of science and other policy factors, whereas the peer review must be limited to the science alone.

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

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43. For information on EPA's Science Advisory Board, see Envtl. Prot. Agency, About the EPA Science Advisory Board, http://www.epa.gov/sab/about.htm (last visited Mar. 31, 2006). For information on the FDA's Advisory Committees, see Carol Rados, *Advisory Committees: Critical to the FDA's Product Review Process*, FDA CONSUMER, Jan.–Feb. 2004, at 17.

44. *See supra* note 26.

45. 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 13, at 73.

dedicated to conserving and restoring populations of endangered species;[46] as a result, it provides numerous opportunities for agency officials to rely on scientific data in a policy setting.[47] Section 4 of the Act, for example, authorizes the Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration (NOAA) to identify "endangered" and "threatened" species, known as the listing function,[48] and then to designate "critical habitat,"[49] and to develop "recovery plans" for the species.[50] 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 "result in the destruction or modification" of their critical habitat.[51] Section 9 requires that all persons, including all private and public entities subject to federal jurisdiction, avoid committing takings of listed species of fish and wildlife.[52] Sections 7 (for federal actions) and 10

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46. *See* 16 U.S.C. § 1531(b).

47. 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 25, 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 MICHAEL J. BEAN & MELANIE J. ROWLAND, THE EVOLUTION OF NATIONAL WILDLIFE LAW (3d ed., 1997); ENDANGERED SPECIES ACT: LAW, POLICY, AND PERSPECTIVES (Donald C. Baur & Wm. Robert Irvin eds., 2002) [hereinafter LAW, POLICY, AND PERSPECTIVES]; LAWRENCE R. LIEBESMAN AND RAFE PETERSEN, ENDANGERED SPECIES DESKBOOK (2003); STANFORD ENVTL. LAW SOC'Y, THE ENDANGERED SPECIES ACT (2001); TONY A. SULLINS, ESA: ENDANGERED SPECIES ACT (2001).

48. 16 U.S.C. § 1533(a)(1) (2000). For a description of the listing process, see LIEBESMAN & PETERSEN, *supra* note 47, at 15–20; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 38–58; SULLINS, *supra* note 47, at 11–25; J.B. Ruhl, *Section 4 of the ESA: The Keystone of Species Protection Law*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 47, at 19.

49. 16 U.S.C. § 1533(a)(3) (2000). For a description of the critical habitat designation process, see LIEBESMAN & PETERSEN, *supra* note 47, at 20–24; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 59–69; SULLINS, *supra* note 47, at 26–28; Federico Cheever, *Endangered Species Act: Critical Habitat*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 47, 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* Part V.B.

50. 16 U.S.C. § 1533(f) (2000). For a description of the recovery plan process, see LIEBESMAN & PETERSEN, *supra* note 47, at 24–26; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 71–77; SULLINS, *supra* note 47, at 34–37; John M. Volkman, *Recovery Planning*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 47, at 71.

51. 16 U.S.C. § 1536(a)(2) (2000). For a description of the consultation process, see LIEBESMAN & PETERSEN, *supra* note 47, at 27–39; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 83–103; SULLINS, *supra* note 47, § 5; Marilyn Averill, *Protecting Species Through Interagency Cooperation*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 47, at 87.

52. 16 U.S.C. § 1538(a)(1) (2000). For a description of the cases developing the legal standards for what constitutes "take," see LIEBESMAN & PETERSEN, *supra* note 47, at 39–45; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 104–12; SULLINS, *supra* note 47, at 44–54; Alan M. Glen & Craig M.

(for actions not subject to section 7) establish a procedure and criteria for FWS and NOAA to approve "incidental" takings of listed species.[53]

Each of these provisions involves an intersection between policy decisions and 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 whether it is likely to become so in the foreseeable future (threatened).[54] This requires a series of scientific determinations about the taxonomy of the species—if indeed it is a species[55]—its range, the present and threatened injuries to its habitat, whether it is being over-utilized for commercial purposes or threatened by disease or predation, whether these threats are enough to cause it to go extinct, and, if so, when.[56] A similar law-science confluence appears in policy application settings such as enforcement of the jeopardy prohibition found in section 7,[57] which was the driving legal standard in the Klamath River conflict.[58] The statute requires FWS and NOAA to assess whether the direct and indirect effects of a proposed federal agency action will

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Douglas, *Taking Species: Difficult Questions of Proximity and Degree*, 16 NAT. RESOURCES & ENV'T 65 (2001); Gina Guy, *Take Prohibitions and Section 9*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 47, 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 47, at 207.

53. 16 U.S.C. §§ 1536(b)(4), 1539(a)(1) (2000). An incidental taking, although not the subject of a specific statutory definition provision, is described in section 10 as a taking that is "incidental to, and not the purpose of, the carrying out of an otherwise lawful activity." § 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 (2005). For a description of the incidental take authorization procedures, see LIEBESMAN & PETERSEN, *supra* note 47, at 46–50; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 127–73; SULLINS, *supra* note 47, at 87–102.

54. *See* 16 U.S.C. § 1532(6), (20) (2000).

55. 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). Hood notes, "[t]he scientific consensus on 'species' . . . is that no complete consensus exists and that different definitions suit different purposes." *Id*. 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. *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 debate surrounding how to define a species, both legally and scientifically, see LIEBESMAN & PETERSEN, *supra* note 47, at 11–15; STANFORD ENVTL. LAW SOC'Y, *supra* note 47, at 31–38; SULLINS, *supra* note 47, at 6–11; Doremus, *supra* note 37, at 1087–112. 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 47, at 11–15 (providing comprehensive discussion about definition of species).

56. 16 U.S.C. § 1533(a)(1) (2000).

57. § 1536(a)(2) (requiring agencies to ensure no agency action jeopardizes a listed species).

58. *See* Doremus & Tarlock, *supra* note 1, at 319–20.

jeopardize the continued existence of the species[59] by appreciably reducing its chances of recovery and survival in the wild.[60] To reach a decision on that question, FWS and NOAA must determine as a scientific matter the nature and magnitude of the impact the action will have on reproduction, numbers, or distribution of the species, and how much any such impacts will reduce the chances of the species surviving and recovering in the wild.[61]

Clearly, regulatory agencies such as FWS and NOAA cannot easily avoid the science component of their mandates in regulatory applications. Indeed, to manage these and other necessary scientific judgments under the ESA, the statute mandates that agencies apply 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 habitat using only "the best scientific and commercial data available."[62] Similarly, the biological component of the decision whether to designate critical habitat must use the "best scientific data available."[63] 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,[64] adopt the same standard.[65]

While these provisions clearly infuse a science-based mandate into the agencies' regulatory functions, they just as clearly provide that the agencies will *use* science rather than *do* science.[66] As described earlier, peer review is normally associated more with the latter—with the actual practice of science and presentation and defense of scientific conclusions.[67] Regulatory agencies generally do not engage in original scientific research to make regulatory decisions.[68] Perhaps they have decided that so long as they rely on peer-reviewed science, subjecting their decisions to a second layer of peer review would be redundant.

Indeed, few regulatory agencies ever subject their regulatory decisions to peer review, and those that do usually limit the practice to standard-

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59. *See* 16 U.S.C. § 1533(a)(2).
60. *See* 50 C.F.R. § 402.02 (2005) (defining jeopardy).
61. *See id*.
62. § 1533(b)(1)(A).
63. § 1533(b)(2).
64. § 1536(a)(2), (b)–(c).
65. § 1536(c); 50 C.F.R. § 402.14(g)(8) (2005).
66. *See* Sw. Ctr. for Biological Diversity v. Norton, No. 98-934, 2002 WL 1733618, at *9 (D.D.C. July 29, 2002).
67. *See supra* Part II.A.
68. *See infra* Part III.A.

setting decisions.[69] 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 in listing and recovery activities."[70] 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.[71] This goes farther than most regulatory agencies have been willing to consider, yet does not reach what Congress and the White House would require.[72]

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 methodologies to ensure sound agency decisions are already firmly embedded in the basic standards of administrative law prescribed under the Administrative Procedure Act (APA).[73] 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.[74] 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."[75] An agency decision is arbitrary and capricious if the agency either has relied on factors which

> Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so

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69. *See* Noah, *supra* note 25, at 1034–37, 1050–57.

70. 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 Part IV.B, *infra*.

71. *See id*. For example, neither FWS nor NOAA instituted peer review for their respective decisions in the Klamath controversy.

72. *See infra* Part III.C.

73. 5 U.S.C. §§ 551–59, 701–06 (2000).

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

75. 5 U.S.C. § 706(2)(A) (2000).

> implausible that it could not be ascribed to a difference in view or the product of agency expertise,[76]

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.'"[77]

A scientist would be accused of practicing unsound science in research if he or she declared that relevant data were ignored or altered in reaching the research conclusion simply because the data did not support the conclusion.[78] Likewise, under the foregoing rules of judicial review an agency would be chastised for doing the same in reaching rulemaking or adjudication decisions. Such misuse of scientific data would be arbitrary and capricious, and any court reviewing the decision would know to strike it down as a violation of the APA.[79] 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 respond to arguments for using regulatory peer review to identify cases in which, as in the Klamath, an agency uses properly assembled scientific data but reaches a policy decision not supported by the data. Recall that the available fisheries data did not provide a clear basis for concluding that reduced water levels would jeopardize the endangered fish populations.[80] The policy decision to halt irrigation flows was not a *misuse* of science, but it certainly was not dictated by the science either. Such a decision could result from an agency's innocent misunderstanding of the science or from its lack of expertise. Or, of course, it could result from an agency's deliberate attempt to stretch the available science in support of its policy decision farther than is justified. Whether innocent or deliberate, this kind of misuse of science does not necessarily lead to poor policy decisions. After all, agencies may have no choice but to extrapolate from incomplete data when a decision needs to be made at that moment. It can raise

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76. Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

77. *Id*. (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)).

78. *See, e.g*., Donald Kennedy, Editorial, *Retraction*, 311 SCI. 335 (2006) (editor of *Science* retracts article journal published on stem cell research because of fabricated data); Gretchen Vogel et al., *Ecologists Roiled by Misconduct Case*, 303 SCI. 606 (Jan. 30, 2004) (reporting developments concerning allegations that a world-renowned ecologist fabricated data in a published study of genetic fitness traits).

79. *See, e.g*., N. Spotted Owl v. Hodel, 716 F. Supp. 479, 482–83 (W.D. Wash. 1988) (holding the decision not to list the owl was arbitrary and capricious in light of the biologists' findings).

80. *See supra* note 10 and accompanying text.

concerns, however, if an agency justifies its decision to the public, courts, and legislature as being driven chiefly by the science when it is in fact based on a policy judgment informed by inconclusive science.

Whether an agency's overreliance on data is intentional or not, the APA's procedural safeguards are unlikely to be an effective safeguard when no overt suppression or manipulation of data is involved. Interested parties may argue that the agency has oversold its science, but, as *interested parties*, they may be equally guilty of that offense. Faced with competing versions of what the available science means, a court is in no position to conduct a reliable peer review and would thus lean decidedly toward deferring to the agency's version, as it must under the APA. Regulatory peer review therefore may have something to offer in such cases, which, given the scientific uncertainty present in many regulatory decisions, may be quite common.

Peer review, however, is neither mandated by most environmental laws nor required through the default administrative law doctrines of the APA. Procedures with some of the attributes of regulatory peer review are already present in conventional administrative law processes, but these fall short of peer review's promise. Public participation in regulatory rulemaking decisions through notice and comment and in adjudicatory proceedings through representation, for example, provide forms of outside review.[81] But they are neither limited to experts nor do they screen out biased members of the public.[82] Indeed, quite the opposite is likely—one can reasonably expect that only members of the public with a personal stake in the matter will be prone to get involved. After all, if one does not have a vested interest in the regulation, why bother to get involved? Judicial review of agency decisions ensures a close review by an ostensibly unbiased party, but it cannot approach the same level of expertise provided by peer review. Moreover, judges must adhere to the review standards of the APA, not those of scientific peer review.[83] Peer review, in other words, is the one clear demand of the "sound science" movement that administrative law does not already require.

Still, that regulatory peer review is not already required hardly compels the case for requiring it. So why do it? What benefits does peer review offer regulation that other procedural safeguards do not? The promised

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81. *See* 16 U.S.C. §§ 553–54 (2000).

82. *See* Noah, *supra* note 25, at 1074–76. OMB makes the point, in its final peer review policy, that "[p]eer review should not be confused with public comment and other stakeholder processes." Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2665 (Jan. 14, 2005).

83. *See* 16 U.S.C. § 706 (2000); Noah, *supra* note 25, at 1076–77.

benefits of integrating peer review into the regulatory decision making process are both substantive and procedural. Advocates argue that providing independent expert feedback will generally improve the *quality* of regulatory decisions.[84] Like Representative Walden's folksy reference to a doctor's second opinion,[85] 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."[86] Proponents also argue that the use of independent, outside experts in regulatory peer review should enhance the legitimacy of the regulatory *process* by reducing the appearance of agency bias and conflict of interest.[87]

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? This section lays 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 systematically lead employees to overstate how much the available science supports a particular policy decision. In addition, our survey revealed that practitioners of environmental law working primarily in the private sector harbor a deep distrust of agencies in this regard, a distrust based, we presume, not primarily on political theory but on personal perspective and practical experience. The push for 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 there is a problem that needs to be fixed—agencies often, perhaps systematically, present scientific data as supporting a policy decision more than is justified. 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, quite apart from anti-regulatory agendas, one might be concerned over agency use of science.

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84. *See* Lars Noah, *Peer Review and Regulatory Reform*, 30 Envtl. L. Rep. (Envtl. Law Inst.) 10,606, 10,608 (2000).

85. *See supra* note 19 and accompanying text.

86. Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023, 54,024 (Sept. 15, 2003).

87. *Id.*

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.[88] 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.[89] This is a variant on the theories of agency capture and public choice, in which 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.[90]

Personal bias can also play a role. Most biologists who work for the FWS or NOAA, one could reasonably imagine, care personally about conserving wildlife—that is why they became wildlife biologists and have devoted their careers to working in an agency dedicated to wildlife conservation. 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 with "shared biases," not because they are simply biologists.[91]

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 decisionmakers dissembled or acted in bad faith. One need not adopt a cynical view of agency behavior to understand why the exigencies of making complicated decisions in a short period based on uncertain or conflicting data can sometimes lead to decisions with inadequate scientific support.[92] Sympathy for agencies may be due on this score; nevertheless, time and resource constraints do appear to be yet one more reason to believe that agencies may reach decisions that lack a firm scientific basis.

Arguing against the use of peer review in regulatory agencies, therefore, invites accusations of trying to obscure the flaws of agency practice. Advocates of peer review contend that it is the light that will expose those flaws, leading to the improved quality of agency decisions

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88. Wendy Wagner provides a comprehensive study of these institutional forces in the context of science and policy. *See* Wagner, *Science Charade*, *supra* note 13, at 1650–73. *See generally* RICHARD J. PIERCE, JR. ET AL., ADMINISTRATIVE LAW AND PROCESS § 1.7–1.10 (3d ed. 1999).

89. *See* PIERCE ET AL., *supra* note 88, § 1.9.

90. *Id*. § 1.7.2.

91. *Id*. § 1.9.

92. 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 practice in many situations where information is inadequate for development of scientifically rigorous decisions." KLAMATH COMMITTEE FINAL REPORT, *supra* note 8, at 35.

and revealing the biases of agency decisionmakers. On the surface, therefore, peer review may have something to offer administrative law in general.

At the same time, regulatory peer review clearly imposes costs on agencies that are already operating under tight resource constraints. One can believe that agencies might portray science as doing more for their policy decisions than is justified and that peer review will improve agency decisions in this respect. But that alone does not provide compelling justification for greater use of regulatory peer review, because it is just not clear how many Klamaths are out there. Whether intentionally or as a result of a good-faith mistakes, how frequently would agency regulatory decisions purported to be based on science fail the test of peer review? Without a sense of how big a problem this poses, advocates of regulatory peer review cannot state with any confidence that its theoretical benefits outweigh the actual costs of implementation.

B. Empirical Analysis: Faith, Perceptions, and Demand

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

Faith, however, is a powerful force when shared by a multitude. 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 those who share these beliefs are experienced in administrative law and policy—can claim to have practical experience with agency regulatory practices—then the public is less likely to demand an empirical study of the issue before supporting proposals to put regulatory peer review in place. Indeed, this is precisely what our survey showed to be the case.

The survey was designed to elicit respondents' perceptions about the performance of regulatory agencies, the merits of regulatory peer review, and the design of regulatory peer review.[93] With respect to agency

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

performance, the survey posed a general question and many detailed ones relating to different attributes of agency use of science. Responses indicated a significant background level of concern over agency use of science among experienced practitioners.[94] Indeed, in more detailed questions, respondents revealed a deep mistrust of agency behavior. Figure 1 shows the percentage of responses to specific aspects of agency use of science.

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.

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

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

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

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

Unsurprisingly, and consistent with the institutional theory reviewed above, many respondents indicated they believe that agencies face significant time and resource constraints in their use of science (questions a through c). More troublesome was the level of concern respondents revealed about how agencies prioritize their search for data and about how they select and rely on data in support of their decisions: almost half of the respondents expressed negative perceptions of agency behavior (questions d through f). Most startling, however, were the responses to the final two questions in the series (questions g and h). Over 70% of respondents disagreed, 20% strongly so, with the statement that agencies generally give appropriate recognition to scientifically reliable data that contradict their preferred decisions; 56% of respondents disagreed with the statement that agencies usually employ adequate scientific analysis when using the data they present as supporting their final decisions. The overall picture these responses paint is that many experienced practitioners understand that agencies face time and resource constraints in their use of science, but even more believe agencies make poor use of what science they have at their disposal, which leads to the potential overstatement of the scientific support for their regulatory decisions.

Of course, not all respondents felt this way, and the difference of opinion is starkest when the backgrounds of respondents are considered.[95] Not surprisingly, respondents who indicated federal or state agency government employment (combined in a regrouping designated as "Govt") as their primary career experience, which made up 15% of the respondent pool, were far more likely to hold favorable views of agency use of science than were respondents with primarily private law firm or in-house careers representing corporations (combined in a regrouping designated "Corp"), which accounted for 73% of respondents. For example, government respondents were over four times more likely than industry respondents to agree with the general statement that agencies usually employ adequate procedures.[96] Figure 2 shows how extensive this difference of opinion was for each of the specific questions about agency performance:

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

96. Since the responses called for in our survey are clearly ordinal in nature, we used the logistic regression method of statistical analysis for answering various questions of interest throughout our study. For example, to determine the influence of government work on perceptions of regulatory peer review, we treated the two practice setting categories as the explanatory variable X, and the responses to perceptions of regulatory peer review were coded on a scale from 1 to k; for example, 1-5, corresponding to strongly agree, somewhat agree, no opinion, somewhat disagree, and strongly disagree. The score for each question was treated as the response variable Y and the k possible scores of Y are called the response categories. The principal objective of a statistical analysis is to investigate the relationship between the explanatory variable X and the response variable Y. The ordinal nature of the responses leads naturally to statistical models based on the cumulative response probabilities of observing response categories less than or equal to a given score j, when the covariate is X. More specifically, we are interested in investigating the influence of the explanatory variable X on the cumulative response probability up to and including category j. The logistic regression method of examining such relationships involves modeling the logarithm of the odds of the event of observing response categories up to and including category j as a function of the explanatory variable X through a linear regression equation.

Figure 2. The second column shows which group, federal or state government career (Govt) or private firm or in-house corporate career (Corp), was significantly more likely to agree with the statement in the first column (i.e., to answer "strongly agree" or "somewhat agree"), based on the breakdown between the two groups who agreed (third and fourth columns). To indicate the strength of the difference, if any, between the two groups, the fifth column shows the odds that a person selected randomly from the more likely group would agree with the statement compared to a person selected randomly from the less likely group.

	More Likely to Agree	% agreeing that were Govt	% agreeing that were Corp	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.	Govt	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.	Govt	64	36	3.3:1
d. Agencies generally place an adequate priority on searching for scientific data relevant to their decisions.	Govt	63	37	2.9:1
e. Agencies usually select data that have adequate scientific reliability.	Govt	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.	Govt	75	25	8.8:1
h. Agencies usually employ adequate scientific analysis when using the data they present as supporting their final decisions.	Govt	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 fell in line with institutional theory in expressing tremendous support for agency performance—far more so than did the industry attorneys. Moreover, with government attorneys accounting for most of the favorable opinion of agency performance (notwithstanding their lower representation numbers in the survey), the negative perception of agency use of science among industry attorneys was remarkably deep and broadly shared.

Our survey reveals a sharp difference of opinion between agency lawyers and lawyers representing industry about agency use of science. Interest groups associated with environmental causes, however, also hold to the faith that agencies may not adequately ground their decisions in science. Studies have shown that support for peer review under the ESA, for example, is strong in both the industry and the environmental camps, but such support is almost always limited to applying review to the types 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."[97]

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.[98] One group of prominent scientists endorsed a statement accusing the Bush Administration in general of misusing science.[99] Democratic members of Congress have produced reports accusing agencies of intentional suppression and distortion of scientific data[100] and of practicing "weird science."[101] Even scientists within NOAA have recently claimed that they have witnessed outright suppression and distortion of science within their agency.[102] In short, the perception that agencies rely on inadequate scientific support for their decisions has begun to transcend neat political boxes.

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

98. *See generally* MOONEY, *supra* note 13, at 14–24, 78–248.

99. *See* Union of Concerned Scientists, Scientific Integrity Statement Signatories, http://www.ucsusa.org/RSI_list/index.php (last visited apr. 2, 2006). For the scientists' statement, see Union of Concerned Scientists, Restoring Scientific Integrity in Policymaking (Feb. 18, 2004), http://www.ucsusa.org/scientific_integrity/interference/scientists-signon-statement.html.

100. *See* MINORITY STAFF SPECIAL INVESTIGATIONS DIV., H. COMM. ON GOV'T REFORM, POLITICS AND SCIENCE IN THE BUSH ADMINISTRATION (2003), *available at* http://www.house.gov/reform/min/politicsandscience/pdfs/pdf_politics_and_science_rep.pdf.

101. *See* DEMOCRATIC STAFF, H. COMM. ON RES., WEIRD SCIENCE: THE INTERIOR DEPARTMENT'S MANIPULATION OF SCIENCE FOR POLITICAL PURPOSES (2002), *available at* http://www.ourforests.org/weirdscience.pdf.

102. *See Officials, Scientists Spar over Whether Politics Trumps Science at NMFS*, ENDANGERED SPECIES & WETLANDS REP., June 2005, at 14, 14.

It is not surprising that different denominations share the faith that agencies sometimes oversell the extent to which science supports their decisions. Regulatory agencies deal with so many issues affecting so many interest groups that an agency will eventually offend almost every interest group with whom it deals enough times to raise the group's concern over the use of science in decisions that went against them. Perhaps in each matter it depends on whose ox the agency gores, but over time, if the agency gores everyone's ox, the reliability of agency use of science can become 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 view regulatory peer review as an answer to the perceived misuse of science by agencies:

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 the 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	15	9	2
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% agreeing that it will improve the quality of agency decisions, expose flaws in agency use of science, and improve public confidence in agencies, and only 20% or less disagreeing that each of those expected benefits will accrue. 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% 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 had different expectations about the effects of regulatory peer review, as shown in Figure 4, though we were shocked by the degree of disagreement.

Figure 4. The second column shows which group (federal or state government career (Govt) or private firm/in-house corporate career (Corp)), was significantly more likely to agree with the statement in the first column (i.e., answer "strongly agree" or "somewhat agree"), based on the breakdown between the two groups who agreed (third and fourth columns). To indicate the strength of the difference, if any, between the two groups, the fifth column shows the odds that a person selected randomly from the more likely group would agree with the statement compared to a person selected randomly from the less likely group.

	More Likely to Agree	% agreeing that were Govt	% agreeing that were Corp	Odds
a. It is likely to lead to substantial improvements in the quality of agency decisions	Corp	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	Corp	22	78	12.5:1
c. It is likely to improve public confidence in agency decisions	Corp	19	81	20:1

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

C. Meeting the Demand

Our survey results suggest that demand for regulatory peer review is strong among experienced practitioners of regulatory law, particularly those who represent industry clients before agencies. 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.[103] 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,[104] OMB's approach requires federal agencies to conduct "a peer review of influential scientific information" and of "highly influential scientific assessments" an agency disseminates to the public.[105] In its initial September 2003 proposal, OMB claimed this mandate would "improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public," because it would "provide a vital second opinion on the science that underlies federal regulation."[106]

OMB responded to a wide range of comments on its initial proposal[107] and published a revised proposal in April, 2004.[108] 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 product.[109]

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103. *See* Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23,230, 23,230 (Apr. 28, 2004) ("[P]eer review improves both the quality of scientific information and the public's confidence in the integrity of science."); Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023, 54,024 (Sept. 15, 2003) ("Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses.").

104. 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 . . . ." consolidated Appropriations Act, 2001, Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153 to 54 (2000). For a history of the political figures and events that led to the Data Quality Act, see MOONEY, *supra* note 13, at 102–20.

105. Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2675 (Jan. 14, 2005). Some observers have questioned OMB's authority to require peer review. *See* Shapiro, *supra* note 25, at 10,064–65.

106. Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023, 54,023-24 (Sept. 15, 2003).

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

108. Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. at 23,230–31.

109. *Id*. at 23,231.

OMB received more comments on the revised policy,[110] though far fewer than on the original proposal, and adopted a final policy in December 2004 with relatively minor refinements.[111] Under the final policy, agency information subject to review would include data, synthesis of facts, models, analyses, and assessments that would "have a clear and substantial impact on important public policies or private sector decisions."[112] This could range from state of science reports, meta-analyses, and risk assessments to toxicity profiles and health and ecology assessments.[113] Not all science underpinning decisions can be peer reviewed, of course, and OMB's strictest peer-review requirements are reserved for science affecting decisions with $500 million of regulatory or private-sector impact, novel, precedent-setting impact; or significant interagency interest.[114] If the data have already been subject to adequate peer review (e.g., journal review), no further review is needed.[115] Otherwise, the agency must apply internal or external peer review by technical experts not associated with the work product and must provide a summary or copy of comments to the public.[116] The agency must publicly respond to the peer review report, and in some cases public comment and hearing on the draft peer review report may be appropriate.[117]

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,[118] introduced by Representative James Hansen (R-Utah), is the genesis of a line of such legislation that has followed in similar spirit.[119] In general, these proposals would alter the procedures, standards of evidence, and burdens of proof under which federal agencies operate in carrying out ESA programs.[120] The legislation would stiffen ESA procedures in many respects, requiring FWS and NOAA to give preference to certain forms of evidence and apply

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

111. Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005).

112. *Id*. at 2667.

113. *Id*.

114. *Id*. at 2671.

115. *Id*.

116. *Id*. at 2675.

117. *Id*. at 2672.

118. H.R. 4840, 107th Cong. (2002).

119. For a more recent version, see H.R. 1662, 108th Cong. (2003); S. 369, 108th Cong. (2003). For a history of peer review provisions in ESA reform bills preceding H.R. 4840, see Michael J. Brennan et al., *Square Pegs and Round Holes: Application of the "Best Scientific Data Available" Standard in the Endangered Species Act*, 16 TUL. ENVTL. L.J. 387, 433–40 (2003).

120. *See* Burke, *supra* note 8, at 506–07.

more rigorous burdens of proof to a long list of specified decisions.[121] 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.[122] 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 ESA reforms have enjoyed strong support[123] and engendered equally strident criticism.[124] Testimony from agency officials generally supported the reforms with only minor suggested changes.[125] The House Resources Committee held hearings on Representative Hansen's bill in June 2002[126] and reported it favorably on July 10, 2002, in a 22–18 vote that largely followed party lines.[127] Peer review proposals like the ESA bills continue to have considerable traction in Congress.[128]

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,[129] and the perception that agencies overstate how far their science gets them appears to be widely held by attorneys and interest groups that appear before regulatory agencies.[130] In politics, that is usually more than enough. The debate has not been one-

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121. *See* H.R. 4840, 107th Cong. (2002) § 2.

122. *See id.* §§ 2–3.

123. *See, e.g.*, NAT'L ENDANGERED SPECIES ACT REFORM COAL., H.R. 4840, the Sound Science for Endangered Species Act Planning Act of 2002, http://www.nesarc.org/walden.htm (last visited Apr. 2, 2006) (providing links to several relevant sites).

124. *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), http://www.defenders.org/releases/pr2002/pr071102.html (calling the proposal "one more effort by the 'development at any environmental cost' crowd to gut the ESA").

125. *See* http://laws.fws.gov/testimon/2001/main2001.html (resonating that "sound science" has become a theme across many programs in the Bush Administration).

126. *"Sound Science for Endangered Species Act Planning Act of 2002": Hearing on H.R. 4840 Before the H. Comm. on Resources*, 107th Cong. (2002).

127. *See* Press Release, Nat'l Endangered Species Act Reform Coal., ESA Victory: Sound Science Legislation Passes House Resources Committee (July 11, 2002), http://www.nesarc.org/4840alert.pdf (last visited Nov. 7, 2003).

128. *See, e.g.*, H.R. 4940, 109th Cong. § 3 (2006); H.R. 5018, 109th Cong. § 3 (2006) (proposing peer review for agency decisions about fisheries management).

129. *See supra* Part III.A.

130. *See supra* Part III.B.

sided, however, for there are significant objections to imposing regulatory peer review. These are explored in the next section.

IV. THE CASE AGAINST PEER REVIEW

Critics of mandating regulatory peer review have advanced two positions: First, evidence that agencies frequently overstate the extent to which science supports a regulatory decision is insufficient. Second, absent such evidence, even if there is a problem, they argue, peer review is not the solution but rather a practice to be avoided at all costs. Not only will it fail to provide the promised benefits, they argue, but it will further politicize the decision making process and slow the agency process to the point of frustrating agencies' missions to protect the public welfare. They may be right in some circumstances, but when examined closely these arguments turn out to rest on simply a different faith than the one held by the supporters of regulatory peer review.

A. There is No Problem

As discussed above, our survey revealed that attorneys representing agencies tend to believe that regulatory agencies adequately describe the scientific support for their regulatory decisions which, if true, means there is no justification for adding the burden of regulatory peer review. To evaluate this position carefully, however, it is critical to distinguish between cases in which an agency produces or employs "bad science" and cases in which an agency misuses "good science." For example, Wendy Wagner asserts that "the examples of regulatory bad science are winnowed down to a few, virtually all of which are contested."[131] This assertion refers, however, to the quality of science an agency has produced or relied on—e.g., whether the data were biased or whether the agency ignored relevant data—not whether the agency has taken what might be perfectly credible science and stretched it too far to support a policy decision.[132] Moreover, studies of agency practices with respect to science do not cover "the larger universe of regulatory decisions involving the grant of permits and licenses,"[133] which is, of course, a principal target of many current

131. Wagner, *Bad Science*, *supra* note 13, at 73; *see* Sidney Shapiro, *The Case Against the IQA*, ENVTL. F., July/Aug. 2005, at 26, 28.

132. *See* Wagner, *Bad Science*, *supra* note 13, at 73–77. Of course, Wagner was the first to comprehensively explore the institutional reasons why agencies may overstate the extent to which science supports their policy decisions. *See* Wagner, *Science Charade*, *supra* note 13.

133. *See* Wagner, *Bad Science*, *supra* note 13, at 73.

proposals for regulatory peer review. In fact, no critique of regulatory peer review has presented empirical evidence based on systematic, objective analysis of how accurately agencies apply science—perhaps perfectly sound science—in this meaningful universe of regulatory decisions.

Hence, although there is substantial evidence that agencies do not systematically produce or use flawed scientific evidence, there is almost no empirical evidence on the question of how agencies use the available credible science to support their policy decisions, particularly in permitting and licensing decisions. Indeed, if the argument were simply that there has been no comprehensive empirical examination of whether and how often agencies overstate the support science lends to their policy decisions, we would agree. As the previous section shows, however, such an assertion is not an 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 frequently exhibit this problem, in which case that burden unquestionably has not been met.[134] But why place the burden of empirical proof on the side that wishes to apply a bedrock principle of science with a 300-year tradition to agencies that base their decisions in whole or in part on science? Given how crucial peer review is to the scientific method, given the institutional forces that suggest agencies may often overstate how far science gets them, and given the belief held by many industry and environmental interests alike that agencies in fact do so, it is not unreasonable to expect critics of regulatory peer review to demonstrate that what is good for science is ill-advised for regulation. Observing that a data vacuum exists does not meet this burden.

B. If There Is a Problem, Peer Review Is Not the Solution

Our survey also revealed that attorneys representing agencies as the primary focus of their careers generally do not believe regulatory peer review can improve agency decisions or public confidence in them. 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

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134. Wagner points this out with respect to the charge that agencies practice poor science, *see id.* at 76–79 (demonstrating "the failure of the reformers themselves to document a problem" with respect to poor agency practice of science).

the quality of science used in the regulatory process."[135] Of course, there is no evidence regulatory peer review is *unlikely* to do so either. Yet, 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."[136] That sounds pretty attractive—after all, who would not 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 diagnosis. 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."[137]

This concern is particularly acute in regulatory settings in which the best available science is likely to prove inconclusive, forcing the agency to rely on professional judgment to interpret the data and then, when permitted or required, to employ other policy considerations to reach a final decision. Regulatory peer review will not close the data gaps.[138] If advocates of regulatory peer review suggest otherwise, they oversell 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 mask their biases with 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, reliant on informal channels of scientific communication, and generally unwilling to communicate their data and

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135. Am. Ass'n for the Advancement of Science AAAS Resolution: *On the MB Proposed Peer Review Bulletin* (Mar. 9, 2004), http://archives.aaas.org/docs/resolutions.php?doc_id=434.

136. *See supra* notes 19, 86 and accompanying text.

137. Noah, *supra* note 25, at 1046.

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

scientific reasoning in a manner that facilitates review by the public and the courts.[139] The 1994 peer review policy, described earlier,[140] 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."[141] 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."[142] With this, the agencies proclaimed to have put the attributes of peer review into motion.

In 2003, however, the GAO conducted a study of how FWS had implemented the peer review policy.[143] Its findings were disturbing. Perhaps most important, the process was informal and actually seemed to invite bias. The report noted that FWS "officials told us that they have not adopted a formal procedure to assess peer reviewers' independence, and the [FWS] does not publicly disclose . . . potential conflicts or prior involvement by its peer reviewers."[144] 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," and that "those selected [should] have demonstrated expertise and specialized knowledge related to the scientific area under consideration,"[145] it was the agencies who selected their peer reviewers, reviewed the peer reviews, and reported the results of the peer reviews.[146] The GAO found that FWS "[p]eer reviewers are selected at the discretion of the field office scientists responsible for developing listing and critical habitat decisions."[147] Not

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139. *See* Doremus, *supra* note 37, at 1082–87.

140. *See supra* notes 70–71 and accompanying text.

141. 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).

142. *Id.*

143. GEN. 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 (2003).

144. *Id.* at 16.

145. Endangered and Threatened Wildlife and Plants: Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities, 59 Fed. Reg. at 34,270 (July 1, 1994).

146. *See, e.g.*, Endangered and Threatened Wildlife and Plants; Final Rule to Reclassify and Remove the Gray Wolf from the List of Endangered and Threatened Wildlife in Portions of the Conterminous United States, 68 Fed. Reg. 15,804, 15,819–20 (Apr. 1, 2003) (discussing FWS's use of the peer review process in connection with a decision about the status of gray wolves (*Canis lupus*)).

147. GEN. ACCOUNTING OFFICE, *supra* note 143, at 15. By contrast, the NRC peer review policy,

surprisingly, the study noted that the peer reviewers chosen by FWS usually agreed with the agency's positions.[148] Without clearly independent reviewers, this process and its results are open to charges of manipulation.[149]

Ironically, OMB provides no more encouraging an example in its own actions. OMB has been required since 1997 to provide Congress an accounting statement and a report on the guidelines it has issued estimating the total annual costs and benefits of agency regulation and analyzing the impact of regulation on small businesses, local, state and tribal governments, and economic growth.[150] In 2000, Congress required OMB to ensure an "independent and external peer review of the guidelines and each accounting statement and associated report."[151] Research by Joanna Goger on 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.[152] One reviewer wrote to OMB following his review of the 2001 report, "[a]t 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."[153] 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

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under which the Klamath Committee was formed, provides:

> [t]he 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 Acadamies, THE NATIONAL RESEARCH COUNCIL PROCESS, http://www.nationalacademies.org/about/faq4.html (last visited Apr. 4, 2006).

148. GEN. ACCOUNTING OFFICE, *supra* note 143, at 21–22.

149. For example, the ability of an author to suggest or exclude reviewers in the scientific-journal-publishing context has been shown to increase the chances of being selected for publication. *See* David Grimm, *Suggesting or Excluding Reviewers Can Help Get Your Paper Published*, 309 SCIENCE 1974, 1974 (2005).

150. *See* GEN. ACCOUNTING OFFICE, GAO/GGD-99-59, REGULATORY ACCOUNTING: ANALYSIS OF OMB'S REPORTS ON THE COSTS AND BENEFITS OF FEDERAL REGULATION 14–15 (1999). 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).

151. Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, § 624(d), 114 Stat. 2763, 2763A-162 (2000).

152. Goger, *supra* note 150.

153. *Id.*

followed the FWS example of cherry-picking reviewers. 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 of regulatory peer review is, even if the preceding concerns—that peer review will not improve agency decisions and will be politically manipulated—are mistaken, the demand on 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."[154] 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.[155]

Indeed, the statutory and regulatory deadlines frequently placed on agency decision making acknowledge the pressing need in many cases to intervene on policy problems.[156] Agencies already have difficulty meeting those deadlines,[157] 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 would be unable to act before it is too late, for example, allowing an endangered species to move ever closer to extinction while the agencies engage in further process. In the context of regulatory regimes in which decision

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154. Noah, *supra* note 25, 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").

155. 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, environmental and other regulations." Letter from Carol M. Browner et al., to Joshua B. Bollen, Dir., Office of Mgmt. & Budget (Jan. 9, 2004), http://www.progressive regulation.org/articles/Letter_Bolten_Sig.pdf.

156. *See, e.g.*, 16 U.S.C. § 1533(b) (2000) (ESA deadlines for listing of species and designating critical habitat); *Id.* § 1536(b) (deadlines for interagency consultations).

157. *See* GEN. ACCOUNTING OFFICE, GAO-04-93, ENDANGERED SPECIES: MORE FEDERAL MANAGEMENT ATTENTION IS NEEDED TO IMPROVE THE CONSULTATION PROCESS 14–17 (2003), (explaining how frequently the agencies exceed deadlines applicable to consultation under Section 7(a)(2) of the ESA).

time matters, mandatory regulatory peer review may well cause greater harms of omission than of commission.[158]

Figure 5. Respondents were asked 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 the percentage of respondents in each category.

	Strongly Agree	Somewhat Agree	No Opinion	Somewhat Disagree	Strongly Disagree
a. It is likely substantially to slow down agency decisionmaking processes.	17	47	15	18	3
b. It is likely to add substantially to the costs of agency decisionmaking.	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	28	19	5
g. It is likely to be subject to manipulation by interest groups to serve their interests.	24	37	20	16	3

Our survey showed 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. The results indicated no 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, and government attorneys are more likely to believe it will add to litigation and erode agency morale; the two groups agreed that regulatory peer review would likely add to agency costs, and were equally mixed in feeling it would steer agencies away from making decisions subject to peer review.

Figure 6: The second column shows which group (federal or state government career (Govt) or private firm/in-house corporate career

158. *See* McGarvey & Marshall, *supra* note 7, at 108–09 (suggesting this is a serious concern under the ESA).

(Corp)) was significantly more likely to agree with the statement in the first column (i.e., answer "strongly agree" or "somewhat agree"), based on the breakdown between the two groups who agreed (third and fourth columns). To indicate the strength of the difference, if any, between the two groups, the fifth column shows the odds that a person selected randomly from the more likely group would agree with the statement compared to a person selected randomly from the less likely group.

	More Likely to Agree	% agreeing that were Govt	% agreeing that were Corp	Odds
a. It is likely substantially to slow down agency decision making processes.	Corp	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.	Govt	71	29	6.2:1
d. It is likely to lead to erosion of agency personnel morale.	Govt	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.	Corp	35	65	3.6:1
g. It is likely to be subject to manipulation by interest groups to serve their interests.	Corp	37	63	2.9:1

Overall, therefore, the arguments against regulatory peer review, while not based on persuasive empirical evidence, do find support in basic institutional theory and in perceptions that are widely held among experienced practitioners of regulatory law. Hence, while the 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.[159] Rather than never employing regulatory peer review, or employing it all the time, a balanced approach seems appropriate.

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159. 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.

Yet peer review has become a pawn in a much larger debate over the appropriate roles of science and policy in our society.[160] As such, its supporters and its opponents alike overstate its advantages and disadvantages.[161] There is little question increased use of regulatory peer review would detect some cases of agency failure, but it could also create considerable drag on agency process. After all, the Klamath Committee confidently concluded 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, how much benefit or burden to expect from wholesale or strategic application of regulatory peer review to administrative decisions is really unknown.

V. RECONCEIVING THE ROLE OF REGULATORY PEER REVIEW

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

A. Defining Potential Benefits

Most of the fog surrounding regulatory peer review arises from the proclivity of almost everyone involved in the debate to conflate science and policy, as if agencies make one holistic conclusion about each particular regulatory decision. After the Klamath Committee issued its report, for example, one 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."[162] In science, of course, that is enough—one generally does not get published in scientific journals based on a claim that one's research did not prove *anything*. Yet, the FWS

160. *See supra* notes 11–17 and accompanying text.
161. *See supra* Parts III–IV.
162. Michael Grunwald, *Scientific Report Roils a Salmon War*, WASH. POST, Feb. 4, 2002, at A1.

official clearly took solace in the peer review's finding a lack of scientific support for the agency's position rather than finding that scientific data actually refuted the agency's position.

The difference, for regulatory decisions at least, is grounded in the policy component of administrative decisions. In fact, Congress rarely commands that an agency decision be based solely on scientific evidence conclusively proving the decision correct. In the Klamath setting, for example, the decision FWS was required to make involved an evaluation of whether the Bureau of Reclamation's proposed water diversions would jeopardize the continued existence of the protected fish species,[163] and Congress has commanded that FWS use the "best scientific and commercial data available" to make that decision.[164] This standard's "obvious purpose . . . is to ensure that the ESA not be implemented haphazardly, on the basis of speculation or surmise."[165] But that does not preclude an agency's well-reasoned use of professional judgment in the face of incomplete scientific evidence. Frequently, perhaps most of the time, it will be the case that an agency must use some basis in addition to the best scientific data available for reaching a jeopardy decision. In some regulatory settings Congress might prescribe additional policy-based factors, such as cost-benefit analysis, that an agency must meld with its scientific analysis to reach a final regulatory decision.[166] In other cases, such as the ESA jeopardy analysis, it may come down simply to 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 the species in such cases.[167] This may be a perfectly appropriate policy decision, but it forecloses the agency's use of science to prove itself right in particular cases.

The problem is that agencies might not make explicit the policy-based preferences or findings underlying their decisions. In the Klamath experience, for example, neither FWS nor NOAA presented any basis to

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163. *See* 16 U.S.C. § 1536(a)(2) (2000).

164. 16 U.S.C. § 1536(a)(2),(c); 50 C.F.R. § 402.14(g)(8) (2005).

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

166. *See, e.g.*, 16 U.S.C. § 1533(b)(2) (requiring cost-benefit analysis for designation of critical habitat under the ESA).

167. *See* Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule, 51 Fed. Reg. 19,926, 19,952 (June 3, 1986) (to be codified at 50 C.F.R. pt. 402) ("[T]he Service must provide the 'benefit of the doubt' to the species concerned."); U.S. FISH & WILDLIFE SERV. & NAT'L MARINE FISHERIES SERV., 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.

the Klamath Committee other than science for their respective decisions.[168] In other words, once the Klamath Committee "said there wasn't enough science to prove us right,"[169] 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 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 also take no pride when science fails to prove their decisions correct 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 our survey's potentially biased industry attorneys who believe this is an important goal of administrative law. A National Research Council committee of experts recently convened to review the scientific support for federal agency management decisions in the Platte River Basin explained the difficulty agencies face in integrating incomplete and inconclusive science into regulatory decisions that involve value judgments.[170] 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

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168. This is based on J.B. Ruhl's personal experience as a member of the Klamath Committee.

169. Grunwald, *supra* note 162.

170. *See* COMM. ON ENDANGERED & THREATENED SPECIES IN THE PLATTE RIVER BASIN, NAT'L RESEARCH COUNCIL, ENDANGERED AND THREATENED SPECIES OF THE PLATTE RIVER 92–100 (2005).

> 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 of nonscientific factors to reach a final decision.[171]

Similarly, Cary Coglianese and Gary Marchant recently observed that

> [e]mbedded 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 resulting policy outcomes, as well as any explanations or rationalizations offered in their defense, will likely be inconsistent if not unreasonable.[172]

If a 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 sharpening that line than regulatory peer review.[173] As a committee of scientists speaking on behalf of the Society for Conservation Biology observed well before the peer review debate flew into high gear:

> Independent scientific review (ISR) can help ensure that environmental decisions and policy making reflect the best scientific knowledge of the day. Most environmental issues are burdened with historical momentum, economic implications, and cultural values that may dominate decision making in the absence of scientific information. An ISR can help decision makers focus on the oxbjective [sic], scientific variables apart from economic, historical, or cultural factors and to interpret issues in the context of great ecological complexity and uncertainty. Also ISR can raise the level of public trust in the process, alleviating fears that industries, environmental protection organizations, or government agencies are

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171. *Id.* at 99–100.

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

173. As Professors Doremus and Tarlock observe, "[a]ppropriate outside review which generates a publicly available report can . . . make scientific, political, and even management judgments more transparent." Doremus & Tarlock, *supra* note 16, at 32; *see also* Holly Doremus, *Science Plays Defense: Natural Resources Management in the Bush Administration*, 32 ECOLOGY L.Q. 249, 302 (2005) ("Peer review . . . can, under the best circumstances, also increase transparency by pointing out limitations in the data, unconventional scientific judgments, or places where policy judgments must have been made.").

simply promoting their own interests or moving ahead without benefit of relevant scientific information.[174]

And this message from the scientific community has persisted through the throes of the debate. Yet another National Research Council committee recently concluded, for example, that peer review when properly conducted is a critical component of the objectivity, transparency, and openness desired to instill public confidence in regulatory decisions.[175]

Perhaps it is time to start listening to the scientists about the virtues of 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.[176] If peer reviewers in regulatory settings 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.[177] But 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 we believe accurately) point out that the movement's primary aim seems to be to increase the quantity rather than the quality of the agencies' science—i.e., to impose on agencies the duty to *do* science more often rather than to *use* science more carefully.[178] Some agencies, of course, engage in pure research, and presumably no one is opposed to having those agencies undergo *scientific* peer review. But most regulatory agencies, such as FWS in conducting a jeopardy evaluation, are neither expected by law nor

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174. Gary K. Meffe et al., *Independent Scientific Review in Natural Resource Management*, 12 CONSERVATION BIOLOGY 268, 268 (1998).

175. *See* COMM. ON DEFINING BEST SCIENTIFIC INFO. AVAILABLE FOR FISHERIES MGMT., NAT'L RESEARCH COUNCIL, IMPROVING THE USE OF THE "BEST SCIENTIFIC INFORMATION AVAILABLE" STANDARD IN FISHERIES MANAGEMENT 56–57 (2004) (noting that "peer review is the most accepted and reliable process for assessing the quality of scientific information. Its use as a quality control measure enhances the confidence of the community (including scientists, managers, and stakeholders) in the findings presented in scientific reports.").

176. *See supra* Part II.A.

177. By doing so, moreover, regulatory peer review might improve not only the quality of agency use of science, but also the quality of agency policy justifications by inducing agencies to make those justifications more explicit. Our attention is devoted strictly to the former effect, but scholars studying how to improve the transparency and legitimacy of agency policy rationales, *see, e.g.*, Markell, *supra* note 14, may find our proposal beneficial to their cause.

178. *See* Burke, *supra* note 8, at 512–14; Wagner, *Bad Science*, *supra* note 13, at 109–32.

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.

Peer review, however, is simply one component of the practice of competent science, and it does not directly require researchers 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. 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 above, the following model compares scientific peer review to the four stages where science is used 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 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, on whether 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."[179] 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 considerations or protection."[180] Areas outside the geographic range of the species may be designated if they are "essential for the conservation of the species."[181] These determinations must be made "on the basis of the best scientific data available."[182] 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."[183] Taking those impacts into consideration, the agency "may exclude any area from critical habitat if . . . the benefits of such

179. 16 U.S.C. § 1533(a)(3) (2000).
180. § 1532(5)(A)(i).
181. § 1532(5)(A)(ii).
182. § 1533(b)(2).
183. 16 U.S.C.A. § 1533(b)(2) (Supp. 2005).

exclusion outweigh the benefits of specifying such area as part of the critical habitat."[184] 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."[185]

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?

This is depicted graphically as a flow chart on the following page.

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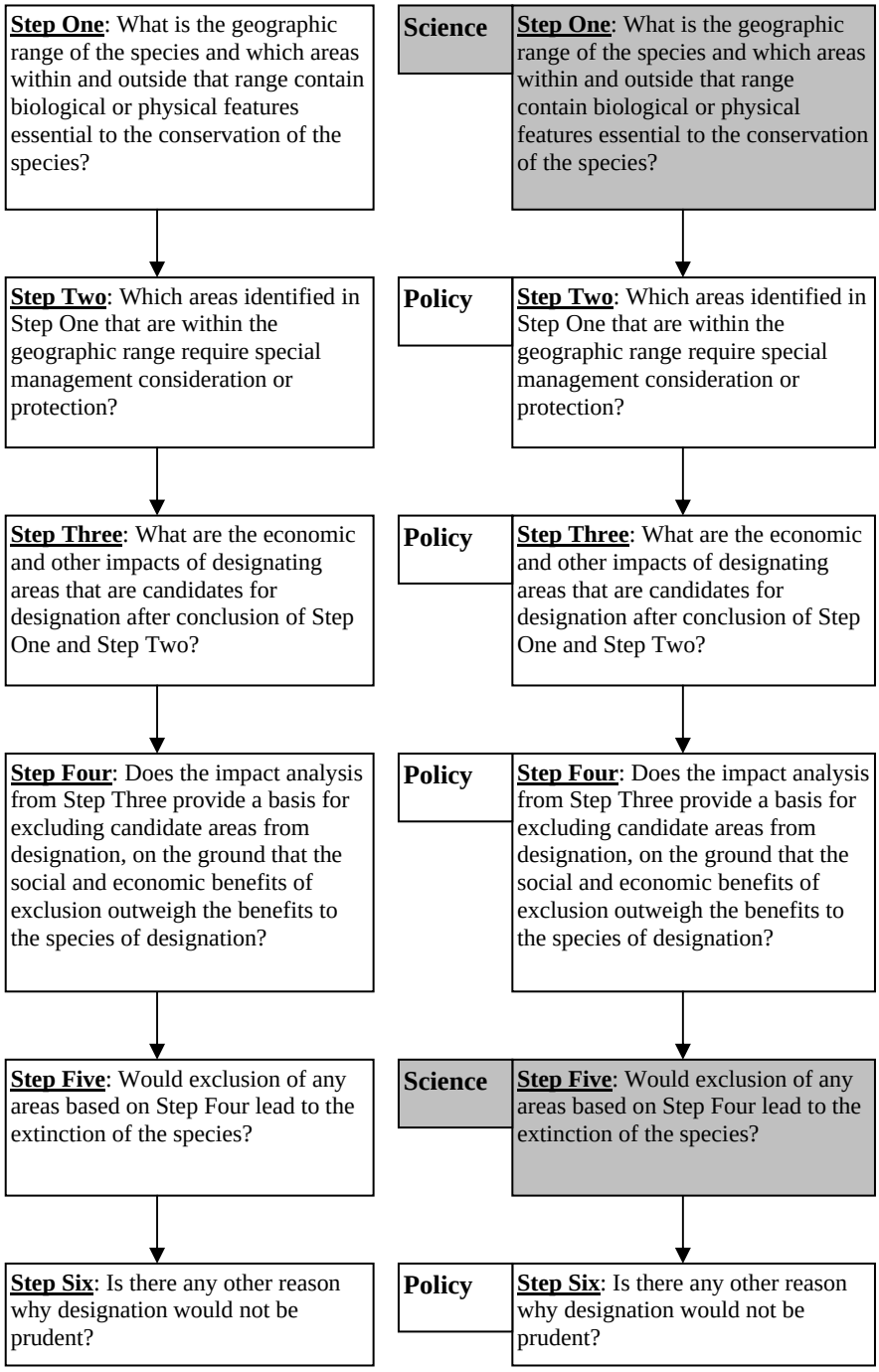
184. 16 U.S.C. § 1533(b)(2).
185. *Id*.


Step One: 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?
Science
Step One: 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?
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Policy
Step Two: Which areas identified in Step One that are within the geographic range require special management consideration or protection?
Step Three: What are the economic and other impacts of designating areas that are candidates for designation after conclusion of Step One and Step Two?
Policy
Step Three: 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: 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?
Policy
Step Four: 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: Would exclusion of any areas based on Step Four lead to the extinction of the species?
Science
Step Five: Would exclusion of any areas based on Step Four lead to the extinction of the species?
Step Six: Is there any other reason why designation would not be prudent?
Policy
Step Six: 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:

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 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 inappropriate reasons? Did the agency rely on data or research of questionable reliability?
Agency's interpretation of data and research selected	Are the agency's conclusions about the geographic range of the species, biological and physical features essential to the conservation of the species, and the threat of extinction if specific areas were 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, and interpretation of scientific data and research. Scientific peer review, in other words, maps quite nicely onto the regulatory process to produce regulatory peer review.

C. Avoiding Drag

And what of the legitimate concern over making agencies jump through more hoops? Our formulation of regulatory peer review focuses on the quality of the agency's use of science, not the quantity of how much science it conducts. 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 scientific claims ought not strike anyone as repugnant to appropriate administrative procedures.

As to the concern that regulatory peer review imposes unrealistic burdens of proof, that also is not the case under our formulation of the process. Regulatory peer review does *not* import the default scientific burden of proof: that the data support the conclusion within a 95% 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 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 integration of the agency's 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 must be conducted properly if it is to be conducted at all. Wendy Wagner and

others have argued persuasively that sham regulatory peer review may actually prove counterproductive by *helping* agencies overstate the extent of support they derive from science by giving policy decisions the appearance of a scientific exercise.[186] Moreover, regulatory peer review will take time and money to conduct, resources that may be taken away from other important agency functions. Both are legitimate concerns. Peer review can be misused, just as science can be misused. The answer to both concerns is the same: design matters. Accordingly, we next outline a proposal for implementing regulatory peer review which we believe would yield all the major benefits without compromising effectiveness.

VI. A PROPOSED MODEL OF RANDOMIZED PEER REVIEW

This Article has set out the main arguments in favor of and opposed to regulatory peer review, described the major peer review initiatives in Congress and OMB, and looked at 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, how many agency decisions actually would be improved by peer review is unknown. And this matters because, third, the practice of peer review imposes costs. The policy question thus 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.[187] This approach is senselessly over-inclusive (imposing peer review on all ESA protection measures would significantly weaken the statute's ability to conserve biodiversity) as well as 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 the respondents opposed applying it to *all* regulatory decisions of an agency.

The OMB proposal, which became effective in December, 2004, implicitly recognizes 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, agency decisions that impose private sector impact of over $500 million,

186. *See, e.g.*, Wagner, *Science Charade*, *supra* note 13, at 1700.
187. *See supra* notes 118–23 and accompanying text.

and decisions that involve precedent-setting, novel and complex approaches.[188] A slim majority—55 percent—of our survey respondents favored this approach. Nevertheless, while these thresholds do provide cut-off points, they could also screen out many discrete regulatory actions from consideration. The OMB proposal seems to either assume that these actions would not benefit from peer review (which seems questionable) or that review would prove 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 review is eliminated. This highlights the ultimate shortcoming of the OMB guidelines—peer review is required only for "information products," not for how the agencies use the "information products" in their regulatory decisions.[189] 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 only in an indirect manner.[190] By focusing on information products and excluding peer-reviewed research, the key steps of search, selection, and interpretation set out in Section V are missed. 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. Sidney Shapiro takes a more nuanced approach, recommending that agencies be allowed to employ ad hoc procedures for deciding when peer review is appropriate.[191] Given the self-serving experiences of FWS, NOAA, and OMB with peer review, however,[192] 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

188. *See supra* notes 105–17 and accompanying text.

189. *See* Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2665 (Jan. 14, 2005).

190. Given the wording of the Data Quality Act, OMB likely had no choice but to restrict its guidelines to information products. Shapiro, *supra* note 25, at 10,066–68.

191. Letter from Sidney A. Shapiro, Bd. Member and Treasurer, Ctr. for Progressive Regulation, to Dr. Margo Schwab, Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget 5–6 (May 27, 2004), http://www.progressivereform.org/articles/shapiro_omb.pdf.

192. *See supra* notes 140–48, 150–53 and accompanying text.

different proposal, that OMB should "limit peer review to circumstances where scientific assessments set a new precedent or are reasonably controvertible."[193] 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 regulatory 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 about what the most significant benefits of peer review are. Debate and scholarship to date have largely focused on three 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.[194] 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.[195] This is the reason most scientists believe that peer review is "essential to the integrity of scientific and scholarly communication."[196] Peer review also serves a *deliberative function*, providing for give and take between proponent and reviewers.[197]

Serious debate continues over how substantial these potential benefits are, however, because of significant uncertainty with respect to how often agencies overstate the extent of scientific support for their regulatory decisions. Implicit in the arguments of Representative Walden and OMB is the assumption that agencies do overstate support frequently enough to justify making peer review commonplace. Otherwise their proposals would be pointless, requiring extensive reviews to address a negligible problem. Critics of these proposals similarly argue that the problems surrounding agencies' use of science have been exaggerated. As noted in the Introduction, though, it is simply not clear how many Klamaths are out there.

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193. Shapiro, *supra* note 191, at 5–6.

194. Quality control is equally important in the context of journal peer review. Rowland's study of scientists' perceptions of peer review found that "[i]t is widely agreed that this improving function by referees is of value in maintaining the overall quality of the scholarly literature." ROWLAND, *supra* note 32, at 1.

195. *See* Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023, 54,024 (Sept. 15, 2003).

196. WELLER, *supra* note 29, at 322.

197. This is particularly evident in journal peer review, in which approximately 80% of submitted papers are in the "publishable with amendments and improvements" category. ROWLAND, *supra* note 32, at 1.

Yet 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.* Neither advocates nor critics of regulatory peer review can intelligently assess the merits of requiring it—whether restricted to major decisions, decisions that create precedent, or decisions that protect species—without first having a clear sense of whether none, a few, or many of these decisions would benefit from peer review. Yet this critically important issue has received little consideration in the current debate.[198] The greatest benefit of peer review may lie in providing empirical data on the scope of the problem that can then tell us whether broader or reduced use of peer review is warranted.[199]

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 description of the critical habitat designation decision shown in Part IV). Within this broad class of decisions, randomly select a subset of specific regulatory decisions within a six-month period.[200] To commence, we would suggest following the IRS audit practice of selecting roughly 1-2% of the eligible decisions.[201]

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198. 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. Monique Waples, Comment on Peer Review Standards, (Dec. 23, 2003), http://www.whitehouse.gov/omb/inforeg/2003iq/72.pdf

199. Professors Doremus and Tarlock recognize that "[e]ffective outside reviews can also spur learning, by inspiring new thinking, demanding accountability, and highlighting gaps in the existing data base that could be filled." Doremus & Tarlock, *supra* note 16, at 33. We are suggesting that peer review also spurs learning about the quality of agency practices in general.

200. 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. *See supra* notes 105–17 and accompanying text. 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 is accurate and properly interpreted.

201. As regulators well know, deterrent effects can be realized even when compliance inspections are conducted less than 100% of the time for fewer than 100% of the regulated facilities. The number of reviews, of course, could not exceed the review budget, which would ultimately determine the percent used. In 2005, for example, the IRS audited only 0.93% of all individual returns. By contrast, roughly one in five large corporations (with returns of $10 million and over) were audited. *See* Posting of Charles Rubin to http://www.rubinontax.blogspot.com/2006/03/latest-irs-audit-data.html (Mar. 28, 2006, 18:08 EST).

Stage Two: Peer Review Decisions

The peer review of the science underpinning these decisions would be conducted by groups of three experts selected from standing panels established by the NRC. Peer reviewers would be compensated in order to attract competent experts and encourage timely performance, vetted for potential bias by the NRC through its standard practice, appointed for a limited term, and kept anonymous to the decision making agency except in cases in which the reviewers' desire to conduct field investigation and interviews precludes anonymity.[202] The peer review committees would not be asked to conduct a de novo review of the agency's entire record and decision. Rather, the committee would be asked to evaluate the agency's protocol for identifying relevant scientific data and research, its rationale for selecting and prioritizing data and research from the identified pool, and its interpretation of this body of science. When necessary, the peer reviewers could request important data compilations or research reports relied upon by the agency in making these evaluations. The peer review would be completed in no more than ninety days and would not be subject to the public meeting and other procedural requirements of the Federal Advisory Committee Act.[203]

Stage Three: Disseminate and Analyze Reviews

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

How well does this proposal capture the benefits yet minimize the costs of regulatory peer review? For those decisions that are reviewed, the proposal ensures quality control in particular cases. Based on the IRS

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202. *See supra* note 147.
203. 5 U.S.C. app. §§ 1–11 (2000).

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 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 may not substantially change the outcome of many regulatory decisions, but it would beneficially influence the way in which regulatory decisions are carried out. The proposal also helps further legitimize agency decisions, ensuring 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 importantly, it provides a way to empirically diagnose whether agency use of science really should be of concern and to finally answer how many Klamaths are out there.

But what of the downsides? As noted earlier, paralysis by analysis is a real concern for resource-strapped agencies working under tight deadlines. At some point, the quest for relevant, reliable, and reviewed data may add so much time to the 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, yet find the species extinct by the time the decision to protect it is finally 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.[204]

Our proposal has its costs, to be sure, but they are significantly less than those of other proposals. If a 1-2% audit rate can serve as a meaningful general deterrent and provide an accurate sample for analysis, the most important benefits of more comprehensive review requirements can be satisfied at a fraction of the cost.[205] Appropriating funds for the

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204. 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).

205. In order to make these decisions, more information would be needed on the likely costs and

NRC rather than the target agencies to pay for the reviews would also ensure that agencies are not forced to sacrifice other activities in order to carry out reviews.

And what about concerns that the peer review process will become politicized or captured? Our proposal represents a measured approach that enhances regulatory peer review but puts the decision about whether to use it and how to conduct it outside of the agencies' control—and in the hands of a generally respected neutral player. Although many stakeholders disagreed with the Klamath Committee's conclusions and how the Departments of Interior and Commerce incorporated them into policy,[206] 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.[207]

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 differently 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.[208] 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 giving it the heightened deference accorded to views expressed by sister agencies.[209]

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

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number of reviews. It is worth noting that, for a fraction of its $650,000 total budget, the Klamath Committee was able within ninety days to conclude its initial peer review of the agency decisions.

206. *See* MOONEY, *supra* note 13, at 152–54.

207. *See supra* Part IV.B.

208. 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, 53,093 (Sept. 9, 2003) (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).

209. *See, e.g.*, Sierra Club v. U.S. Army Corps of Eng'rs, 701 F.2d 1011, 1031 (2d Cir. 1983) (criticizing the Corps for disregarding negative comments in the environmental impact statement by the Fish and Wildlife Agency).

science debate, simple political expediency would likely force the agency's hand. It would be a cocky agency director, indeed, who simply ignored a critical peer review report (and likely a director who did not mind traveling up to Capitol 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—when some evidence exists in the record to support a decision in either direction and the statute imposes no default position—strikes us as unwarranted.[210] Fundamentally, it must be remembered, the purpose of peer review is to improve agency decision quality, not to arm litigants or undermine agency discretion.

VII. CONCLUSION

Agency use of peer review processes is neither new nor, until recently, particularly controversial, yet it has not 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 bind the regulatory arms of the ESA through peer review, however, 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 seek 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.

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210. *See supra* notes 73–77 and accompanying text.