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# Prescribing the Right Dose of Peer Review for the Endangered Species Act

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1. I 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 the legal background section of this Article are a variation, tailored for the instant purposes, of a template I have used and will continue to use. Similar treatments, in other words, appear elsewhere, so that readers may access the descriptive material necessary to evaluate the particular analytical topic of each article without having to consult a series of other articles.

## I. INTRODUCTION

Environmental law stands out among all fields of law as the one most concerned with the physical world around us. This distinction is both a great appeal and a heavy burden. If environmental law has done anything in the epistemological sense, it has taught us how little we know about the physical world and, even more so, how little we know about how to improve the physical world through law. Alas, environmental law seems puny and confused compared to its intended beneficiary, and we have made many mistakes as it has developed. The history of water management offers no shortage of examples in that respect.

Lately, however, we hear much about science coming to the rescue of environmental law. The so-called "sound science" movement claims to be able to improve decisionmaking under environmental law—to make it more rational and objective by infusing the field with more and better practice of science.[2] Of course, I am not about to argue against sound science,[3] whatever it means, as it is a loaded term that

2. *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."). The discussion and debate regarding the use of "sound science" in environmental law is pervasive—I found over 2600 websites through a Google search of "'sound science'" AND 'environmental law.'" Many observers trace the origins of the "sound science" movement to the Phillip Morris Corporation's creation in 1993 of The Advancement of Sound Science Coalition ("TASSC"). *See* Elsia K. Ong & Stanton A. Glantz, *Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms*, 91 AM. J. PUB. HEALTH 1749 (2001). Now defunct, TASSC was formed initially to assemble and propagate counter-evidence of tobacco's effects on human health, but later was funded by a wider variety of corporations. Although TASSC officially has disbanded, the "sound science" movement lives on. *See JunkScience.com: All the Junk That's Fit to Debunk*, *at* http://www.junkscience.com (last visited Nov. 7, 2004). Indeed, the movement now enjoys substantial political cachet. The Bush Administration has aggressively advanced "sound science" principles, such as data quality. *See, e.g.*, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452 (Feb. 22, 2002). Legislative proposals routinely use the "sound science" label to gain support. *See, e.g.*, Sound Science for Endangered Species Act Planning Act of 2003, H.R. 1662, 108th Cong. (2003). A counter-movement also has emerged. For example, a group of legal scholars openly skeptical of its motives has formed to, among other things, monitor and challenge the "sound science" movement. *See* Center for Progressive Regulation, *at* http://www.progressiveregulation.org/index.html (last visited Nov. 7, 2003). The Bush Administration strongly challenges their assertion that the "sound science" movement inherently politicizes the use of sound science. *See* David Malakoff, *White House Rebuts Charges It Has Politicized Science*, 304 SCIENCE 184 (2004).

3. I use the term here and elsewhere without bracketing it in quote marks to refer to practices that the scientific community in general would regard as appropriate

almost begs a fight. Who is for *un*sound science? Not I—but I am for a sound approach to sound science. Maybe sound science is good for environmental law, but we all know that too much of a good thing can be bad. So, I ask, could sound science, depending on how it is dosed out to environmental law, be counterproductive?

I am by no means the first to ask this question, or to suggest as I do, that the answer is yes.[4] But I wish to focus on the one component of sound science that is most often held out as the panacea by some and the problem by others: peer review. To be more precise, what I examine here is whether scientific-style peer review, depending on how it is dosed out, could be counterproductive for environmental law.

The use of peer review as a component of regulatory procedure has not received much discrete attention in environmental law literature,[5] but it is truly the sleeping dog of the "sound science" movement. Understanding this concept requires some background on science and administrative law. The "sound science" movement, as its name suggests, advocates that environmental law decisions be based principally on scientific information and conclusions that have been derived through the rigorous, unbiased practice of science. Science is generally regarded as a formalized system for gathering and evaluating information about the world in which prescribed methods of observation, communication, informed criticism, and response must

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use of the scientific method for the given scientific inquiry. I place the term in quotes when I wish to refer to the policy-based movement—some would say ideology-based movement—advocating more use of any or all of scientific practices in administrative decisions required under environmental laws. For example, peer review is unquestionably a practice of sound science, as well as a cornerstone of the "sound science" movement. I do not question for a moment the consequences of the former proposition; rather, my focus is entirely on the latter.

4. For a historical perspective on the use of science in environmental law, referencing a wealth of literature on the topic and suggesting several "cautionary tales" about the promotion of using more "good science," see Oliver Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 302 SCIENCE 1926 (2003). Professor Wendy Wagner has produced the most extensive body of work examining the claim for using more and better science in environmental law. *See* Wendy E. Wagner, *The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63 (2003); Wendy Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181 (1999); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

5. For a general discussion of the role of peer review in regulatory law, see Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1045 (2000). More directly, Professor Sidney Shapiro has recently examined proposals the Bush Administration has advanced regarding peer review in federal agencies, which are discussed *infra*. *See* Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 34 ENVTL. L. REP. NEWS & ANALYSIS 10,064 (2004).

be carefully followed.[6] If these steps work for science, so goes the argument, they should work for environmental law as well.

One difficulty the "sound science" movement faces, however, is that many of the methodological components of science are already firmly embedded in environmental law through basic standards of administrative law prescribed under the Administrative Procedure Act ("APA").[7] A scientist would be accused of practicing unsound science in research if he or she declared that relevant data was ignored or altered in reaching the research conclusion simply because the data did not support the conclusion.[8] Likewise, an agency would be chastised for doing the same in reaching the decision of a rulemaking or an adjudication—that conduct would be arbitrary and capricious, such that any court acting on judicial review of the decision would know to strike it down as a violation of the APA.[9] A court would not need to employ the principles of sound science to get to such a ruling.

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6. *See* Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 WASH. U. L.Q. 1029, 1057–64 (1997). Professor Doremus, a trained biologist and leading environmental law scholar, provides a concise summary of the scientific method:

> Procedurally, science is a formalized system for gathering and evaluating information about the world. Its essential steps are observation, communication, informed criticism, and response. A scientist gathers data through observation or experimental manipulation. She then communicates those data, together with an explanation of the methods used to gather them, to the community of scientists in her field. The scientific community reviews and critiques the work, commenting in ways that may inspire the original scientist and others to seek additional data or alternative explanations.

*Id.* at 1057.

7. 5 U.S.C. § 706 (2000).

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

9. *See* Motor Vehicle Mfrs. Ass'n of the United States v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 34 (1983) [*State Farm*] (holding the revocation of a motor vehicle safety standard arbitrary and capricious where agency "failed to present an adequate basis and explanation"). 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. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971). 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." 5 U.S.C. § 706(2)(A); Biodiversity Legal Found. v. Babbitt, 146 F.3d 1249, 1252 (10th Cir. 1998). An agency decision is arbitrary and capricious if the agency either "has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," *State Farm*, 463 U.S. at 43, 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.'" *Id.* (citation omitted).

Indeed, even statute-specific references to using science in regulatory contexts add little, if anything, to this feature of administrative law. For example, although the Endangered Species Act ("ESA")[10] ominously requires that many decisions called for under the statute be based on the "best scientific data available,"[11] there is no evidence that this standard has made a bit of difference in terms of how agency decisions are examined in judicial review settings.[12] Courts do not implement the ESA standard in ways that add anything beyond the demands that are already placed on the decisionmaker under the APA.

The "sound science" movement thus has a difficult time articulating exactly what it seeks when it comes to methodological matters such as data quality, because many of the sound practices of science already are required of agencies in some degree or another. What is sound science supposed to add? To be sure, one can envision requiring that agencies take additional steps to assure the public about such matters as data quality—in essence, enforcing sound science by mandating more science *procedure*—but it is simply not the case that the *substantive* demand for data quality is something new that the "sound science" movement brings to the table for environmental law.

By contrast, peer review is a practice of science that is neither specifically required by most environmental laws, nor generally required through the default administrative law doctrines of the APA. Peer review is generally described as a scientifically rigorous review and critique of a study's methods, results, and findings that is conducted by others in the relevant field who have the requisite training and expertise, who have no pecuniary or other disqualifying bias with respect to the topic, and who are independent of the persons who performed the study.[13] Public participation in regulatory decisions through notice

10. Endangered Species Act of 1973, 16 U.S.C. §§ 1531–1544 (2000).

11. 16 U.S.C. § 1533(b)(1)(A) (2000). For extensive discussions of this requirement, see Southwest Ctr. for Biological Diversity v. Norton, 2002 WL 1733618, at *8 (D. D.C. 2002) (summarizing the existing body of case law); Laurence Michael Bogert, *That's My Story and I'm Stickin to It: Is the "Best Available" Science Any Available Science Under the Endangered Species Act?*, 31 IDAHO L. REV. 85 (1994); 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, 409–12 (2003); Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Best Available Science Mandate*, 34 ENVTL. L. 397 (2004) [hereinafter Doremus, *Best Science Mandate*]; Doremus, *supra* note 6, at 1051–85; John Earl Duke, *Giving Species the Benefit of the Doubt*, 83 B.U. L. REV. 209 (2003).

12. *See* J.B. Ruhl, *The Battle Over Endangered Species Act Methodology*, 34 ENVTL. L. 555 (2004) (reviewing legislative history and judicial and administrative implementation of the ESA's best science mandate).

13. NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, PEER REVIEW IN ENVIRONMENTAL TECHNOLOGY DEVELOPMENT PROGRAMS 2 (1998), *available at* http://www.nap.edu/books/0309063388/html/index.html. A peer is "a person having technical exper-

and comment in rulemakings or representation in adjudicatory proceedings does not serve this role, as it does not screen out biased members of the public and is not limited to experts.[14] Judicial review of agency decisions does not ensure the same level of expertise that can be provided in peer review, and in any event judges must adhere to the review standards of the APA, not those of scientific peer review.[15] Peer review, in other words, is the one thing the "sound science" movement has that administrative law does not already demand.

Peer review is a practice most strongly associated with scientific journal publication decisions, where it has been in use for over 300 years and widely employed for over 200 years, but it also applies in a wide array of settings, including, most prominently, grant-funding decisions and faculty and student evaluations.[16] Within science, peer review is widely considered "essential to the integrity of scientific and scholarly communication."[17] For many scientists, indeed, peer review "does not merely reflect the scientific method, it *is* the scientific method."[18]

The "sound science" movement thus holds out peer review as an immutable component of environmental decisionmaking through the following syllogism:

*Premise 1*: The practice of sound science is an essential component of many decisions required by environmental law.

*Premise 2*: Peer review is an essential component of the practice of sound science.

*Conclusion*: Therefore, peer review is an essential component of those environmental law decisions for which sound science is an essential component.

The Bush Administration certainly acts as if this is an ironclad proposition, proposing that federal agencies broadly employ more rigorous peer review in their decisionmaking processes.[19] Indeed, on its

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tise in the subject matter to be reviewed (or a subset of the subject matter to be reviewed) to a degree at least equivalent to that needed for the original work." *Id.* at 28. The peer's independence from the work being reviewed "means that the peer, a) was not involved as a participant, supervisor, technical reviewer, or advisor in the work being reviewed, and b) to the extent practical, has sufficient freedom from funding considerations to assure the work is impartially reviewed." *Id.*

14. *See* Noah, *supra* note 5, at 1074–76.
15. *See* Noah, *supra* note 5, at 1076–77.
16. *See* ANN C. WELLER, EDITORIAL PEER REVIEW: ITS STRENGTHS AND WEAKNESSES 1–7 (2001).
17. *Id.* at 322.
18. Noah, *supra* note 5, at 1045.
19. *See* Office of Mgmt. & Budget, Executive Office of the President, Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23,230 (Apr. 28, 2004) [hereinafter OMB, Revised Bulletin] ("peer review improves both the quality of scientific information and the public's confidence in the integrity of science"); Of-

surface this argument appears unassailable—if peer review is part of sound science, which it is, and sound science is part of environmental decisionmaking in many instances, which it is, ought not peer review be a part of environmental decisionmaking? But the answer is: not necessarily.

What the argument fails to reveal is that, even with respect to environmental decisions for which sound science is an essential component, sound science is not the *only* essential component. This is because science, even sound science, usually does not lead to compelling answers about the questions posed in environmental law. Indeed, it frequently leads in no particular direction at all.[20] Sound science could produce a mountain of relevant data of the highest quality and still provide no clues as to what to do for purposes of the environmental law decision. In at least those cases something else will be needed in order to reach decisions, such as sound judgment by agency decisionmakers, sound procedures for weighing alternatives, sound methods of providing public information and soliciting public views, and even sound politics. Even when science does produce robust results, in many value-laden societal decisionmaking contexts scientific findings simply are not all that matter. In short, "decisionmaking is often driven by a variety of nonscientific, adversarial, and stakeholder dynamics. Thus, even though science helps inform choices, it is only one of many values and interests considered by each stakeholder."[21]

Thus, there are many ingredients to sound decisionmaking in environmental law, with sound science being only one among them. But advocates of using more peer review in environmental regulation decisions are likely to observe that this argument alone does not refute the case on behalf of including peer review, for it does not demonstrate why peer review should *ever* be left out of the package even if other components of sound science are. Particularly because peer review is the one element of sound science not already incorporated at some level or another through administrative law rules, advocates may argue that it should be the last to be excluded from the "sound science" mix for environmental law.

Nevertheless, the complexity of environmental decisionmaking will rarely allow us to practice all of the ingredients of decisionmaking to their "soundest" degrees. Even where time and money would allow

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fice of Mgmt. & Budget, Executive Office of the President, Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023, 54,024 (Sept. 15, 2003) [hereinafter OMB, Proposed Bulletin] ("Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses."). The proposal is discussed *infra* note 35, section IV.A, and accompanying text.

20. *See* Doremus, *supra* note 6, at 1065–82.

21. Herman A. Karl & Christine E. Turner, *Incorporating Science into Decision-Making*, 300 SCIENCE 1370 (2003).

the possibility of engaging in any one of the ingredients to the highest standards, there will be cases in which attempting to do so for all at the same time would pose conflicting constraints between the respective ingredients. For example, at some point the quest for relevant, reliable, and reviewed data may add too much time to the decisionmaking process—such as the decision whether a species is endangered—that the policy effectiveness of the decision is impeded. What a hollow victory for sound science it would be, for example, to spend so much time ensuring the reliability of the data proving the species is endangered, that the species is already extinct by the time the decision to protect it is made. Adding time and budget constraints to the picture amplifies the prospect and potential intensity of these conflicting constraints. Sound *decisionmaking*, in other words, may require that we practice all of the decisionmaking components, including sound science, at, say, only eighty percent of their respective "soundest" levels.[22]

Taking this phenomenon of conflicting constraints to heart, the central thesis of this Article is that, of all the components of sound science, peer review presents one of the highest potentials for triggering conflicting constraints with other components of sound decisionmaking. I examine this quality of peer review using the Endangered Species Act as a case study for this symposium's principal topic of water management.[23] The ESA, perhaps more than any other environmental law, has become a lightning rod of controversy in water

22. 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). Evolutionary biologists have long observed the effects of conflicting constraints on the fitness of different species in different environments—*i.e.*, traits improving fitness in one environment may reduce fitness in others. *See* Santiago F. Elena & Rafael Sanjuán, *Climb Every Mountain?*, 302 SCIENCE 2074 (2003) (description of "fitness landscapes" depicting the traits tradeoff problem); Elizabeth Pennisi, *The Primate Bite: Brawn Versus Brain?*, 303 SCIENCE 1957 (2004) (discussing the hypothesis that nonhuman primates' massive jaw muscles, useful in forage and combat, limited the growth of their brains).

23. This Article is not intended to provide a comprehensive overview of the ESA. Rather, it focuses attention on programs and features of the statute for which questions of methodology bear particular importance. For comprehensive treatments of the ESA, several of which are referred to frequently *infra*, see ENDANGERED SPECIES ACT: LAW, POLICY, AND PERSPECTIVES (Donald C. Baur & Wm. Robert Irvin eds., 2002) [hereinafter LAW, POLICY, AND PERSPECTIVES]; LAWRENCE R. LIEBESMAN & RAFE PETERSEN, HOLLAND & KNIGHT LLP, ENDANGERED SPECIES DESKBOOK (2003); STANFORD ENVTL. LAW SOC'Y, THE ENDANGERED SPECIES ACT (2001) [hereinafter SELS]; TONY A. SULLINS, ENDANGERED SPECIES ACT (2001); and MICHAEL J. BEAN & MELANIE J. ROWLAND, THE EVOLUTION OF NATIONAL WILDLIFE LAW (3d ed. 1997).

management contexts.[24] At the same time, the ESA has also become the poster child for the "sound science" movement, and for the peer review argument in particular. The role and consequence of peer review under the ESA, in other words, will have much to say about the resolution of water management issues in many parts of the nation.

Using this confluence of themes, I lay out my thesis in three steps. Part II of the Article provides some background on the "medicine," peer review, as it is prescribed in regulatory contexts in general—*i.e.*, what is it and why do it? I conclude that, as a general proposition, there is no *a priori* reason to reject the use of regulatory peer review in administration of the ESA—*i.e.*, a closer examination of the ESA and the potential effects of peer review is necessary.

Part III thus provides the diagnosis of the "patient," the ESA. The ESA is a science-driven law, which suggests peer review may fit, but it is also a policy-driven law for which many policy questions have no definitive scientific solution. In such a context, whether peer review adds or detracts from policy outcomes is a matter of fitting the timing and size of the dose to the diagnosis of the ESA.

Part IV of the Article then describes the three conflicts that unrestrained doses of regulatory peer review pose for ESA decisionmaking in particular, and for environmental law and water management generally. First, because its advocates regularly overstate what peer review will accomplish for environmental law decisionmaking, mandating peer review across the board raises unrealistic expecta-

24. *See, e.g.*, Antonio Rossman, *A New Law and the "Era of Limits" on the Colorado*, 18 NAT. RESOURCES & ENV'T 3, 4 (2003) (statutes such as the ESA create a "New Law of the River" that "adds to the proprietary determinations of the old [water use] law the jurisprudence that defines and enforces the nonproprietary rights of the commons and public domain"); William Stelle, Jr., *Implementing ESA Salmon Listings—Untangling Overlapping Programs*, 16 NAT. RESOURCES & ENV'T 112, 112 (2001) ("The major listings of salmon, steelhead, and bull trout across a wide swath of the Pacific states . . . have created a unique overlay of the Endangered Species Act (ESA) on both urban and rural populations . . . [and] placed enormous strains on an already complex and poorly integrated set of programs pertaining to aquatic health . . . ").

Recently, at the American Bar Association's 2004 Annual Conference on Water Law, a federal official summed up the growing influence of the ESA by observing that "federal environmental law represents a major insertion into a structure that did not take it into consideration" and identifying the ESA as a "law that calls into question current water uses by focusing on their environmental qualities." *See* Stephen Siciliano, *Official Says Endangered Species Act Altering Balance of Water Uses in West*, DAILY ENV'T REP. (BNA), Feb. 24, 2004, at A-6 (quoting Robert Lohn, Northwest Reg'l Comm'r, Nat'l Marine Fisheries Serv.). At the same conference, a noted ESA citizen suit attorney explained that "when we use the Endangered Species Act, we are trying to create incentives to change the status quo" of water use in the West. *See* Stephen Siciliano, *Officials, Environmental Attorney Debate Utility of Litigation in Silvery Minnow Case*, DAILY ENV'T REP. (BNA), Feb. 24, 2004, at A-7 (quoting Laird Lucas, Executive Dir., Advocates for the West).

tions of the quality of agency decisions and weakens the position of other important components of decisionmaking. Second, inflexibly mandating rigorous peer review adds substantial demands on agency resources, potentially draining resources from other decisionmaking components and, in many cases, impeding decisionmaking altogether. Finally, peer review is subject to abuse if it is implemented in ways that allow agencies to manipulate the process and thereby rig outcomes so as to justify agency decisions that would not withstand legitimate peer scrutiny. Peer review, in other words, can be prescribed at overdose levels for the ESA, and environmental law generally, even though it is an essential component of sound science.

So, what is the right dose? In Part V of the Article, I continue to use the ESA as a model for exploring ways peer review could be incorporated into environmental laws so as to retain its value while minimizing its potential adverse effects. One approach is to identify criteria which, when present, suggest that a particular decision could benefit from rigorous "microscope" peer review, with the idea being that the criteria would screen out most cases so as to produce a limited set of cases justifying substantial expenditure of resources for peer review. Another approach is to develop an independent peer review "SWAT team" that would conduct random peer reviews of agency decisions more frequently than the "microscope" style, but less intensely in each case, with the idea being to derive much of the decisionmaking quality incentives peer review can produce without suffocating overall agency practice. These uses of peer review would substantially reduce the potential for conflicting constraints while still allowing environmental law to reap most of its benefit. More potent doses of peer review, I contend, offer little incremental benefit but risk significant adverse effects.

Arguing against broad use of peer review in environmental law invites accusations of trying to hide the flaws of agency practice in the shadow of "agency expertise." Advocates of peer review contend that it is the light that will expose those flaws. But while that is indeed the purpose of peer review in science, I question whether those who advocate it unyieldingly for the ESA and throughout environmental law really have that purpose in mind. The optimal use of peer review in environmental law, I contend, is not all the way all of the time, but in the right dose at the right time. The *sound* use of sound science demands nothing less than a careful approach to writing that prescription.

## II. THE MEDICINE: WHAT IS REGULATORY PEER REVIEW AND WHY DO IT?

Most scientific peer review takes place in the context of journal publication and grant award decisions. Procedurally, in this and simi-

lar settings, the journal or granting institution acts as a "middleman" to find independent reviewers with relevant expertise who will review the science, not the scientists. The journal review process, for example, has been summarized as follows:

> An aspiring author sends a manuscript to a journal's editorial office. The journal editor, or for large journals one of the associate editors, logs in the manuscript, selects two or three reviewers to evaluate the manuscript, and sends each a copy. Reviewers are asked to assess the manuscript and make a recommendation to accept, accept with revisions, or reject the manuscript. The editor or associate editors then decide if they will accept the recommendation of the reviewers.[25]

Grant-funding peer review follows a similar process.[26] In both cases 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.[27] Also, although most peer review is merely anonymous, meaning the author does not know the identity of the reviewers, some journals and grant institutions use "blind" review, in which the reviewers also do not know the identity of

25. WELLER, *supra* note 16, at 1. *See also* FYTTON ROWLAND, THE PEER REVIEW PROCESS: A REPORT TO THE JISC SCHOLARLY COMMUNICATIONS GROUP 1 (2002), *available at* http://www.jisc.ac.uk/uploaded_documents/rowland.pdf (JISC is the Joint Information Systems Committee, the UK's higher education support agency.). When a submitted report first arrives at the editorial office of a journal, it is first vetted by the editor, who may reject it out of hand—either because it is "out of scope" (not dealing with the right subject matter for that journal) or because it is manifestly of such low quality that it cannot be considered at all. Papers that pass this first hurdle are then sent to experts in the field of the paper—usually two—who are generally asked to classify the paper as publishable immediately, publishable with amendments and improvements, or not publishable.

26. For example, the National Science Foundation ("NSF") advises persons submitting grant proposals as follows:

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

OFFICE OF BUDGET, FIN., & AWARD MGMT., NAT'L SCI. FOUND., NSF 03-041, GRANT PROPOSAL GUIDE 35 (June 2003), *available at* http://www.nsf.gov/pubs/2003/nsf03041/nsf03_041.pdf.

27. *See* WELLER, *supra* note 16, at 2.

the authors.[28] These procedures "have been championed to help reduce any reviewer bias."[29]

Substantively, the peer review process is far from 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.[30] Of course, the "sound science" movement is less concerned with writing style, and thus focuses on factors in the *Ecology* list such as "scientific soundness" and "degree to which conclusions are supported." Even in this respect, however, the intensity of journal and grant peer review is nothing like *de novo* review. *Ecology* explains, for example, that in assessing "scientific soundness" the reviewer should examine the methods, data presentation, and statistical design of the paper, but the instructions do not include engaging in independent data authentication.[31] Obviously, 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. Nevertheless, it is widely believed that even this appellate style review provides tremendous quality-improving benefits to scientific scholarship.[32]

As Holly Doremus has explained, journal and grant peer review is this "coarse," because journals and grant institutions are interested mainly in whether the claims made in the paper or proposal fall within a broad range of publication acceptability or funding merit.[33] Grant institutions may be interested, for example, in funding "cutting-edge" research, and journals may be interested in publishing it. Neither entity, however, is assigned the task of *using* the science it

28. *Id.*
29. *Id.* at 207.
30. PUBLICATIONS OFFICE, ECOLOGICAL SOC'Y OF AM., INSTRUCTIONS FOR REVIEWERS, *at* http://www.esapubs.org/esapubs/reviewers_main.htm (revised Mar. 22, 2004). These criteria are representative of the scientific journal industry in general. *See* WELLER, *supra* note 16, at 160–63.
31. PUBLICATIONS OFFICE, ECOLOGICAL SOC'Y OF AM., INSTRUCTIONS FOR REVIEWERS, *at* http://www.esapubs.org/esapubs/reviewers_main.htm (revised Mar. 22, 2004). As Holly Doremus has explained, "[p]eer reviewers are not expected to authenticate the data presented to them. Rather, their role is to evaluate the methods employed and the facial plausibility of the conclusions drawn." Doremus, *supra* note 6, at 1147.
32. There is some empirical evidence in support of this belief. *See* WELLER, *supra* note 16, at 51–53.
33. *See* Doremus, *supra* note 6, at 1147.

funds or publishes to make policy decisions. This is the principal difference between journal and grant peer review and what the "sound science" movement has in mind for regulatory peer review.

In regulatory settings, in other words, peer review would most often involve a review of how an agency used available scientific data in reaching a policy decision. This requires that conventional scientific peer review be adapted in three respects. First, it will often be the case that the agency is not actually doing the science that produces the data upon which it relies for its decision, but rather uses data already made available through other scientific research efforts. Thus, regulatory peer review will often involve reviewing how the agency incorporates preexisting scientific knowledge into its own scientific processes. Second, it will not always be the case that the data upon which the agency relies are the result of peer reviewed studies. Regulatory peer review, therefore, must also provide some review function of those studies in the form of an evaluation of the agency's choices as to which data to use. Next, 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 must disentangle the policy judgment from the underlying science if it is to remain true to the underlying scientific spirit of peer review.

Although regulatory peer review differs from conventional scientific peer review in these respects, incorporating the basic procedure and substance of peer review into regulatory frameworks is rather straightforward. Reviewers could be instructed, for example, to take into consideration limits on the agency's ability to conduct original scientific studies, to evaluate the soundness of relying on the kind of data upon which the agency based its decision (*e.g.*, field data versus published peer reviewed studies), and to limit their review to the scientific component of the agency's decision. Indeed, several federal agencies have incorporated some form of peer review in their regulatory decisionmaking processes.[34]

The "sound science" movement would implement this model across the spectrum of regulatory agencies, arguing that what is good for science is good for regulation. The promised benefits of integrating peer review into the regulatory decisionmaking process are, not surprisingly, both procedural and substantive—*i.e.*, enhancing the legitimacy of the regulatory process by reducing the appearance of agency bias

34. *See* Noah, *supra* note 5, at 1052–57 (discussing the Environmental Protection Agency, Food and Drug Administration, and Consumer Product Safety Commission).

and conflict of interest,[35] and improving the quality of regulatory decisions by providing independent expert feedback.[36]

Many commentators argue, however, that this effort is simply misguided because peer review is inherently incapable of producing for regulation the same benefits it produces for science. One argument frequently advanced in this regard is that is that its bias control procedures will not enhance the legitimacy of agency decisions. Holly Doremus suggests, for example, that peer review of decisions whether to list species as endangered under the ESA would be redundant or fruitless:

> The agencies' review of the data should already provide the impartial screening mechanism peer review generally offers. If, on the other hand, the agencies' neutrality cannot be trusted, peer review will not help. After all, if the shared biases of biologists lead to unreliable listing decisions, submitting proposals to additional biologists for review is not likely to improve them.[37]

If the neutrality of agency biologists is not trusted, however—and this is clearly an underlying premise of the "sound science" movement—it is because they are *agency* biologists, not because they are simply biologists. There may be a set of "shared biases" for members of a discipline such as biology, but there just as surely will be a set of divergent biases based on the particular experience of each person in that discipline. Peer review in any context would be pointless if this were not the case.

Another argument against regulatory peer review is that peer review is simply too coarse substantively to protect against fraud or to detect all errors.[38] While these points are true, they underplay the important role of peer review as a force of improvement in final manuscripts and grant proposals. Most journal peer review decisions, for example, are in the "publish with changes" category—approximately eighty percent of submitted papers receive this result.[39] Rowland's study of scientists' perceptions of peer review found that "it is widely agreed that this improving function by referees is of value in maintaining the overall quality of the scholarly literature."[40] Putting aside for the moment the question of time and resources, which I take up *infra*, there is no structural feature of regulatory decisionmaking that comes to mind that would prevent peer review from producing similar improving functions in the substantive quality of decisionmaking.

My point here is that there is nothing about peer review *in principle* that makes it inherently useless in the realm of regulatory deci-

35. *See* OMB, Proposed Bulletin, *supra* note 19, 68 Fed. Reg. at 54,024.
36. *See* Lars Noah, *Peer Review and Regulatory Reform*, 30 ENVTL. L. REP. (Envtl. L. Inst.) 10,606, 10,608 (2000).
37. Doremus, *supra* note 6, at 1148.
38. *See, e.g.*, Doremus, *supra* note 6, at 1147.
39. BEAN & ROWLAND, *supra* note 23, at 1.
40. *Id.*

sionmaking. Peer review could lead to improved quality of agency regulatory decisions, and it could expose biases of agency scientists. On the surface, therefore, peer review may have something to offer environmental law in general, and the ESA in particular. Some veteran Fish and Wildlife Service ("FWS") field personnel believe, in fact, that "application of peer review to proposed listings and draft recovery plans has fallen short of its potential to promote scientifically sound decision making."[41] I see the same *potential*. The problems I see with regulatory peer review, however, are more practical in nature, having to do with the ways in which the "sound science" movement proposes to dose peer review out to regulatory contexts such as the ESA. To examine that implementation issue, however, one first must have some background in the regulatory framework into which peer review is proposed to be inserted. The next Part provides that background for the ESA.

## III. THE PATIENT: THE ESA CONTEXT FOR REGULATORY PEER REVIEW[42]

The ESA requires the Secretary of the Interior, who acts through the FWS, and the Secretary of Commerce, who acts through the National Marine Fisheries Service ("NMFS"), to make various decisions about the status and protection of animal and plant species.[43] FWS and NMFS administer several core programs in that regard, the details of which are explored more fully *infra*:

- Section 4 authorizes FWS and NMFS to identify "endangered" and "threatened" species, known as the "listing" function,[44] and then to designate their "critical habitat."[45]

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

42. *See supra* note 1.

43. *See* 16 U.S.C. § 1532(15) (2000) (defining Secretary); 50 C.F.R. § 424.01 (2000) (FWS and NMFS joint regulations). FWS generally is responsible for terrestrial and freshwater species, while NMFS is responsible for marine and anadromous species. NMFS, a division of the National Oceanic and Atmospheric Administration ("NOAA"), is also known as NOAA Fisheries.

44. 16 U.S.C. § 1533(a)(1). For a description of the listing process, see LIEBESMAN & PETERSEN, *supra* note 23, at 15–20; SELS, *supra* note 23, at 38–58; SULLINS, *supra* note 23, at 11–25; J.B. Ruhl, *Section 4 of the ESA: The Keystone of Species Protection Law*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 23, at 19.

45. 16 U.S.C. § 1533(a)(3) (2000). For a description of the critical habitat designation process, see LIEBESMAN & PETERSEN, *supra* note 23, at 20–24; SELS, *supra* note 23, at 59–69; SULLINS, *supra* note 23, at 26–28; Federico Cheever, *Endangered Species Act: Critical Habitat*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 23, at 47; Murray D. Feldman & Michael J. Brennan, *The Growing Importance of Critical Habitat for Species Conservation*, 16 NAT. RESOURCES & ENV'T 88 (2001).

- Section 4 also requires FWS and NMFS, once the agency has listed a species, to develop a "recovery plan" for the species.[46]
- Section 7 requires all federal agencies to ensure that actions they carry out, fund, or authorize do not "jeopardize" the continued existence of listed species or "adversely modify" their critical habitat.[47]
- Section 9 requires that all persons, including all private and public entities subject to federal jurisdiction, avoid committing "take" of listed species of fish and wildlife.[48]
- Sections 7 (for federal actions) and 10 (for actions not subject to Section 7) establish a procedure and criteria for FWS and NMFS to approve "incidental take" of listed species.[49]

A reader unfamiliar with the ESA may find its structure quite simple and its application quite straightforward. Indeed, by comparison to other federal environmental laws, the ESA is streamlined.[50] The core programs seem to fit together logically: identify problem species and their essential habitat areas; stop public and private actions from further significantly deteriorating their condition; allow actions that kill or injure species members only under strict permitting guidelines;

46. 16 U.S.C. § 1533(f). For a description of the recovery plan process, see LIEBESMAN & PETERSEN, *supra* note 23, at 24–26; SELS, *supra* note 23, at 71–77; SULLINS, *supra* note 23, at 34–18; John M. Volkman, *Recovery Planning*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 23, at 71.

47. 16 U.S.C. § 1536(a)(2) (2000). For a description of the consultation process, see Marilyn Averill, *Protecting Species through Interagency Cooperation*, *in* LAW, POLICY, AND PERSPECTIVES, *supra* note 23, at 87; LIEBESMAN & PETERSEN, *supra* note 23, at 27–39; SELS, *supra* note 23, at 83–103; SULLINS, *supra* note 23, at 59–86.

48. 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 23, at 39–45; SELS, *supra* note 23, at 104–112; SULLINS, *supra* note 23, at 44–53; Alan M. Glen and Craig M. 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 23, 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 23, at 207.

49. 16 U.S.C. §§ 1536(b)(4), 1539(a)(1) (2000). "Incidental take," although not the subject of a specific statutory definition provision, is described elsewhere in the statute as a take that is "incidental to, and not the purpose of, the carrying out of an otherwise lawful activity." *Id.* § 1539(a)(1)(B). The FWS and NMFS have adopted this meaning for purposes of the regulations implementing Section 7. 50 C.F.R. § 402.02 (2002). For a description of the incidental take authorization procedures, see LIEBESMAN & PETERSEN, *supra* note 23, at 46–50; SELS, *supra* note 23, at 127–73; SULLINS, *supra* note 23, at 87–102.

50. In one unannotated collection of environmental statutes, the ESA takes up forty-four pages compared to 181 pages for the Clean Water Act and 304 pages for the Clean Air Act. *See* ROBERT V. PERCIVAL, ENVIRONMENTAL LAW: STATUTORY SUPPLEMENT AND INTERNET GUIDE (2002).

figure out ways to help them recover to sustainable populations. As is often the case with seemingly uncomplicated statutes, however, the devil is in the details. Each of the administrative programs outlined above involves an intersection between the decisionmaking demands of legal standards and a multitude of scientific determinations that involve very fluid, unpredictable, and, oftentimes, unascertainable environmental conditions. Consider the following inventory of some of the coupled law–science decisions FWS and NMFS are required to make under the ESA:

| Program | Legal Standard | Science Questions |
|---|---|---|
| Section 4 listing | Is the species in danger of extinction throughout all or a significant portion of its range (endangered) or likely to become so in the foreseeable future (threatened)?[51] | Is it a species?[52] What is its range? What are the present and threatened injuries to its habitat?[53] Is it being overutilized for commercial or other purposes? Is it threatened by disease or predation? Overall, are these threats enough to cause it to go extinct? When? What is the probability? |
| Section 4 critical habitat designation | What habitat is essential to the conservation of the species and requires special management considerations?[54] | How much space does the species need for individual and population growth?[55] What are its food, water, air, light, mineral, shelter, and other nutritional and physiological requirements? Where does it breed, reproduce, and rear offspring? What are the constitutive elements of habitat serving these functions and needs? Where is such habitat? How much of it does the species require? |

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

52. To complicate this question, the ESA defines species as including "any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature." *Id.* § 1532(16).

53. This and the remaining questions posed for the listing function are taken from the statutory criteria. *See id.* § 1533(a)(1)(A)–(E).

54. This is taken from the definition of critical habitat. *See id.* § 1532(5).

55. This and the other critical habitat designation questions are summarized in the agency regulations. 50 C.F.R. § 424.12(b)(1)–(5) (2003).

| Program | Legal Standard | Science Questions |
|---|---|---|
| Section 4 recovery planning | What measures are necessary to bring the species to the point at which it is no longer endangered or threatened, and by what objective, measurable criteria can that determination be made?[56] | What site-specific and general management actions can reduce the threats that caused the species to be listed?[57] How will we measure the magnitude of those benefits? When will the benefits have reached the point that we can justify removing the species from the lists? |
| Section 7 jeopardy prohibitions | Will the direct and indirect effects of the federal action jeopardize the continued existence of the species[58] by appreciably reducing its chances of recovery and survival in the wild?[59] | What are the impacts of the action on reproduction, numbers, or distribution of the species?[60] How much do such impacts reduce the chances of the species surviving and recovering in the wild? |
| Section 7 adverse modification prohibition | Will the direct and indirect effects of the federal action result in the destruction or adverse modification of critical habitat of the species[61] by appreciably diminishing the value of the habitat for the survival and recovery of the species?[62] | How does the action alter any of the physical and biological features that were the basis for determining the habitat to be critical?[63] How much do such impacts reduce the chances of the species surviving and recovering in the wild? |

56. This is taken from the definition of "conservation," which is what recovery plans are supposed to accomplish. *See* 16 U.S.C. §§ 1532(3) (definition of conservation); 1533(f) (recovery plans are for conservation of species).
57. These questions are from the statutory procedure for recovery plan development. *See id.* § 1533(f).
58. This is the statutory prohibition of jeopardy. *See id.* § 1536(a)(2).
59. The agency regulations elaborate on the statute with this definition of "jeopardize." *See* 50 C.F.R. § 402.02 (2003).
60. These are the criteria set forth in the regulatory definition. *See id.*
61. This is the statutory prohibition of adverse modification. *See* 16 U.S.C. § 1536(a)(2).
62. The agency regulations elaborate on the statute with this definition of "destruction or adverse modification." *See* 50 C.F.R. § 402.02.
63. These are the criteria set forth in the regulatory definition. *See id.*

| Program | Legal Standard | Science Questions |
|---|---|---|
| Section 9 take prohibition | Will a person's action harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect any individuals of the species?[64] | Does the action actually kill or injure wildlife? For the "harm" determination, does it modify or degrade habitat so as to impair behavioral patterns such as breeding, feeding, or sheltering, and if so, has that killed or injured individuals of the species?[65] |
| Section 7 incidental take permitting | What reasonable and prudent measures are necessary or appropriate to minimize the impact of the incidental taking?[66] | What is the nature and magnitude of the take being authorized, and by what measures and magnitude has the agency minimized such take? |
| Section 10 incidental take permitting | Has the applicant minimized and mitigated the impacts of the incidental taking to the maximum extent practicable, and not appreciably reduced the likelihood of the survival and recovery of the species?[67] | What is the nature and magnitude of the take being authorized, and by what measures and magnitude has the applicant minimized and mitigated such take? What is the net effect of the take, as minimized and mitigated, on the ability of the species to survive and recover? |

Any one of the questions embedded in the ESA's science-driven legal framework could be unpacked to reveal a wealth of additional inquiries that press even harder on the question of how to make decisions under the applicable legal standard. For many species, the series of scientific questions the ESA raises could be the foundation for years of research by a university or agency scientist, and even with

64. This is the statutory definition of take. *See* 16 U.S.C. § 1532(19) (2000).

65. This is the regulatory definition of harm. *See* 50 C.F.R. § 17.3 (2003). For a recent summary of the history of this administrative interpretation of "harm" and the caselaw construing it, see Steven G. Davison, *The Aftermath of* Sweet Home Chapter*: Modification of Wildlife Habitat as a Prohibited Taking in Violation of the Endangered Species Act*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 541, 557–69 (2003); Glen & Douglas, *supra* note 48.

66. This is the statutory standard for issuance of a Section 7 incidental take statement. *See* 16 § U.S.C. 1536(b)(4).

67. These are the statutory criteria for issuance of a Section 10 incidental take permit. *See id.* § 1539(a)(2).

ample time and resources conclusive answers would remain elusive.[68] Seen from this scientist's perspective, the sharp yes/no character of the ESA's regulatory decisions must seem preposterous.[69]

Indeed, the gap between what agencies do under the ESA and what scientists do under science is inevitable. Agencies do not *do* science under the ESA, they merely *use* it. This is all the ESA demands of agencies when it commands that they make decisions on the basis of the best scientific data *available*. Unless we want to go so far as to demand that agencies also use the available science in their decisions as if they are doing science—*i.e.*, with the same rigors and to the same level of confidence as the scientific method demands of scientists—what we really want them to do is use the available science in a manner consistent with sound professional judgment.[70] As the next Part demonstrates, introducing peer review into that setting can present more pitfalls than promise.

## IV. THE DANGERS OF PEER REVIEW OVERDOSE

Over the past few years the national media have followed the tumultuous events of ESA implementation in the Klamath River Basin, which straddles the Oregon–California border.[71] There, for over one

68. For example, even the threshold question of whether a species really is a species in the legal and scientific sense has sparked intense debate. *See* LIEBESMAN & PETERSEN, *supra* note 23, at 11–15; SELS, *supra* note 23, at 31–38; SULLINS, *supra* note 23, at 6–11. Several cases turn on whether FWS or NMFS has correctly defined what constitutes a species within the meaning of the statute. *See* LIEBESMAN & PETERSEN, *supra* note 23, at 11–15 (reviewing cases).

69. As two close observers of the ESA have put it, "the ESA requires scientists to provide clear answers to fuzzy questions that many scientists do not define as 'scientific,' such as whether a species is endangered or whether a specific project is likely to cause jeopardy." Holly Doremus & A. Dan Tarlock, *Fish, Farms, and the Clash of Cultures in the Klamath Basin*, 30 ECOLOGY L.Q. 279, 325 (2003).

70. This is the theme of my contemporaneous work on the methodology of the ESA. *See* Ruhl, *supra* note 12.

71. This brief recitation of the history of events taking place in the Klamath River Basin is not intended to be comprehensive. It is derived from personal knowledge and my work on the National Research Council's Committee on Endangered and Threatened Fishes in the Klamath River Basin, which thoroughly studied the area's land use and water management history. *See* NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN: CAUSES OF DECLINE AND STRATEGIES FOR RECOVERY 46–94 (2004) [hereinafter KLAMATH COMMITTEE FINAL REPORT] (describing, in depth, the land use and water management of the Klamath River area). Additional detail 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); Doremus & Tarlock, *supra* note 69; Julia Muedeking, *Taking the Heart of the Klamath Basin: Is It Free?*, 8 DRAKE J. AGRIC. L. 217 (2003); and Cori S. Parobek, *Of Farmers' Takes and Fishes' Takings: Fifth Amendment Compensation Claims When the Endangered Species Act and Western Water Rights Collide*, 27 HARV. ENVTL. L. REV. 177 (2003).

hundred years, the Bureau of Reclamation ("BOR") has operated an irrigation water diversion project at a dam impounding Upper Klamath Lake. Over that time, however, two species of sucker fish—the shortnose sucker (*Chasmistes brevirostris*) and the Lost River sucker (*Deltistes luxatus*)—now inhabiting lake and tributary habitat above the dam, and a population of coho salmon (*Oncorhyncus kisutch*) inhabiting the river and tributary system below the dam, have dwindled in population. They have been listed under the ESA and thus are monitored and protected under the watchful eyes of the FWS (for the suckers) and NMFS (for the salmon). In 2001, a year of severe drought, FWS and NMFS concluded that continued flow of irrigation water out of the system would jeopardize the species in violation of section 7 of the ESA. The BOR closed the headgates, and hundreds of farms dried to dust. Following public outcry over this fish-versus-humans saga, the Secretaries of Commerce and the Interior asked the National Academy of Science's National Research Council ("NRC") to convene a committee of experts to conduct a scientifically rigorous peer review of the agencies' respective decisions—the first ever to be conducted of a discrete agency decision of this magnitude under the ESA.[72]

As a member of the NRC's Committee on Endangered and Threatened Species of the Klamath River Basin (Klamath Committee), I saw first hand the difference peer review can make for the ESA. The Klamath Committee's initial charge was to "assess whether the [FWS and NMFS] biological opinions are consistent with the available scientific information."[73] The Klamath Committee, in other words,

72. One earlier study purported to conduct some level of scientific peer review of 43 HCP incidental take permits that FWS had issued under section 10 of the ESA through late 1997. *See* NAT'L CTR. FOR ECOLOGICAL ANALYSIS AND SYNTHESIS & AM. INST. OF BIOLOGICAL SCIENCES, USING SCIENCE IN HABITAT CONSERVATION PLANS (1999), *available at* http://www.nceas.ucsb.edu/nceas-web/projects/97KAREI2/hcp-1999-01-14.pdf. The methodology of the study, however, did not produce a rigorous peer review of each HCP, and did not purport to apply the procedures usually associated with producing independent scientific peer review. *See* U.S. FISH & WILDLIFE SERVICE, DEP'T OF THE INTERIOR, U.S. FISH AND WILDLIFE SERVICE'S RESPONSE TO AIBS/NCEAS'S STUDY: USING SCIENCE IN HABITAT CONSERVATION PLANS, *available at* http://endangered.fws.gov/hcp/response.htm (last visited Nov. 7, 2004).

73. The "statement of task" for the Klamath Committee at this juncture thus was quite narrow, requiring that the group "review and evaluate the science underlying" the agencies' decisions and "assess whether the [decisions] are consistent with the available scientific information." NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, SCIENTIFIC EVALUATION OF BIOLOGICAL OPINIONS ON ENDANGERED AND THREATENED FISHES IN THE KLAMATH RIVER BASIN: INTERIM REPORT 32 (2002) [hereinafter KLAMATH COMMITTEE INTERIM REPORT]. All discussion of the Klamath Committee's work in this Article reflects my personal views and not those of the NRC, the Klamath Committee, or any other member of the Klamath Committee.

was not filling the shoes of a court on *judicial* review assessing whether the biological opinions were "arbitrary and capricious." Rather, we were asked, in effect, to subject a discrete agency decision to rigorous, independent, scientific *peer* review.

The initial results of the Klamath Committee's preliminary peer review, the so-called *Interim Report*,[74] sparked a firestorm of controversy. The Klamath Committee found, based on an independent, objective, scientifically rigorous review of available information in the available time period, that "no sound scientific basis" existed for the two central recommendations that FWS and NMFS made regarding the most controversial features of the Klamath Project—effects of lake levels and river flows on the fish.[75]

Predictably, these findings catapulted the Klamath into the position of exhibit number one for the "sound science" movement, with "sound science" agitators using the *Interim Report* conclusions to support charges that the ESA is "scientifically flawed" in that it allows the agencies to work on the basis of so-called "junk science."[76] A court using the conventional rules of judicial review would not, and could not, apply scientific peer review procedures to the agencies' decisions, and thus may have upheld FWS and NMFS.[77] Hence, goes the argument, we must introduce peer review more systematically into the ESA in order to avoid more "Klamaths."

Not so fast! The Klamath is only one data point, and sound science itself would not countenance making sweeping policy decisions on that sole basis. Even "sound science" wouldn't do that! Before we rush to judgment about the import of the Klamath experience as evidence that peer review is needed to stamp out widespread agency failure, we should consider the potential for peer review to detract from the exercise of agency professional judgment. Three concerns in this respect

74. *See id.*, at 3–4 (summarizing the Committee's principal findings that the agencies had no scientific basis for requiring increased lake levels or increased stream flow).

75. *Id.* (finding no scientific evidence supporting requirement of increased lake levels or increased stream flow). The Committee also found that BOR's proposed operational changes had no scientific basis. *Id.* at 4–5.

76. *See* Chris Mooney, *Sucker Punch*, LEGAL AFFAIRS, May–June 2004, at 23, 25. The Klamath Committee also was the target of much criticism and, in general, the situation deteriorated into what some observers referred to as "combat biology." Robert F. Service, *"Combat Biology" on the Klamath*, 300 SCIENCE 36, 36 (2003). The lack of established structure for carrying out the peer review probably contributed to the ways in which the findings were used and abused, and that is one reason for my proposal *infra*.

77. My personal view is that it is almost certain a court would have upheld the FWS and NMFS biological opinions as not arbitrary and capricious. That likelihood was severely diminished, if not reversed, by the Klamath Committee's *Interim Report*, though events have overtaken the possibility of that precise question ever being decided.

are: the problem of inflated public expectations of the benefits of peer review; the effects the time and expense peer review will have on the efficiency of agency decisionmaking; and the incentives agencies may have to manipulate peer review in their favor.

### A. Overselling Peer Review to the Public: The OMB Peer Review Guidance

The centerpiece of the Bush Administration's "sound science" push is a policy bulletin the Office of Management and Budget ("OMB") has proposed that purports to require federal agencies to conduct "appropriate and scientifically rigorous peer review" of "influential scientific information" and "highly influential scientific assessments" an agency disseminates to the public."[78] In its initial September 2003 proposal, OMB claimed this mandate will "improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public," because it will "provide a vital second opinion on the science that underlies federal regulation."[79] But this oversold to the public what regulatory peer review offers. In the first place, peer review does *not* provide a second opinion in the conventional sense. Medical doctors providing a second opinion examine the patient, not just the other doctor's written opinion; whereas scientists providing peer review for professional journals do not "examine the patient" in the form of conducting independent experimentation or data analysis. As Lars Noah has put it, "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."[80] OMB did just that, suggesting to the public that federal agencies will be providing the results of "second opinions" when in fact they will be subjecting decisions only to the coarse review commensurate with journal publication and grant-funding peer review. OMB even conceded that "peer review undertaken by a scientific journal may generally be presumed to be adequate" to satisfy its peer review mandate,[81] yet nonetheless described regulatory peer review to the public as the equivalent of a "second opinion."

Responding to this and other criticisms of its initial proposal,[82] OMB revised the proposal in April 2004,[83] deleting any suggestion

78. OMB, Proposed Bulletin, *supra* note 19, 68 Fed. Reg. at 54,027. I describe the bulletin as purporting to require peer review because some observers have questioned OMB's authority to do so. *See* Shapiro, *supra* note 5. I do not take up the authority question herein.
79. *See* OMB, Proposed Bulletin, *supra* note 19, 68 Fed. Reg. at 54,023–24.
80. Noah, *supra* note 5, at 1046.
81. OMB, Proposed Bulletin, *supra* note 19, 68 Fed. Reg. at 54,027.
82. Public comments on the OMB Proposed Bulletin are posted at http://www.whitehouse.gov/omb/inforeg/2003iq/iq_list.html.
83. *See* OMB, Revised Bulletin, *supra* note 19, 69 Fed. Reg. at 23,231.

that regulatory peer review is tantamount to a "second opinion." Indeed, OMB succinctly explained what regulatory peer review would provide in much more cogent terms:

> Peer review typically evaluates the clarity of hypotheses, the validity of the research design, the quality of the data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall project.[84]

Even having corrected its case of false advertising, however, OMB never explains precisely how far the broad peer review mandate will "improve both the quality of scientific information and the public's confidence in the integrity of science." I have little doubt that it will lead to some improvement in all respects, but it is unlikely to do so significantly in all cases, or even in more than a small percentage. There are, I suspect, few "Klamaths" lurking out there for which peer review will turn things around and upside down. The reason is that, as explained above, agencies already operate under an institutional framework that provides review functions through public participation and judicial review. Peer review would add only an incremental review effect, albeit by reviewers who have expertise not necessarily shared by the public or judiciary. OMB fails to identify the magnitude of benefits it expects this increment of additional review to produce.

Indeed, the deficiencies in the FWS and NMFS opinions issued in the Klamath context were revealed only through an intense peer review process—the *Interim Report*, in which the Committee issued its initial "without basis" finding, was prepared by a team of twelve experts from several fields working over a ninety-day time frame to examine and evaluate reams of source data and documentation. In other words, we went far beyond the coarse filter of journal publication peer review, and I strongly doubt a review undertaken at any less intense level would have uncovered the gaps in reasoning we revealed. The OMB sells its peer review mandate, however, by suggesting to the public that it may receive Klamath-style error detection benefits on a journal peer review budget, and thereby sets up agencies for a fall.

Supporters of OMB's proposal may argue, and I would agree, that the benefits of regulatory peer review are more likely to be institutional in nature rather than identifiable in discrete cases. In other words, the prospect of peer review will inherently lead agencies incrementally to improve the quality, objectivity, utility, and integrity of their work, so that some form of regulatory peer review framework ultimately may not substantially change the outcome of any single regulatory decision, but will beneficially influence the way in which all regulatory decisions are carried out. This clearly is the reason most scientists believe that peer review is "essential to the integrity of sci-

84. OMB, Revised Bulletin, *supra* note 19, 69 Fed. Reg. at 23,231.

entific and scholarly communication."[85] As I demonstrate *infra*, however, the prospect of *mandatory* peer review—peer review applied across the board to classes of regulatory decisions without respect to time, cost, or need—raises other institutional concerns that must be considered before we can appreciate the net effects on agency performance.

### B. Using Peer Review to Smother Agencies: The ESA "Sound Science" Bills

For many ESA stakeholders, the risk of overselling the policy value of peer review is outweighed by the risk of allowing the ESA to apply in instances where it should not as a scientific matter. In other words, peer review might not improve all ESA decisions, but if it can avoid a few "mistakes" some observers believe it is worth demanding that agencies do it as part of the decisionmaking routine. Such a rationale was embodied in the Sound Science for Endangered Species Act Planning Act of 2002,[86] which Representative James Hansen (R-Utah) introduced on May 23, 2002, as one in a long line of so-called ESA "sound science" bills. In general, this and similar "sound science" proposals[87] would alter the procedures, standards of evidence, and burdens of proof, under which federal agencies operate in carrying out ESA programs. The legislation would "raise the bar" for ESA procedures in many respects, requiring FWS and NMFS to give preference to certain forms of evidence and apply more rigorous burdens of proof to a long list of specified decisions. In particular, the bill would institute a more formal and probing peer review step for many more ESA decisions than the agency has imposed on itself under the 1994 policy. These changes likely would increase the procedural and financial burdens associated with carrying out the affected functions.

Assuming sufficient time and resources to allow the agencies to carry out diligently the new requirements, it is possible that, by enhancing the evidentiary record and burden of proof, the changes would reduce agency error in carrying out those functions. Indeed, like OMB, the ESA "sound science" bill proponents routinely liken regulatory peer review to getting a second opinion from a doctor:

> 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

85. WELLER, *supra* note 16, at 322.

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

87. For a more recent version, see S. 369, 108th Cong. (1st Sess. 2003), and H.R. 1662, 108th Cong. (1st Sess.) (2003). For a history of peer review in ESA reform bills preceding HR 4840, see Brennan et al., *supra* note 11, at 433–40.

> 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.[88]

Folksy wisdom indeed, but in fact few people seek a second opinion for, say, a hangnail—the point being that not every ESA decision is the regulatory equivalent of cutting off a right leg. "Klamaths" don't happen every day. But the ESA "sound science" bills make no distinction based on diagnosis—all listings, critical habitat designations, recovery plans, and jeopardy consultations are, for their purposes, limb amputations necessitating a second opinion. Even if regulatory peer review were to provide a true second opinion, which it won't (see *supra*), it would be wasteful to require it in every case.

With this kind of fast and loose portrayal of why regulatory peer review is needed for the ESA, "sound science," I would say, is beginning to look like something other than sound science. It is beginning to look like sandbagging, which, in fact, is the chief accusation made against proponents of regulatory peer review. The "paralysis by analysis" charge leveled against broad, mandatory regulatory peer review alleges that "these sorts of reform proposals are designed for precisely that purpose, offering regulatory relief for industry in the guise of more rational procedures."[89]

Indeed, there is good evidence that this smothering effect is the intended consequence of proposals for mandatory peer review under the ESA. As noted above, most of the "sound science" bills apply their version of science primarily to agency decisions that involve the extension of protection to species, such as listing of species under section 4 and the finding of jeopardy under section 7, and not to decisions to allow development, such as the issuance of incidental take permits under section 10.[90] The "sound science" bill proponents could hardly commit a more obvious tipping of the hand, reserving the purported "second opinion" benefits of peer review for the decisions they dislike the most. Surely they understand that the clear effect of altering the decisionmaking methodology will be to alter some, if not many, substantive outcomes.

To be fair in this criticism, though, studies have shown that support for peer review under the ESA is strong in both the industry and the environmental camps and is almost always limited to applying the review to the type of decisions each interest group finds the most troublesome. Dr. Deborah Brosnan has found, for example, that more

88. *Walden Testifies on Need for Endangered Species Act Reform* (Feb. 4, 2004) (testimony of Rep. Greg Walden (R-Or), bill sponsor of H.R. 1662), *at* http://www.house.gov/apps/list/press/or02_Walden/pr_040205_esa.html.

89. Noah, *supra* note 5, 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").

90. *See* H.R. 4840, 107th Cong. (2d Sess. 2002).

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."[91] Even those favoring *increased* species protection, in other words, are willing to use peer review as a strategic weapon.

Of course, strategic sandbagging can be reduced though adequate funding, ample time frames, and even-handed implementation practices. But even if Congress were, contrary to all indications, adequately to fund ESA peer review and eliminate political bias by mandating peer review across the board for all types of decisions, the result could be to actually *increase* agency error rates. Time deadlines for ESA decisions *do* make sense—species on their way to extinction do not have time to spare—thus Congress wisely imposed time limits for listing and jeopardy decisions.[92] If mandatory peer review were enforced under the ESA in those settings, the lack of complete data about imperiled species, compounded by the lack of time sufficient to collect more complete data before the possibility of extinction grows larger, would mean that most peer reviews would find that proposed decisions to protect species rest on thin scientific footings.[93] If such a finding were to make it more difficult for the agency to extend protection to species as a matter of policy, mandatory peer review could create a structural risk asymmetry in the ESA, under which "the probability that the species will not be protected when protection is needed is greater than the probability that the species will be protected unnecessarily."[94]

In other words, even with adequate funding and uniform application across all ESA programs, some species simply do not have the time that peer review and other components of sound science demand. If a species is endangered, it is past the "limb amputation" stage where a second opinion makes sense. Second opinions, after all, are not usually called for on the battlefield. Indeed, the deadlines Congress has placed in the ESA on agency decisionmaking acknowledge the pressing need in many cases to intervene quickly on behalf of species, lest they vanish before we decide what to do. The agencies al-

91. Deborah M. Brosnan, *Can Peer Review Help Resolve Natural Resource Conflicts?*, 16 ISSUES IN SCI. & TECH. 32, 33 (2000).

92. *See supra* notes 44 and 45.

93. I take up *infra* the fact that the peer review program FWS has imposed on itself as an agency policy has produced overwhelmingly affirmative peer reviews findings. *See infra* notes 104–110 and accompanying text. When things appear too good to be true, perhaps something is amiss.

94. NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, SCIENCE AND THE ENDANGERED SPECIES ACT 167 (1995).

ready have a difficult time meeting those deadlines,[95] and adding peer review steps to the process will not improve that experience. Over time, therefore, under a mandatory peer review regime, we most likely would experience even more errors of omission than of commission—*i.e.*, we will amass more species that should have been protected, but were not, than those which should not have been protected, but were. In the end, mandatory ESA peer review might not smother only the agencies, but the endangered species too.

### C. Rigging Peer Review to Validate Decisions: The ESA Peer Review Policy

One of the arguments advanced against the ESA "sound science" bills is that FWS and NMFS already incorporate peer review a policy that FWS and NMFS adopted in 1994 and have implemented with respect to ESA species listing and recovery plan decisions.[96] Peer review, however, should satisfy four key characteristics—it must be expert, independent, external, and technical.[97] The NRC takes great care to ensure these qualities in its peer review procedures by carefully soliciting expert reviewers, vetting them for bias, and even subjecting their initial report to another level of peer review.[98] Although many stakeholders disagreed with the Klamath Committee's conclusions and how the Departments of Interior and Commerce incorporated them into policy, no allegations were heard that the committee somehow was influenced by bias. The same cannot be said of peer reviews carried out under the ESA peer review policy.

In the ESA policy, the agencies explain that they will "incorporate independent peer review in listing and recovery activities."[99] This step, 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."[100] The problem is that, although the agencies reassuringly explain that "[i]ndependent peer reviewers should be selected from the academic and scientific community, Tribal and other Native American groups, Federal and

95. *See* U.S. GENERAL ACCOUNTING OFFICE, GAO-04-93, ENDANGERED SPECIES: MORE FEDERAL MANAGEMENT PROTECTION IS NEEDED TO IMPROVE THE CONSULTATION PROCESS (2003) (explaining how frequently the agencies exceed deadlines applicable to consultation under Section 7(a)(2) of the ESA).
96. 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).
97. *See* NAT'L RESEARCH COUNCIL, *supra* note 13, at 2.
98. *See, e.g.*, KLAMATH COMMITTEE FINAL REPORT, *supra* note 71, at xiii–xiv.
99. *See* NAT'L RESEARCH COUNCIL, *supra* note 13, at 2.
100. *Id.*

State agencies, and the private sector,"[101] and that "those selected have demonstrated expertise and specialized knowledge related to the scientific area under consideration,"[102] it is the agencies that select their peer reviewers, review the peer reviews, and report the results of the peer reviews.[103]

Whether these conditions can ensure expert, independent, external, and technical peer review is no idle concern. A recent General Accounting Office ("GAO") study of how FWS has implemented the peer review policy noted that "Service officials told us that they have not adopted a formal procedure to assess peer reviewers' independence, and the Service does not publicly disclose . . . potential conflicts or prior involvement by its peer reviewers" and concluded that other agencies "use more rigorous forms of peer review."[104] The study also found that the people FWS chose to serve as peer reviewers usually agreed with the agencies' positions.[105] Yet, with virtually no information at hand with which to test the independence of peer reviewers, one cannot reliably conclude from this seemingly strong track record whether FWS subjected its decisions to peer *review* and received consistently good marks, or simply sought peer *approval* and ensured the process would produce plenty. The GAO observed that FWS "peer reviewers are selected at the discretion of the field office scientists responsible for developing listing and critical habitat decisions."[106] This

101. *Id.*

102. *Id.*

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

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

105. *Id.* at 21–22.

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

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

NAT'L RESEARCH COUNCIL, NAT'L ACADEMIES, THE NATIONAL RESEARCH COUNCIL PROCESS (2004), *at* http://www.nationalacademies.org/about/faq4.html. Because

simply invites charges of manipulation. Indeed, even putting aside the possibility of self-serving motives, the agencies' peer review policy generally fits the type of sloppy, *ad hoc* model many observers, and not just "sound science" advocates, find objectionable in administrative agency practice.[107]

Some experiences with FWS and NMFS peer review suggest that these general concerns have manifested with suspect consequences in specific cases. FWS and NMFS had long been criticized for operating a "black box" style of decisionmaking—relatively closed to the public, relying on informal channels of scientific communication, and generally unwilling to communicate their data and scientific reasoning in a manner that facilitated review by the public and the courts.[108] The peer review policy, presumably, was intended to fix that—to instill greater confidence in the public and the courts. But the holes in the policy have allowed the agencies to perpetuate "black box" practices. In listing decisions, for example, FWS has refused to release the names and reports of peer reviewers prior to its listing decision, thus precluding the peer review results from informing public comment, and has often selected peer reviewers whose work formed the basis of the agency's decisions, meaning that the peer reviewer was asked to review his or her work.[109] In other cases, the agency has simply ignored the peer reviewers' comments, reaching a decision contrary to what peer review concluded is the best available science.[110] Overall, therefore, the ESA peer review policy may lead to review of FWS and NMFS decisions, perhaps by peers, and even by peers who are scientists, but its independence and objectivity are inherently suspect as well as tainted by actual experience.

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of the consequences peer review would have under my proposal with regard to judicial review, I would require that the NRC appointment procedures be used.

107. *See, e.g.*, OMB, Proposed Bulletin, *supra* note 19, 68 Fed. Reg. at 54,024–25 (discussing the flaws in different federal agency peer review procedures that lead to reduced reliability and credibility of the reviews, but not going so far as to require NRC's appointment procedures, discussed *supra* note 106).

108. *See* Doremus, *supra* note 6, at 1082–87.

109. *See* Letter from Robert D. Thornton, to Craig Manson, FWS Assistant Secretary, Re: California Tiger Salamander (Feb. 18, 2003) (detailing these claims in the context of a proposed listing deision) (on file with author and available in the Schmid Law Library at the University of Nebraska College of Law.).

110. *See* 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); *Mountain Plover Listing Proposal Withdrawn*, ENDANGERED SPECIES & WETLANDS REP., Sept 2003, at 16. In the Mountain plover decision, FWS proposed a rule listing the species as endangered, which the agency's hand-picked peer reviewers agreed was supported by the best available science. The agency later withdrew the proposal based on what it described as "additional information," but without subjecting the new agency decision to peer review.

## V. A PRESCRIPTION FOR USEFUL REGULATORY PEER REVIEW

What does the Klamath experience have to say about the use of peer review under the ESA? Some observers have argued that the Klamath experience proves that without peer review the agencies practice "junk science."[111] Nonsense! If that charge is true, it is true of virtually every other environmental law, for *any* decisionmaking process is bound eventually to make mistakes that might have been detected through ever more rigorous peer review. Rather, all the *Interim Report* demonstrates in the way of broader policy questions is that there is a decision to be made about peer review—when and where to use it, and at what level of intensity. The Klamath Committee revealed that the agencies, while perhaps exercising sound professional judgment in their biological opinions (something the Klamath Committee was not asked to decide), did not produce a decision that passed what happened to be a particularly rigorous peer review. Those who charge the agencies with practicing "junk science" on that basis either have no idea what sound science is or are simply being dishonest about their true intent—to influence the substantive outcomes of the ESA process by demanding that the agencies satisfy "sound science." As the Klamath Committee observed in its *Final Report*:

> [A]gencies charged with ESA responsibilities can be expected to use professional judgment when no scientifically supportable basis is available for a decision, or where they judge the scientific support to be inadequate. Thus, the 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.[112]

The challenge, in other words, is to craft peer review procedures that assist agency exercise of professional judgment, not interfere with it. At one end of the spectrum is the OMB-like prescription of mandatory peer review applied across the board to all regulatory decisions, an approach I hope to have demonstrated *supra* to be unwise at best. At the other end of the spectrum (short of no peer review at all), some observers suggest allowing agencies to employ *ad hoc* procedures for deciding when peer review is appropriate.[113] I am fearful, however, that this would politicize peer review, and undermine its legitimacy by making its availability subject to agency discretion—the same problem the ESA peer review policy has had. What is needed then, is a more measured approach to regulatory peer review, but one

111. I certainly heard this repeatedly as a member of the Klamath Committee after NRC released the *Interim Report*.

112. KLAMATH COMMITTEE FINAL REPORT, *supra* note 71, at 35.

113. *See, e.g.*, Shapiro, *supra* note 5.

that puts the decision to use it and how to conduct it outside of the agencies' hands.

A starting point is to remind ourselves what benefits we hope to derive from having any regulatory peer review at all. One objective is to avoid decision "disasters" such as the Klamath experience—*i.e.*, where discrete agency decisions have potential consequences to species or society of extremely high magnitude. The other objective is to promote the background quality improving effect peer review can have on decisionmaking, but without generating the decision paralysis effect of broad-based mandated peer review.

The first objective can be met by defining a set of conditions which, when present, would lead any reasonable observer to value a "second opinion," and then to provide a peer review process as rigorous as that used in the Klamath context. Screening criteria could be based on economic impact, precedent-setting nature of the proposal, and level of controversy surrounding the proposal. By setting the criteria high enough to screen out most proposals, the few proposals that would trigger intensive peer review would justify the expense. For example, for a fraction of the $650,000 total budget, the Klamath Committee was able within ninety days to conclude its initial peer review of the agency decisions (our remaining work was devoted to broader evaluation of the Klamath River Basin). This does not seem too high a price to pay to add a layer of insurance against faulty decisionmaking that presents an appreciable risk of drastic consequences.

The second objective presents a less straightforward challenge—until one considers what lies behind the quality-improving function of peer review in the publication setting. Presumably, journal peer review has "lifted" the quality of scholarship not only through the direct effect of reviewer comments, but also through the deterrent effect presented by the fact that each author knows his or her article will be reviewed. As regulators well know, however, deterrent effects can be realized even when compliance inspections are conducted less than one hundred percent of the time for fewer than one hundred percent of the regulated facilities. In the same way, a standing panel of experts could conduct peer reviews of a random sample of manuscripts—or for our purposes, proposed ESA regulatory actions—and thereby generate significant deterrence of shoddy submissions for the entire industry. In the regulatory setting, these peer reviews would not have to be as intense as the "microscope" level of review applied to the high-risk decisions, but rather could approximate the standards of journal publication peer review so as to reduce costs and delays. The random sample element applied over a continuous stream of decisions would remove any concern as to selection bias and would further mitigate any sandbagging effect on the agency at programmatic levels.

As to procedure, both categories of peer review would be implemented by an independent entity (*e.g.*, the NRC) so as to ensure the integrity of the process. Peer reviewers would be compensated so as to attract competent experts and improve timely performance, vetted for potential bias by the coordinating entity, and kept anonymous to the decisionmaking agency except in cases in which the reviewers' desire to conduct field investigation and interviews preclude the ability to ensure anonymity. The results of peer review would be released to the public prior to conclusion of any public notice and comment procedures applicable to the underlying decision.

Overall, by ensuring expert, independent, external, and technical peer review of the "big" cases and a sample of the "small" cases, my proposal can deliver substantial peer review benefits without resorting to false advertising, without risk of smothering agency work, and without even the appearance of manipulation. It would be impractical to import journal publication peer review for all regulatory decisions, yet it is just as improvident to resist peer review in all cases. Rather, as I have tried to do, we ought to write the prescription to fit the patient.

## VI. CONCLUSION

The regulatory peer review question is just one component, albeit perhaps the most prominent component, of the larger "sound science" debate. And the "sound science" debate, in turn, is embedded in the even broader question of "[w]hat is the optimal level of sensitivity for society's environmental alarm."[114] In other words, how much "error" are we willing to tolerate on behalf of exercising caution towards the environment? Peer review, its advocates promise, will weed out error in the environmental decisionmaking process, thus making environmental policy more efficient. But will peer review also quiet alarms that should have rung, and which we will know should have rung only long after it is too late?

Certainly there is no universally true answer for these questions, simply because there is no universally standard case in environmental policy. Peer review, as "medicine" for too much caution, has no standard dose. Recognizing this—that different diagnoses call for different doses—I have proffered two uses of peer review designed to adjust its use and intensity in the ESA context to the circumstances that seem most amenable to benefiting from the advantages that peer review can offer. First, when the potential cost to society of extending protection are high, focused, rigorous peer review can promote focused, rigorous decisionmaking. Second, limited, random "SWAT

114. *See* S.W. Pacala et al., *False Alarm over Environmental False Alarms*, 301 SCIENCE 1187 (2003).

team" peer review pitched at the conventional journal publication level of intensity may provide a sufficient background level of review to foster, through deterrence of poorly conducted decisionmaking, much of the quality-improving effects for regulation that are thought to be enjoyed in scholarship as a result of peer review. Neither of these uses of peer review, however, presents strong concerns regarding what are identified as the pitfalls of regulatory peer review—overselling, sandbagging, and rigging. I may have missed something, however, so I am pleased to offer the proposal as the subject of peer review. Have at it!