

Regulatory *Daubert*: A Panacea for the Endangered Species Act’s “Best Available Science” Mandate?

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I. INTRODUCTION

The Endangered Species Act (ESA) is one of the most controversial statutes in effect today.¹ Some regard it as a stalwart and just environmental law, while

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1. See, e.g., Chad Hanson, Op-Ed., *Open Forum: Environment vs. Property Rights: Endangered Species Act Reform Needed? NO: Protections are Threatened with Extinction*, S.F. CHRON., July 5, 2006, at B7 (arguing against ESA reforms); Richard W. Pombo, *Open Forum: Environment vs. Property Rights:*

others consider it overly burdensome or merely an illusory scheme for the policy choices of the implementing agencies.² Regardless of one's view on the proper characterization of the ESA, there can be no denying its power.³ The ESA's toothy provisions ensure that it is a major source of litigation.⁴

One frequent battleground involves the perceived quality of the science that supports decisions made under the ESA.⁵ Decisions to "list" a species (i.e., to provide ESA protections to a species in question) are to be made "solely on the basis of the best scientific and commercial data available."⁶ Because Congress requires a scientific rationale for a species listing, parties for or against an agency's decision to list a species often rely on challenges to the agency's use of the "best available science."⁷

Within the current administrative law framework, challenges to a listing decision have little hope of overcoming the high degree of deference afforded to scientific and technical matters by the courts.⁸ Additionally, courts have been reluctant to engage in the kind of searching review of the bases for an agency decision that is mandated by precedent.⁹

Endangered Species Act Reform Needed? YES: The Law is Outdated, S.F. CHRON., July 5, 2006, at B7 (advancing the position in favor of reform).

2. See, e.g., Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's Best Available Science Mandate*, 34 ENVTL. L. 397, 399 (2004) ("Depending upon who is telling the story, the Endangered Species Act (ESA) is either the 'pit bull of environmental laws' or a political fig leaf providing cover for business as usual." (footnotes omitted)); Mike Lee, *Protection in Jeopardy? Federal Officials Say They Cannot Determine Effectiveness of Endangered Species Act*, SAN DIEGO UNION-TRIB., Apr. 3, 2006, at A1 ("The vagueness also leaves a wide field for interest groups—from environmentalists to property-rights activists—to spin the data. With glossy mailers, news releases and Web sites, the groups tout what suits their political agendas and downplay the rest.").

3. See, e.g., *Tenn. Valley Auth. v. Hill*, 437 U.S. 153 (1978) (enjoining the completion and operation of the virtually finished Tellico Dam to protect the Snail Darter, a small species of perch).

4. See Michael J. Brennan et al., *The Endangered Species Act: Thirty Years of Politics, Money, and Science: Square Pegs and Round Holes: Application of the "Best Scientific Data Available" Standard in the Endangered Species Act*, 16 TUL. ENVTL. L.J. 387, 389 (2003).

Born during a time of unparalleled congressional focus on environmental issues, the Endangered Species Act of 1973 (ESA) stands out among its contemporaries not only for its comprehensiveness, but also for its extreme dedication to endangered and threatened species conservation, to the exclusion of virtually every other interest, including economic considerations. In light of the unprecedented importance the ESA accords to protecting endangered and threatened species, it is not surprising that the ESA has been a lightning rod for controversy and litigation.

Id. (footnotes omitted).

5. See *infra* note 7.

6. 16 U.S.C.A. § 1533(b)(1)(A) (West 2000). The ESA's listing standard is often shorthand as the "best available science" standard. Reference in this Comment to the "best available science" is intended as a reference to the standard required by § 1533(b)(1)(A).

7. See, e.g., *Cook Inlet Beluga Whale v. Daley*, 156 F. Supp. 2d 16, 18-20 (D.D.C. 2001) ("Plaintiffs argue that the agency decision in this case [listing of the Cook Inlet Beluga Whale as "depleted" under the Marine Mammal Protection Act, but not as "endangered" under the ESA] . . . failed to apply the best scientific and commercial data available.").

8. See *infra* notes 113-16 and accompanying text.

9. See *infra* notes 108-16 and accompanying text.

This Comment argues that the current framework for review of ESA listing determinations causes untenable problems and provides insufficient protections from the inherent flaws of agency decision-making predicated on science. The pitfalls of the current framework include a lack of separation between policy and science—that is, pure policy decisions are being passed off as wholly scientific matters.¹⁰ This creates three distinct problems: the risk of substantive bias in scientific studies,¹¹ a lack of accountability on the part of the agency,¹² and a general lack of transparency to the detriment of public understanding and participation in agency decision-making.¹³ An additional pitfall of the current framework is poor articulation of the scope and role of judicial review in the listing process, which corresponds to a lackluster interpretation of congressional mandate.¹⁴

In a legal context completely separate from the ESA and administrative law, federal courts are determining the admissibility of scientific and technical evidence in criminal and civil cases.¹⁵ With an eye toward relevance and reliability, federal courts employ the flexible inquiry laid out by the U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁶ *Daubert* provides federal judges with a method for testing scientific claims that is based on universal principles of sound scientific research.¹⁷ Although, as an evidentiary doctrine concerning admissibility, *Daubert* has no current application in the administrative law context of the ESA, this Comment argues that the ESA listing process could benefit greatly from the importation of the *Daubert* test (regulatory *Daubert*).¹⁸

Part II of this Comment examines the background and state of the law with regard to the ESA,¹⁹ the Administrative Procedure Act (APA),²⁰ and the Supreme Court's decision in *Daubert*.²¹ Part III explores the downfalls of the current listing scheme and considers the ways in which *Daubert* could be expected to

10. See *infra* notes 74-98 and accompanying text.

11. See *infra* notes 89-93 and accompanying text.

12. See *infra* notes 94-107 and accompanying text.

13. See *infra* notes 99-108 and accompanying text.

14. See *infra* notes 108-21 and accompanying text.

15. STEVEN I. FRIEDLAND, PAUL BERGMAN & ANDREW E. TASLITZ, EVIDENCE LAW AND PRACTICE § 9.03 (2d ed. 2004).

16. 509 U.S. 579 (1993).

17. See *infra* notes 59-60 and accompanying text.

18. The application of *Daubert* in the broad administrative law realm is often referred to as “regulatory *Daubert*.” This Comment applies the term “regulatory *Daubert*” more narrowly; it is used to refer to the concept of applying the scientific assessment standard in *Daubert* to the ESA’s listing process. This is intended to use the ESA listing process as a vehicle to assess the merits of regulatory *Daubert*. As such, this Comment expresses no explicit view on the merits of applying the *Daubert* standard wholesale to all agency or administrative action predicated on scientific or technical information.

19. See *infra* notes 27-40 and accompanying text.

20. See *infra* notes 41-52 and accompanying text.

21. See *infra* notes 53-73 and accompanying text.

improve the ESA.²² Part IV looks at the different ways in which *Daubert* may be applied to the ESA, including congressional action,²³ judicial adoption,²⁴ and agency rulemaking.²⁵ Part V addresses the main concerns raised by opponents of regulatory *Daubert*.²⁶

II. BACKGROUND: *DAUBERT* AND THE ESA

A. *The Endangered Species Act*

The ESA was intended to “provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, [and] to provide a program for the conservation of such endangered species and threatened species.”²⁷ The ESA attempts to satisfy this lofty purpose in a variety of ways, one of which involves providing official protection to species determined to be threatened or endangered.²⁸ The ESA requires that a decision to list (or not list) a species as threatened or endangered be made “solely on the basis of the best scientific and commercial data available.”²⁹

Several avenues exist for the listing of a species. The U.S. Fish and Wildlife Service (FWS), which bears primary responsibility for the implementation and execution of the ESA, may list a species on its own initiative through notice and comment rulemaking.³⁰ Additionally, the APA provides a petition process by which a species may become listed.³¹ Under this provision, any interested person may petition the FWS (or other implementing agency) to add a species or remove a species from the list.³² Once the inquiry into a potential listing has begun, the relevant agency must make a finding on the species within twelve months and

22. See *infra* notes 74-121 and accompanying text.

23. See *infra* notes 144-67 and accompanying text.

24. See *infra* notes 128-43 and accompanying text.

25. See *infra* notes 168-79 and accompanying text.

26. See *infra* notes 180-211 and accompanying text.

27. 16 U.S.C.A. § 1531(b) (West 2000).

28. *Id.* § 1533(a)(1)-(a)(1)(E).

The Secretary shall . . . determine whether any species is an endangered species or a threatened species because of any of the following factors: (A) the present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Id.

29. *Id.* § 1533(b)(1)(A).

30. *Id.* § 1533(b)(5). Notice and comment rulemaking (informal rulemaking) is authorized by the Administrative Procedure Act, and “involves giving notice, inviting written comments, and justifying the rule in a statement of basis and purpose.” WILLIAM F. FUNK, SIDNEY A. SHAPIRO & RUSSELL L. WEAVER, ADMINISTRATIVE PRACTICE AND PROCEDURE 48 (3d ed. 2001).

31. 5 U.S.C.A. § 553(e) (West 2007).

32. *Id.*

publish the results in the Federal Register.³³ Furthermore, “[j]udicial review of an agency decision usually focuses on the administrative record in existence at the time of the decision.”³⁴

The purpose of the “best available science” standard, as noted by the U.S. Supreme Court in *Bennett v. Spear*, “is to ensure that the ESA not be implemented haphazardly, on the basis of speculation or surmise.”³⁵ Despite the language of *Bennett*, the lower courts have interpreted the “best available science” standard to impose no affirmative duty on agencies implementing the ESA to gather additional data or to conduct further studies when the information on hand is uncertain and inconclusive.³⁶ The D.C. Circuit has said that the standard requires that agencies “utilize the ‘best scientific . . . data available,’ not the best scientific data possible.”³⁷ Furthermore, minor flaws in data do not render it per se unreliable.³⁸

The substantive limitations of the “best available science” mandate seem to be limited to preventing an agency from manipulating data by relying unduly on

33. 16 U.S.C. § 1533(b)(3)(B).

34. *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 402 F. Supp. 2d 1198, 1202 (D. Or. 2005).

35. 520 U.S. 154, 176 (1997). Justice Scalia elaborated on this idea, noting that it was “readily apparent that another objective [of the ESA’s “best available science” standard] (if not indeed the primary one) is to avoid needless economic dislocation produced by agency officials zealously but unintelligently pursuing their environmental objectives.” *Id.* at 176-77. Justice Scalia’s characterization has drawn some criticism. *See, e.g.,* Holly Doremus & A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resource Regulation*, 26 PUB. LAND & RESOURCES L. REV. 1, 4 n.12 (2005) (“We do not endorse Justice Scalia’s exercise in statutory interpretation, which ignores both the ESA’s overriding conservation purpose and the specific history of its science requirements.”). This would seem to treat these various objectives as mutually exclusive, though they need not be seen as such. Nonetheless, this reflects much of the controversy over the ESA, which tends to be very polarizing. Despite disagreement over the ESA’s purpose, Justice Scalia’s summary correctly identifies a major source of frustration for those subject to the ESA; namely, that their economic, property, and liberty interests are abridged without a compelling or even persuasive showing of the need for regulation.

36. *See Nat’l Wildlife Fed’n v. Babbitt*, 128 F. Supp. 2d 1274, 1286-87 (E.D. Cal. 2000) (“Where the ‘available data’ is imperfect, the [Fish and Wildlife] Service is not obligated to supplement it or to defer issuance of its biological opinion until better information is available.”); *Sw. Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 59 (D.C. Cir. 2000) (“[T]he District Court was without authority to order the Secretary to conduct an independent population count of . . . [a potentially endangered bird].”); *But see N. Slope Borough v. Andrus*, 486 F. Supp. 332, 352 (D.D.C. 1980) (“[I]nadequate information does not provide a foundation for reckless abandon.”); *Roosevelt Campobello Int’l Park Comm’n v. EPA*, 684 F.2d 1041, 1052-53 (1st Cir. 1982) (considering the lack of information to be a violation of the “best available science” standard where all parties agreed that additional studies would reveal critical information); Doremus, *supra* note 2, at 424-25 (noting that an affirmative obligation to procure data may be emerging in the ESA’s section 7 context (consultation with agencies to avoid jeopardy to existing endangered species), but is not present in the ESA section 4 context (listing decisions)).

37. *Bldg. Indus. Ass’n of Super. Cal. v. Norton*, 247 F.3d 1241, 1246 (D.C. Cir. 2001). The D.C. Circuit’s parsing of words here, while technically accurate, is nonetheless disturbing. Possible sources of information about species are ever-expanding as science progresses and it would likely cause stagnation to require all potentially obtainable information as a prerequisite for listing. That being said, it is another matter entirely to give agencies a pass on collecting data easily within their reach when such data could potentially illuminate the actual status of a species.

38. *Id.*

specific sources and data while ignoring others that are relevant.³⁹ Also, an agency may not ignore “scientifically superior evidence.”⁴⁰

B. The Administrative Procedure Act

In addition to the “best available science” standard provided by Congress, decisions to list a species under the ESA are also subject to the APA.⁴¹ “Federal administrative law revolves around the Administrative Procedure Act (APA), which defines the procedural rights of persons outside of government and structures the manner in which persons inside of government make decisions.”⁴²

The limitations imposed by the “best available science” standard are hard to distinguish from those imposed by the APA, which governs agency actions generally. Under the APA, agency actions are to be set aside if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”⁴³ The “arbitrary and capricious” standard, as it is known, was set out by the Supreme Court in *Citizens to Preserve Overton Park, Inc. v. Volpe*:

To make this finding the court must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency.⁴⁴

Overton Park thus establishes the framework for the scope of judicial review of agency actions under the APA. Elaborating on this standard, the Supreme Court has indicated that the “arbitrary and capricious” standard is violated when

[t]he agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.⁴⁵

39. *Sw. Ctr. for Biological Diversity v. Norton*, No. 98-934 (RMU/JMF), 2002 WL 1733618, at *8 (D.D.C. July 29, 2002).

40. *Las Vegas v. Lujan*, 891 F.2d 927, 933 (D.C. Cir. 1989); *see also Sw. Ctr. for Biological Diversity v. Babbitt*, 926 F. Supp. 920, 927 (D. Ariz. 1996) (finding that agency’s unexplained reliance on earlier data while ignoring more recent data violated § 1533(b)(1)(A)).

41. Pub. L. No. 79-404, 60 Stat. 237, *amended by* Pub. L. No. 89-554, 80 Stat. 381 (codified in scattered sections of 5 U.S.C.).

42. FUNK, SHAPIRO & WEAVER, *supra* note 30.

43. 5 U.S.C.A. § 706(2)(A) (West 2007).

44. 401 U.S. 402, 416 (1971) (citations omitted).

45. *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43

Judicial review of agency decisions under the framework of *Overton Park* is often referred to as the “hard look.”⁴⁶ As one commentator has noted, “[t]he [hard look] doctrine helps to ensure that agency decisions are determined neither by accommodation of purely private interests nor by surreptitious commandeering of the decisionmaking apparatus to serve an agency’s idiosyncratic view of the public interest.”⁴⁷

Also relevant to judicial review of agency decision-making is *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, where the Supreme Court established the principle of deference to agency interpretations of statutory schemes that they are entrusted to administer.⁴⁸ So long as the statute is ambiguous about the method of implementation, a court will defer to any reasonable interpretation made by the relevant agency.⁴⁹ Justice Stevens enunciated the rationale of *Chevron* as follows:

If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.⁵⁰

Known simply as *Chevron* deference, this rule is a formidable obstacle to a potential litigant.⁵¹ As one commentator has observed, “[o]vercoming the APA

(1983).

46. See FUNK, SHAPIRO & WEAVER, *supra* note 30, at 165 (“Judge Harold Leventhal of the District of Columbia Court of Appeals gave the name ‘hard look’ to the scrutiny mandated by *Overton Park*.”).

47. Mark Seidenfeld, *Demystifying Deossification: Rethinking Recent Proposals to Modify Judicial Review of Notice and Comment Rulemaking*, 75 TEX. L. REV. 483, 491 (1997) (“Essentially, under the hard look test, the reviewing court scrutinizes the agency’s reasoning to make certain that the agency carefully deliberated about the issues raised by its decision.” (footnotes omitted)).

48. 467 U.S. 837, 842-44 (1984).

49. *Id.* This deference is perhaps greatest when scientific or technical information is at issue. See *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 377 (1989) (“[When] analysis of the relevant documents ‘requires a high level of technical expertise,’ we must defer to ‘the informed discretion of the responsible federal agencies.’” (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 412 (1976))); *Am. Fisheries Soc’y. v. Verity*, No. CIV.88-0174 RAR-JFM, 1989 WL 644255 at *5 (E.D. Cal. 1989) (“Congress has given expertise to federal agencies and they are expected to possess and exercise this considerable expertise. Courts do not possess, nor should they try to exercise, expert judgment on these matters of technical expertise. Deferral is the general rule.”); *Stewart v. Potts*, 126 F. Supp. 2d 428, 434 (S.D. Tex. 2000) (explaining that the court must “look at the decision not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality” (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (en banc))).

50. *Chevron*, 467 U.S. at 843-44.

51. Of course, the burden is on the party challenging the agency to establish that the agency has acted in

and *Chevron* in a challenge to an ESA listing [is] . . . the litigation equivalent of attempting a Hail-Mary touchdown pass on the last play of the game. . . . [I]n an ESA setting, ‘deference to an agency is greatest when reviewing technical matters within its area of expertise’⁵²

C. Daubert

Daubert v. Merrell Dow Pharmaceuticals, Inc. involved the admissibility of scientific evidence under the Federal Rules of Evidence (FRE).⁵³ In *Daubert*, the plaintiffs contended that the ingestion during pregnancy of an anti-nausea drug, Bendectin, caused birth defects.⁵⁴ The main thrust of the plaintiffs’ argument challenged the continuing authority of the *Frye* test,⁵⁵ which had established that “general acceptance” in the scientific community was the standard of admissibility for scientific evidence.⁵⁶ The *Daubert* Court accepted the plaintiffs’ contention that the *Frye* test had not survived the adoption of the FRE.⁵⁷ Specifically, the Court found that FRE 702 was not intended to preserve a “general acceptance” standard exclusively, as this would be inimical to the FRE’s “liberal thrust” toward relaxing obstacles to opinion testimony.⁵⁸

In place of *Frye*, the Court identified a different set of considerations for the admission of expert scientific evidence, where the primary concerns were relevance and reliability.⁵⁹ Among the factors to consider were whether a scientific theory or technique (1) was or could be tested; (2) was subjected to peer review and publication; (3) had a known or potential rate of error; (4) had standards, adequately maintained, for controlling the technique’s operation; and (5) was generally accepted in the relevant scientific community.⁶⁰

The Court reasoned that modern scientific methodology was predicated on the generation and falsification of hypotheses;⁶¹ that is, answers to scientific questions are advanced and then an attempt is made to *disprove* that hypothesis. This made the potential for testing a scientific theory or technique a prime consideration in any analysis of admissibility. Peer review and publication were

a manner that is arbitrary and capricious.

52. 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, 131 (1994) (quoting *Louisiana v. Verity*, 853 F.2d 322, 329 (5th Cir. 1988) (footnotes omitted)).

53. 509 U.S. 579 (1993).

54. *Id.* at 582.

55. *Id.* at 587.

56. *Frye v. United States*, 293 F. 1013, 1014 (1923).

57. *Daubert*, 509 U.S. at 587.

58. *Id.* at 588.

59. *Id.* at 592-93 (“Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” (footnotes omitted)).

60. *Id.* at 593-94.

61. *Id.* at 593.

identified by the Court as useful factors, since these processes submitted scientific theory to the critical eye of the scientific community, which would help ensure that errors in methodology would be identified.⁶² Furthermore, the Court considered the existence of controlling standards for the integrity of a particular scientific theory or technique, as well as identifying the potential rate of error, as indicative of the scientific method's reliability.⁶³

Daubert also identified general acceptance in a particular scientific field as bearing on the admissibility inquiry.⁶⁴ As the Court explained, “[w]idespread acceptance can be an important factor in ruling particular evidence admissible, and ‘a known technique which has been able to attract only minimal support within the community’ may properly be viewed with skepticism.”⁶⁵ This last consideration was intended to partially retain the *Frye* analysis, but merely as a component of an overarching framework for ensuring reliability and relevance in expert scientific evidence.⁶⁶

The *Daubert* Court did not intend the considerations identified to be exhaustive;⁶⁷ indeed, the new analysis was meant to be flexible.⁶⁸ Nor did the Court limit the analysis to solely novel scientific evidence, and it recognized that “theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under *Federal Rule of Evidence 201*.”⁶⁹ *Daubert* does not suggest that federal judges should substitute their own scientific conclusions for those of the experts; rather, it directs judges to evaluate the underlying principles and methodology supporting scientific conclusions.⁷⁰ In short, *Daubert* instructs federal judges to play a “gatekeeping role” to prevent unreliable and irrelevant evidence from being admitted.⁷¹

62. *Id.* Despite the Court's acceptance of peer review and publication as a valuable tool in assessing the validity of scientific evidence, the Court recognized that this was not the “*sine qua non* of admissibility,” and might not correlate with reliability in all situations. *Id.* It is to be treated as a consideration, but not dispositive of admissibility. *Id.* at 594.

63. *Cf. id.* at 593-94 (“Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.” (quoting Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 645 (1992))).

64. *Daubert*, 509 U.S. at 594.

65. *Id.* (quoting *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985) (citations omitted)).

66. See FRIEDLAND, BERGMAN & TASLITZ, *supra* note 15, at 355 (“[W]hile the *Frye* inquiry is no longer determinative, a *Frye*-like analysis may be one of the factors considered by the trial court in its flexible weighing process under *Daubert*.”).

67. *Daubert*, 509 U.S. at 593 (“Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.”). Thus, the Court recognized that a one-size-fits-all test was ill-suited to inquiries into the cutting edge of science.

68. *Id.*

69. *Id.* at 593 n.11.

70. *Id.* at 595.

71. *Id.* at 597.

Once the gatekeeping role was established in *Daubert*, the Supreme Court went on to smooth out the doctrinal wrinkles. In *General Electric Co. v. Joiner*, the Court established that the standard of review over trial court determinations made pursuant to *Daubert* would be “abuse of discretion.”⁷² In *Kumho Tire Co. v. Carmichael*, the Court clarified that *Daubert*’s gatekeeping function applied to all expert testimony under the federal rules, not merely to novel scientific questions.⁷³ With the addition of *Joiner* and *Kumho* to *Daubert*, the gatekeeping function of the federal judge became firmly established.

III. WHY APPLY *DAUBERT* TO THE ESA?

In its current formulation, the ESA suffers from major drawbacks. Perhaps the greatest of all is the lack of separation between science and policy.⁷⁴ Both are necessary for environmental risk assessment; however, the problem lies in the unwillingness of agencies to differentiate between the two.⁷⁵ The science-policy blend results in some very serious consequences. First, it carries the potential for substantive bias in scientific risk assessment.⁷⁶ Second, it renders agencies unaccountable for their underlying policy choices.⁷⁷ Lastly, it provides little transparency in the scientific decision-making process, resulting in decreased public understanding and participation in agency decision-making.⁷⁸

Regulatory *Daubert* could remedy these problems by implementing a new scientific decision-making dynamic. If the underlying science used to support agency decision-making was subjected to *Daubert* review, agencies would not be able to obscure their policy choices behind a curtain of science so easily. This would reduce the risk of substantive bias by subjecting scientific methodologies to review.⁷⁹ Moreover, *Daubert* could restore political accountability and transparency to agencies by forcing into the sunshine those policy decisions that are ultimately non-scientific. In this way, regulatory *Daubert* could help reveal that which agencies have been so adept at keeping hidden.⁸⁰

Another serious drawback of the current APA and ESA framework is the murkiness that has developed with regard to the judicial role in assessing

72. 522 U.S. 136, 143 (1997).

73. 526 U.S. 137, 147 (1999).

74. See *infra* notes 85-93 and accompanying text.

75. See *infra* notes 85-93 and accompanying text.

76. See *infra* notes 89-93 and accompanying text; see also Robert T. Lackey, *Normative Science*, FISHERIES, July 2004, at 38, <http://www.epa.gov/wed/pages/staff/lackey/pubs/normative.pdf> (on file with the *McGeorge Law Review*) (explaining that substantive bias in this context may be defined as “information that is developed, presented, or interpreted based on an assumed, usually unstated, preference for a particular policy or class of policy choices.”).

77. See *infra* notes 94-107 and accompanying text.

78. See *infra* notes 97-108 and accompanying text.

79. See *infra* notes 89-93 and accompanying text.

80. See *infra* notes 94-107 and accompanying text.

scientific decision-making by agencies. In terms of judicial review, the current ESA-specific standard requiring the “best available science” is given little, if any, significance apart from the generic APA-bound “arbitrary and capricious” standard, as both standards seek to ensure that agency decision-making is based on rational consideration of all known information.⁸¹ This practice allows congressional intent to provide a strong scientific basis for listing decisions to go unfulfilled.⁸²

Moreover, in the context of judicial review of agencies’ scientific decision-making, current administrative law doctrine providing for wide deference to agencies has been overused and stretched to emasculate another tenet of administrative law: that judicial review of agency decisions should encompass a searching, “hard look” review.⁸³

Regulatory *Daubert* responds to these concerns by providing independent legal significance to the ESA’s “best available science” mandate, as well as providing a new judicial review framework that allows judges to continue granting substantial deference to agency statutory interpretations, while nonetheless engaging in required “hard look” review.⁸⁴

A. *The Special Problem of the Science-Policy Blend*

The most serious drawback of the ESA in its current manifestation is the lack of distinction between policy and science. This entails either skewing scientific determinations with implicit policy preferences⁸⁵ or passing policy preferences off as purely scientific.⁸⁶ This creates several distinct problems. It bears the risk of substantive bias in species assessment⁸⁷ and effectively compromises agency accountability and transparency to the public.⁸⁸

1. *The Risk of Substantive Bias in Scientific Assessment*

Robert T. Lackey, a senior fisheries biologist with the U.S. Environmental Protection Agency, has lucidly described the potential for bias in the agency science-policy mix.⁸⁹ Lackey is concerned “that we are heading down a path in fisheries science that risks marginalizing science, if not much of our scientific

81. See *supra* notes 35-47 and accompanying text.

82. See *infra* notes 41-47 and accompanying text.

83. See *infra* notes 41-47 and accompanying text (recall that the “hard look” involves a searching and in-depth review of the bases and reasoning behind agency decision-making).

84. See *infra* notes 117-19 and accompanying text.

85. See *infra* notes 89-92 and accompanying text.

86. See *infra* notes 97-98 and accompanying text.

87. See *infra* notes 89-92 and accompanying text.

88. See *infra* notes 97-108 and accompanying text.

89. See Lackey, *supra* note 76.

enterprise.”⁹⁰ Lackey identifies the problem of policy-riddled science, which he terms “normative science,” and defines as “information that is developed, presented, or interpreted based on an assumed, usually unstated, preference for a particular policy or class of policy choices.”⁹¹ Expanding on this idea, Lackey notes that

[s]cientists can assess, at least with a degree of confidence, the likely effects of removing, or preserving, a particular dam or set of dams, but there is no scientific imperative to remove, or maintain, any dam for any ecological reason, including salmon recovery. Of course, there are ecological consequences of each policy option and those consequences may even be catastrophic from a salmon perspective, but ecological consequences are simply one element that the public and decision-makers must weigh in making a policy choice. Understanding different ecological outcomes is what the public and decision makers need from scientists as they weigh policy alternatives, not our personal opinions on which policy option they ought to choose. . . .

Often I hear or read words like “degradation.” Or words like “improvement.” Or “good” or “poor.” Do not use these in conveying scientific information. Using such words implies a preferred ecological state, a desired condition, a benchmark, a preferred class of policy options. This is not science, it is policy advocacy. Subtle, perhaps unintentional, but still policy advocacy.

The appropriate “science” words are ones such as “alteration” or “change” or “increase” or “decrease.” These words describe the scientific information in ways that are policy-neutral. . . . Be clear, be candid, be brutally frank, but be policy-neutral.⁹²

Lackey gets to the heart of the matter. Because of the pervasiveness of “normative science,” it is critical that a framework be established to keep policy and science relegated to their respective spheres. This is not to imply that the two are independent of each other; indeed, they are both necessary components of natural resource management. The trouble arises when policy informs science, rather than when science informs policy. Aside from the use of methodologically sound scientific principles, this is what a regulatory *Daubert* scheme is intended to effectuate. By subjecting the methodological underpinnings of agency science to review, regulatory *Daubert* can re-organize and improve an agency’s approach to scientific study. When scientists realize that their techniques and methodolo-

90. *Id.*

91. *Id.*

92. *Id.*

gies are going to be assessed for a base level of reliability,⁹³ they will be more inclined to separate their policy preferences from their scientific findings. This will ensure that national species policy is based on solid scientific information, rather than allowing implicit and explicit policy preferences to lead science by the nose toward a national policy. In this regard, regulatory *Daubert* could go far to combat substantive bias, be it intentional or unintentional.

2. *The Current Dynamic: Poor Accountability and Little Transparency*

One of the great failures of the ESA's "best available science" standard is its current inability to provide sufficient transparency and accountability in the science behind the listing process.⁹⁴ The decision to list a species requires both scientific and policy determinations.⁹⁵ Making such determinations does not necessarily raise problems. However, when policy decisions or political choices are clothed in the venerable robes of science, the difficulties emerge.⁹⁶

Professor Wendy Wagner documented a "pervasive 'science charade,' where agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions."⁹⁷ Professor Wagner notes "the tendency of the charade [is] to distance the public, and in some cases even elected or appointed policymakers, from major decisions affecting not only public health but also economic well-being."⁹⁸

The practice of avoiding political responsibility by donning a cloak of science, the "science charade,"⁹⁹ is disturbing in that it acts as a "final

93. See *supra* notes 59-60 and accompanying text.

94. See Doremus & Tarlock, *supra* note 35, at 28.

[A]gency scientific, management, and policy judgments may escape public oversight yet remain vulnerable to focused political pressures, because they are hidden under a veneer of scientific opacity and claims of objectivity. Any steps that make the various types of judgment that go into regulatory decisions more openly apparent should help balance the political scales. . . . [B]y revealing informational gaps and political judgments, it [transparency] can focus the debate, and potentially reveal an expanded menu of choices.

Id. Alan Charles Raul & Julie Zampa Dwyer, *Science in the Regulatory Process: "Regulatory Daubert": A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles into Administrative Law*, LAW & CONTEMP. PROBS., Autumn 2003, at 7, 9 ("Although good science is crucial to sound, efficient, and effective regulations, agency decisions too often either disregard scientific evidence or reflect public policy considerations merely masked as science.").

95. See Holly Doremus, *Science Plays Defense: Natural Resource Management in the Bush Administration*, 32 ECOLOGY L.Q. 249, 267 (2005) ("Listing decisions necessarily combine available data with policy judgments about the level of acceptable risk and the appropriate burden of proof."); see also *id.* at 253 ("When scientific data are limited and legislative value judgments have been made only at the broadest level, political choices necessarily, and legitimately, factor into natural resource decisions.").

96. See Claire R. Kelly, *The Dangers of Daubert Creep in the Regulatory Realm*, 14 J.L. & POL'Y 165, 173 (2006) ("[T]he line between agency policy-making and scientific fact-finding can be blurred.").

97. Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1617 (1995).

98. *Id.* at 1673.

99. See *supra* note 97 and accompanying text.

delegation.” In the American system, the people are the source of power, and they delegate and entrust this power to the officers and agents of the government.¹⁰⁰ The people delegate significant power to Congress in order that it attend to the legislative affairs of the nation and actively represent the interests of their constituents.¹⁰¹ When a representative’s political choices have not served the people, the people have recourse through the ballot box to remove the representative.¹⁰² But as Congress has increasingly delegated authority to administrative agencies to promulgate regulations, the people have become a step removed from electoral power over their lawmakers. This represents two levels of delegation: from the people to Congress and from Congress to the agencies.

The “final delegation” occurs when agencies pose a policy choice as science-based. In this manner, the agency effectively delegates to an inanimate concept (science) the ultimate responsibility for policy choices.¹⁰³ The result of this final delegation is perverse. The buck of political responsibility is passed until it disappears without a trace, having never come close to Truman’s desk. This leaves the people without a direct and effective recourse.¹⁰⁴ When an agency hides its policy choices, Congress (and the public) is denied the ability to substantively know and comment on the policy.¹⁰⁵ This, combined with the already limited control that Congress wields over the respective agencies,¹⁰⁶ ensures that these agencies will not be accountable for their policy choices. Likewise, the people often cannot rely on the judicial system to impose

100. Cf. THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776) (“Governments are instituted among Men, deriving their just powers from the consent of the governed . . .”).

101. See U.S. CONST. art. I, § 8, cl. 1 (“The Congress shall have Power to . . . provide for the . . . general Welfare of the United States . . .”).

102. See *id.* § 2, cl. 1 (“The House of Representatives shall be composed of Members chosen every second Year by the People of the several States . . .”); U.S. CONST. amend. XVII (“The Senate of the United States shall be composed of two Senators from each State, elected by the people thereof . . .”).

103. See Doremus, *supra* note 95, at 290.

At the moment, the determinative points in the decision making process tend to be hidden from public view, so that the public never has the opportunity to untangle the contributions of career scientists and political appointees to the ultimate decision. That can allow decisions that are in fact primarily political to be disguised as scientific ones.

Id. (footnotes omitted).

104. See *id.* at 255-56.

[S]cientizing regulatory decisions can insulate decision makers from the political consequences of their judgments. The American public is notoriously scientifically unsophisticated. Few Americans are able to evaluate claims that particular policy decisions are objectively required by available scientific data. Even public interest groups may have a difficult time overcoming this hurdle, because highly specialized knowledge and a sizeable investment of time may be needed to unpack scientized decisions. As a result, agencies can use the cloak of scientific objectivity to hide, and therefore to evade political responsibility for, their value choices.”

Id. (footnotes omitted).

105. See Raul & Dwyer, *supra* note 94, at 14 (“The pervasive agency practice of disguising policy judgments as science, however, effectively shields agency officials from intense scrutiny by Congress.”).

106. See *id.* (questioning “the true extent of congressional power over agencies” and noting the “limited ability of Congress to impose effective, post-decision sanctions against agency action” (footnote omitted)).

accountability on an agency when judicial deference to agency science is the order of the day.¹⁰⁷

The problem is not simply one of accountability; transparency is also lacking. When an agency presents policy as science, the public is denied the opportunity to meaningfully comment on the agency's actions. This is because agency explanations are muddled with confusing scientific lingo and obscurely embedded policy choices, rather than a clear statement of an easily understood policy direction. This forecloses the opportunity for meaningful comment and participation in rule-making for those who are comfortable in the policy sphere but are ill-at-ease weighing in on matters of pure science. The public is also less likely to have faith in the administrative process and the results it produces when the process is obscured.

B. Clarification of the Judicial Role in the Listing Process

Decisions to list an endangered species are governed by the APA, in addition to the "best available science" standard of the ESA.¹⁰⁸ Judicial review under the APA is marked by two major components: "hard look" review under the arbitrary and capricious standard and *Chevron* deference.¹⁰⁹

In addition to being indistinguishable from the mandate of "best available science," these core administrative law doctrines are confused and misused in and of themselves. As discussed, "hard look" review involves a "searching and careful" inquiry into the bases of an agency decision.¹¹⁰ This does not entitle a reviewing court "to substitute its judgment for that of the agency"; indeed, such action is expressly prohibited.¹¹¹ "Hard look" review requires that the underlying facts and data that support a decision be carefully reviewed to ensure that such decisions are made on the basis of relevant factors and there is a logical relationship between the facts found and the decision reached.¹¹²

Chevron established the principle of judicial deference to reasonable agency interpretations of ambiguous statutes.¹¹³ Called simply *Chevron* deference, or substantial deference, this doctrine was intended to streamline administrative law.¹¹⁴ One of the unfortunate byproducts of *Chevron*, however, has been an undue tendency on the part of reviewing courts to defer to agencies on scientific

107. See *id.* at 32 ("Utilizing *Chevron* to compound the already excessive deference often accorded agency decisions is dangerous, however, particularly when agencies are not held politically accountable through effective checks on the regulatory process." (footnote omitted)).

108. See *supra* notes 27-52 and accompanying text.

109. See *supra* notes 41-52 and accompanying text.

110. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

111. *Id.*

112. *Id.*

113. *Chevron v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-44 (1984).

114. See Kelly, *supra* note 96, at 166 (explaining that *Chevron* has a "normative administrative law goal" that seeks to "improve administrative law functioning.").

and technical matters without first employing the “hard look” mandated by established precedent.¹¹⁵ Judges who are uncomfortable in the scientific arena have turned *Chevron* into a convenient personal escape hatch.¹¹⁶ The result is that agency decisions masked in the trappings of science do not receive probing, in-depth review of their logical and factual underpinnings. In short, *Chevron* deference has swallowed “hard look” review.

One potential benefit of applying a *Daubert*-type analysis to agency science is to provide a framework for judges to review agency actions within the strictures of established administrative law doctrines such as *Chevron* and “hard look” review.¹¹⁷ Analyzing the methodology of agency science, with a focus on relevance and reliability, would provide judges a familiar regime with which to actually evaluate scientific claims.¹¹⁸ The result is that courts could begin to meet the demands of both *Chevron* and the “hard look” review. Judges would evaluate, per *Daubert*, the underlying scientific methodologies employed to reach a decision while still affording substantial deference to the interpretations and

115. See Raul & Dwyer, *supra* note 94, at 26 (“Notwithstanding the call for rigorous review in *State Farm* [Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29 (1983)] and other APA cases [see *supra* text accompanying notes 45-47], many courts accord extreme, almost slavish deference to agency science.”); Patricia Smith King, *Applying Daubert to the “Hard Look” Requirement of NEPA: Scientific Evidence Before the Forest Service in Sierra Club v. Marita*, 2 WIS. ENVTL. L.J. 147, 148 (1995) (“Judicial review at this stage [hard look review] in the process has not been as rigorous as it should be, and courts have often deferred to agencies before scrutinizing their proffered evidence for its reliability.”); cf. Paul S. Miller & Bert W. Rein, “Gatekeeping” Agency Reliance on Scientific and Technical Materials After *Daubert*: Ensuring Relevance and Reliability in the Administrative Process, 17 *TOURO L. REV.* 297, 318-19 (2000).

The Supreme Court’s decision in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, is frequently cited as establishing a ‘principle of deference to administrative interpretations.’ Properly understood, however, that deference applies only to legal interpretations reflecting policy/political judgments delegated to the agencies by the Congress. It does not create an unreviewable mandate permitting an agency to proceed on the basis of scientific or technical speculation.

Id. (footnotes omitted); King, *supra*, at 151-52.

[L]abeling [sic] evidence ‘scientific’ should not mandate judicial acceptance. The cultivated skepticism typical of science should also be embraced by the courts. Scientists are human too, and they sometimes purport to present sound evidence when in fact it has not been properly exposed to the rigors of the scientific method or review. No matter what the source, evidence requires scrutiny. Fortunately, the scientific method includes various safeguards and is largely ‘self-correcting.’ The court’s job is to see that these safeguards were present, and thereby to evaluate the scientific validity of the evidence before it.

Id. (footnotes omitted).

116. See Raul & Dwyer, *supra* note 94, at 32 (“While courts should properly defer to agencies within the boundaries of *Chevron*, deference should not function as a pretext for abdicating responsibility for meaningful judicial review.”).

117. See *id.* (“Incorporating *Daubert*-type review would help ensure that *Chevron* is not extended beyond its intended scope.”).

118. See Miller & Rein, *supra* note 115, at 305 (“[W]here agency rulemaking or similar decisionmaking purports to be based on scientific, technical or other specialized information, *Daubert*-trained judges instinctively and appropriately will recognize that the scientific or technical expertise relied upon by agencies ought not to be mere speculation or subjective belief.” (footnote omitted)).

policy choices of agencies once those interpretations and policy choices are clearly identified and separated from the underlying hard science.¹¹⁹

The other promise of *Daubert* in the ESA listing context is to give effect to the congressional mandate that agencies employ the “best available science.” When the ESA was promulgated in 1973, the APA was firmly in place.¹²⁰ Congress could easily have directed that the principles of APA review should guide agency decisions to list species. But Congress provided something else—the “best available science” standard. By including this standard, Congress must have felt that it was providing something more, namely, a science-based approach to species management.¹²¹ When substantive review of agency science is bypassed in the name of *Chevron* deference, Congress’s science mandate becomes hollow. If Congress demands regulatory action based on science, meaningful scientific review of agency decisions is essential.

IV. METHODS OF APPLYING *DAUBERT* TO THE ESA

As the law stands today, no federal court has ever expressly endorsed *Daubert*’s applicability to judicial review of agency decisions.¹²² At most, federal courts have invoked the “spirit” of *Daubert* when reviewing agency decision-making.¹²³ As such, application of *Daubert* to the ESA requires some affirmative act of Congress or the executive to be effectuated.

Several proposals to amend the ESA have been advanced in recent years, though none of these have garnered enough support to pass both houses of Congress.¹²⁴ The current political climate of Congress indicates that amendments to the ESA are unlikely to be enacted in the foreseeable future.¹²⁵

Another approach could attempt to implement regulatory *Daubert* via an executive order;¹²⁶ however, the most realistic way to apply *Daubert* to the ESA

119. See Raul & Dwyer, *supra* note 94, at 32 (“Under regulatory *Daubert*, agency actions would receive appropriate *Chevron* deference provided the agency relies on relevant and reliable science, offers a rational explanation for its decision, and fully discloses its policy choices and default assumptions, including any relevant scientific bases for its determination.”).

120. See FUNK, SHAPIRO & WEAVER, *supra* note 30, at 28 (“Passage of the APA [in 1946] was the result of a decade long political battle between the friends and foes of the New Deal.”).

121. Brennan et al., *supra* note 4, at 410.

122. Doremus, *supra* note 95, at 291.

123. See *infra* notes 135-37 and accompanying text.

124. See *infra* notes 144-58 and accompanying text.

125. See *infra* notes 159, 166-67 and accompanying text.

126. An Executive Order (EO) is certainly a valid avenue for regulatory *Daubert*. The authority for such presidential power apparently derives from the Constitution, which directs the President to “take care that the laws are faithfully executed.” U.S. CONST. art. II, § 3. The use of EOs has increased over the last thirty years and now they are issued based upon constitutional and statutory authority. Miller & Rein, *supra* note 115, at 321. Miller and Rein have argued persuasively for the validity and desirability of a *Daubert* EO. See generally *id.* But as Miller and Rein recognize, an EO should be used to “prescribe rules and procedures so that diverse agency activities can be coordinated by the President and focused in terms of the President’s priorities.” *Id.* at 321-22. Since the analysis in this Comment focuses narrowly on the application of *Daubert* to the ESA (rather

with lasting effect would be an agency rule. An agency rule requiring listing decisions under the “best available science” standard to embrace *Daubert* would seem to comport with established administrative law doctrine affording agencies substantial deference in interpreting the statutes which they are entrusted to administer.¹²⁷

A. Judicial Adoption

Several federal court cases have commented on *Daubert*'s interaction with administrative law.¹²⁸ While no court has explicitly held *Daubert* applicable to judicial review of agency determinations,¹²⁹ several courts have found the “spirit” of *Daubert* helpful in reviewing agency decisions.¹³⁰

In *Libas, Ltd. v. United States*,¹³¹ the Court notes that while “[t]here is no iron law that the *Daubert* factors be applied in customs classification cases,”¹³² they agreed that “the proposition for which [*Daubert* and *Kumho*] stand, that expert testimony must be reliable, goes to the weight that evidence is to be accorded as well as to its admissibility.”¹³³

In *Niam v. Ashcroft*,¹³⁴ the Seventh Circuit noted that “[j]unk science’ has no more place in administrative proceedings than in judicial ones”¹³⁵ and “the spirit of *Daubert* . . . does apply to administrative proceedings.”¹³⁶ The “spirit” of *Daubert* was implicated despite the acknowledgment that “the federal rules of evidence [on which *Daubert* is based] do not apply to the federal administrative agencies; so, strictly speaking, neither does *Daubert*.”¹³⁷

In a similar vein, *Donahue v. Barnhart*¹³⁸ found that “[Federal] Rule [of Evidence] 702 [and *Daubert* do] not apply to disability adjudications But the idea that experts should use reliable methods does not depend on Rule 702

than *Daubert*'s broad application to administrative law, as Miller and Rein propose), it is unwarranted to explore in detail an EO as a means of “prescrib[ing] rules and procedures” for “diverse agency activities.” *Id.* Suffice to note here the potential for broad application to administrative law of a *Daubert* EO. For an example of a *Daubert* EO, see *id.* at 329-33.

127. See *infra* notes 168-79 and accompanying text.

128. *Libas, Ltd. v. United States*, 193 F.3d 1361 (Fed. Cir. 1999) (review of U.S. Customs classification of imported fabric); *Niam v. Ashcroft*, 354 F.3d 652 (7th Cir. 2004) (review of Board of Immigration Appeals decision denying asylum); *Donahue v. Barnhart*, 279 F.3d 441 (7th Cir. 2002) (review of disability determination for supplemental security income).

129. *Doremus*, *supra* note 95, at 291.

130. *Niam*, 354 F.3d at 660.

131. 193 F.3d 1361 (Fed. Cir. 1999).

132. *Id.* at 1367.

133. *Id.* at 1366.

134. 354 F.3d 652.

135. *Id.* at 660.

136. *Id.*

137. *Id.* (citations omitted).

138. 279 F.3d 441 (7th Cir. 2002).

alone, and it plays a role in the administrative process because every decision must be supported by substantial evidence.”¹³⁹

The respective courts in *Libas*, *Niam*, and *Donahue* all recognized that *Daubert*, anchored as it is to FRE 702, is not applicable in administrative adjudications as a matter of law.¹⁴⁰ Nonetheless, each court invoked the “spirit” of *Daubert*, at least in part, to resolve an administrative law case.¹⁴¹

While these cases are illuminating insofar as they display something of a demand for *Daubert* in the administrative law context, they also reveal the improbability that federal courts will elevate regulatory *Daubert* to the status of black letter law. The gap between administrative law and the FRE is simply too large for any court to comfortably span without some encouragement from Congress or the agencies. Likewise, invoking the “spirit” of *Daubert* haphazardly does not afford *Daubert* the legitimacy and broad application that are necessary to make it beneficial to administrative law.

Another reason that courts may hesitate to employ *Daubert* in administrative law is the potential for conflict with *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*,¹⁴² where the Supreme Court held that “[a]gencies are free to grant additional procedural rights in the exercise of their discretion, but reviewing courts are generally not free to impose them if the agencies have not chosen to grant them.”¹⁴³ Judicial adoption of a *Daubert*-type review standard might be considered to be the addition of a procedural right, thus falling within the prohibition of *Vermont Yankee*. For these reasons, judicial adoption is an unlikely avenue for implementing regulatory *Daubert*.

B. Congressional Action

A number of legislative amendments have been proposed in recent years to address the scientific shortcomings of the ESA.¹⁴⁴ The Endangered Species Conservation and Management Act (ESCMA)¹⁴⁵ was intended to modify how scientific data was assessed and utilized by agencies.¹⁴⁶ Specifically, ESCMA provided a statutory preference for empirical data on species as opposed to modeling data¹⁴⁷ and would have “created a statutory peer review process for all

139. *Id.* at 446.

140. *See supra* notes 132, 137, 139 and accompanying text.

141. *See supra* notes 133, 136, 139 and accompanying text.

142. 435 U.S. 519 (1978).

143. *Id.* at 524.

144. *See Brennan et al, supra* note 4, at 433-42 (discussing various legislative proposals to amend the ESA).

145. H.R. 2275, 104th Cong. (1995).

146. Brennan et al., *supra* note 4, at 433.

147. *Id.* In laymen’s terms, empirical data might be described as actual data collected in the field (e.g., a biologist physically counting the population of a species in its natural habitat), while modeling data is more akin to a scientific reconstruction of field conditions based upon known or suspected factors (e.g., scientists generate

listing determinations.”¹⁴⁸ Moreover, ESCMA sought to define the “best available science” as “factual information, including but not limited to peer reviewed scientific information and genetic data, obtainable from any source . . . which has been to the maximum extent feasible verified by field testing.”¹⁴⁹ ESCMA also would have required peer reviewers to assess scientific deficiencies and the scientific methodologies and analysis to ensure that they were in step with the standards of the scientific community.¹⁵⁰

In the ESA Common Sense Act of 2000,¹⁵¹ treatment of scientific evidence was “virtually identical to those in the ESCMA.”¹⁵² Like the ESCMA, the ESA Common Sense Act of 2000 was never passed into law.¹⁵³

The next attempt at reform was the Sound Science for Endangered Species Act of 2002 (Sound Science Act).¹⁵⁴ Like previous proposals, the Sound Science Act attempted to define the “best available science” standard.¹⁵⁵ The House Committee on Resources found that the “best available science” would be “comprised of data that had been collected by established standards or protocols, properly analyzed, and then peer-reviewed Such information is assumed to be reliable and the conclusions drawn usually can be duplicated to test the accuracy of the information.”¹⁵⁶ The Sound Science Act went slightly further than ESCMA by requiring the responsible agency to promulgate regulations detailing what criteria must be met for scientific data used in listing determinations.¹⁵⁷ But like ESCMA and the Common Sense Act, the Sound Science Act never became law.¹⁵⁸

This is by no means an exhaustive list of the various ESA amendments proposed in recent years,¹⁵⁹ but these failed legislative fixes of the ESA (collectively, the ESA reform bills) do have two important implications: (1) there is congressional preoccupation with the current state of the science undergirding ESA listing determinations; and (2) amendments to the ESA are unlikely to be passed by Congress in the near future.

population estimates by assessing the numbers of one discrete subpopulation and extrapolating those results across the board based on an assessment of the amount of habitat that is available to the species as a whole).

148. *Id.* at 434.

149. H.R. REP. NO. 104-778, at 19 (1996).

150. Brennan et al., *supra* note 4, at 434.

151. H.R. 3160, 106th Cong. (1999).

152. Brennan et al., *supra* note 4, at 435.

153. *Id.* at 434-35.

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

155. Brennan et al., *supra* note 4, at 438-39.

156. H.R. REP. NO. 107-751, at 6 (2002).

157. Brennan et al., *supra* note 4, at 439.

158. *Id.* at 438.

159. See The Endangered Species Listing and Delisting Process Reform Act, S. 369, 108th Cong. (2003) (unsuccessful attempt to amend the ESA); The Threatened and Endangered Species Recovery Act, H.R. 3824, 109th Cong. (2005) (same).

The ESA reform bills show a desire on the part of legislators to provide some substantive meaning to the “best available science” standard. While the provisions of the ESA reform bills are not synonymous with regulatory *Daubert*, they reflect similar concerns about science. Both the ESA reform bills and *Daubert* indicate a preference for peer review.¹⁶⁰ ESCMA and the Common Sense Act purport to keep scientific methodologies within the boundaries of accepted scientific practice,¹⁶¹ which is precisely *Daubert*’s goal.¹⁶² And while *Daubert* expresses no explicit preference for empirical or field tested data like the ESA reform bills,¹⁶³ *Daubert* may favor that data to the extent that empirical and field tested data are superior to modeling data. Moreover, just as *Daubert* does,¹⁶⁴ the Sound Science Act reflects concern about reliability, accuracy, and ability to duplicate scientific conclusions.¹⁶⁵ Mostly, the ESA reform bills and *Daubert* attempt to give substantive, independent significance and meaning to the ESA’s “best available science” mandate.

While the ESA reform bills show continuing attempts to address the science behind the ESA, they also demonstrate that ESA reforms are highly contentious and unlikely to be enacted.¹⁶⁶ Taken with the failure of more recent legislative proposals,¹⁶⁷ a safe conclusion seems to be that the ESA’s “best available science” standard is not susceptible at this time to congressional amendment to institute a regulatory *Daubert* scheme.

C. Agency Rulemaking

Informal rulemaking, authorized by the APA, accounts for most agency rules¹⁶⁸ and is the standard used to make listing decisions under the ESA.¹⁶⁹ Often called notice and comment rulemaking, informal rulemaking is characterized by three main components: notice, opportunity, and incorporation.¹⁷⁰ Under the APA, notice of a proposed rule must be placed in the Federal Register and be sufficient to fairly apprise interested persons of the issues involved.¹⁷¹ The APA also requires interested persons be given the opportunity to

160. See *supra* notes 60, 148, 156 and accompanying text.

161. See *supra* notes 145-51 and accompanying text.

162. See *supra* notes 59-66 and accompanying text.

163. See *supra* notes 147-52 and accompanying text.

164. See *supra* notes 59-71 and accompanying text.

165. See *supra* notes 154-56 and accompanying text.

166. Brennan et al., *supra* note 4, at 441 (“[The ESA reform bills] further emphasize[] the ongoing debate and controversy surrounding the use of scientific data in the ESA, [and] it is unclear whether any substantial legislative amendment of the ESA could, in light of the acrimony often generated by the application of the ESA, successfully emerge from Congress.”).

167. See *supra* note 159 and accompanying text.

168. FUNK, SHAPIRO & WEAVER, *supra* note 30, at 91.

169. 16 U.S.C.A. § 1533(b)(4) (West 2000).

170. 5 U.S.C.A. § 553 (West 2007).

171. *Id.* § 553(b).

participate in the rulemaking through the submission of written comments.¹⁷² Finally, the APA requires the agency to incorporate public input and its own reasoning and data into a “concise general statement of their basis and purpose.”¹⁷³

Since judicial adoption of regulatory *Daubert* and congressional amendment of the ESA are unlikely at this time,¹⁷⁴ an agency rulemaking that establishes *Daubert* as a standard of review would be the most likely method of achieving regulatory *Daubert*. An agency rule establishing the *Daubert* factors¹⁷⁵ as a flexible definition of the “best available science” would seem to comport with established administrative law doctrine that affords agencies wide deference in interpreting vague congressional directives,¹⁷⁶ such as the “best available science” standard. Moreover, the rule would not be a paper tiger because courts are very diligent about requiring agencies to comply with their own rules.¹⁷⁷

A regulatory *Daubert* rule would alter the way agencies approach species assessment. Rather than relying on normal APA review,¹⁷⁸ courts would assess the underlying scientific methodologies for reliability.¹⁷⁹ This would lead the agencies to incorporate *Daubert* principles from the very beginning of their assessment of species risk to avoid later judicial invalidation.

V. ADDRESSING CONTRARY VIEWPOINTS

Proposals to import *Daubert* into the administrative law context have met with controversy. As such, several criticisms of *Daubert* and its application to administrative law have been advanced. In broad strokes, these arguments encompass the following concerns: separation of powers,¹⁸⁰ potential impairment of administrative law,¹⁸¹ and potential impairment of public policy.¹⁸² Each of these concerns will be examined to assess their validity.

A. Separation of Powers

The initial concern raised by the opponents of a regulatory *Daubert* scheme is a potential separation of powers problem. Opponents argue that because agencies make decisions as part of the executive branch, pursuant to powers

172. *Id.* § 553(c).

173. *Id.*

174. *See supra* notes 140-43, 166-67 and accompanying text.

175. *See supra* notes 59-60 and accompanying text.

176. *See supra* notes 48-52 and accompanying text.

177. FUNK, SHAPIRO & WEAVER, *supra* note 30, at 145.

178. *See supra* notes 41-52 and accompanying text.

179. *See supra* notes 59-60 and accompanying text.

180. *See infra* notes 183-90 and accompanying text.

181. *See infra* notes 191-97 and accompanying text.

182. *See infra* notes 198-211 and accompanying text.

delegated to them by the legislature,¹⁸³ when a reviewing court increases its scrutiny of agencies' science and policy decisions, judicial power vis-à-vis the coordinate branches of government is increased in a manner not implicated by the *Daubert* scheme in private litigation.¹⁸⁴ A corollary to this position holds that, "because risk assessment is not a purely scientific enterprise, 'Daubertizing' judicial review of agency risk assessments will bestow upon the courts a policymaking role that is entirely inappropriate for a politically unaccountable institution."¹⁸⁵

Despite its theoretical appeal to federalism, this position assumes a policy-making function for the courts is implicit in any imposition of *Daubert* on agency action. Yet established "hard look" review under the APA already directs federal judges to refrain from substituting their judgment for that of the agency.¹⁸⁶ Furthermore, *Daubert* itself counsels against this outcome by directing judges to focus on "principles and methodology, not on the conclusions that they generate."¹⁸⁷ Indeed, regulatory *Daubert* seeks to create a separation of the underlying science and policy.¹⁸⁸ Separating science from policy mitigates the risk that a federal judge will be able to impose a personal value judgment concerning policy under the auspices of attacking or defending agency science. If a federal judge tries to impose a policy judgment upon the agencies, the separation of science and policy will make such an attempt transparent and presumably will leave the decision vulnerable to reversal on appeal.¹⁸⁹

Aside from the mischaracterization of the federal judge's role as policy-maker, the separation of powers argument also suffers from a practical shortcoming insofar that it assumes the political accountability of the agencies. It is true enough that a federal judge is not accountable in the same manner in which federal agencies are; however, as has been shown above, agencies have become quite adept at avoiding political responsibility for their decisions by

183. See *supra* notes 100-01 and accompanying text.

184. See, e.g., Thomas O. McGarity, *Science in the Regulatory Process: On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, LAW & CONTEMP. PROBS., Autumn 2003, at 155, 156.

[T]he agencies preparing these risk assessments are, as part of the executive branch, performing a function assigned to them by the legislative branch. So the potential for aggrandizing judicial power through intensifying judicial scrutiny of the science-policy determinations underlying agency-prepared risk assessments raises serious institutional issues not present in *Daubert*-style review of expert testimony in private tort litigation.

Id.

185. *Id.* But see D. Hiep Truong, *Daubert and Judicial Review: How Does An Administrative Agency Distinguish Valid Science from Junk Science?*, 33 AKRON L. REV. 365, 367 (2000) ("Agencies have certainly proved to be more susceptible to political influences than the judiciary." (footnote omitted)).

186. See *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971) ("Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency." (citations omitted)).

187. *Daubert v. Merrell Dow Pharm., Inc.* 509 U.S. 579, 595 (1993).

188. See *supra* note 93 and accompanying text.

189. *Cf. Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997) (explaining that abuse of discretion is the standard of review for trial court decisions made pursuant to *Daubert*).

hiding behind a veneer of scientific objectivity.¹⁹⁰ Of course, this is precisely the type of problem that regulatory *Daubert* is intended to address. By subjecting agencies to a searching review of their underlying science, agencies will be forced to reveal their explicit and implicit policy choices. This would *restore* the political accountability of the agency to the public, rather than *remove* it to the unaccountable judiciary.

B. Potential Impairment of Administrative Law?

Another oft-cited criticism of regulatory *Daubert* is that it will hinder the operation and development of administrative law.¹⁹¹ This argument posits that adding an additional layer of procedures and a vehicle for challenging agency science will lead to unwarranted expense and delay in the administrative process.¹⁹² Furthermore, it can lead regulated parties to pursue research that runs counter to that which the agency relies on in support of regulations.¹⁹³ This reflects concerns that regulated parties will pursue self-interested (and likely unsound) science which could be used to undermine agency science and skew the administrative record.

Mitigating these concerns is the fact that the point of regulatory *Daubert* is to provide clarity in a murky world, that is, to get agencies in the habit of explaining to the public the rationale of their decisions. Such explanations should carefully differentiate between science and policy. The grim reality of modern administrative law is that many rulemakings are legally challenged.¹⁹⁴ When the interests of parties favoring more or less regulation are at stake, legal challenges are bound to follow. This is true whether *Daubert* is a factor or not. Nonetheless,

190. See *supra* notes 97-107 and accompanying text.

191. See, e.g., Kelly, *supra* note 96, at 165 (“There is a danger that *Daubert* can undermine administrative law by fostering an attitude of skepticism of agency action based upon science and creating a rhetorical weapon with which to attack agency policy-making.”); McGarity, *supra* note 184, at 223 (“Unaware of which issue might ultimately doom a rulemaking initiative, agencies will be compelled to over-analyze every issue, no matter how trivial, wasting scarce analytical resources responding to minutiae.”).

192. Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897, 935 (2004).

193. See, e.g., McGarity, *supra* note 184, at 171 (“Regulatees will devote greater resources to sponsoring diversionary research. When adverse scientific studies are published, regulatees will hire consultants to fill the scientific literature with critical and contrary commentary that these regulatees will later cite to support claims that the adverse studies are ‘fatally flawed.’”); McGarity, *supra* note 192, at 936 (“Creating fora specifically for the purpose of entertaining attempts to bend science will only reward well-coordinated and vicious attacks on science and scientists.”); see also Wendy E. Wagner, *Science in the Regulatory Process: The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, LAW & CONTEMP. PROBS., Autumn 2003, at 63, 88 (“Agencies might find that incorporating or even publicizing recent scientific discoveries in the course of their regulatory duties is a losing proposition since it opens them up to unending attack under the good-science laws.” (footnote omitted)). “High-quality scientific research could be lost to the strong forces of politically motivated deconstruction . . .” *Id.* (footnote omitted).

194. See FUNK, SHAPIRO & WEAVER, *supra* note 30, at 189 (“Very few significant agency regulations go uncontested in the courts.”).

by clarifying the issues, regulatory *Daubert* could actually make challenges to agency science more transparent and efficient. By segregating the science from the policy,¹⁹⁵ potential litigants would be able to better assess the validity of agency actions and would have a correspondingly better picture of the potential merit of a legal challenge. Critics of regulatory *Daubert* contend that agency policies will be attacked under the guise of challenging agency science.¹⁹⁶ On the contrary, if policy is committed to agency discretion by statute, then separating the science from the policy for purposes of judicial review would make such attacks transparent and render them impotent.

Furthermore, concerns about litigants attempting to skew the scientific record are softened by institutional factors. First, potential challengers of agency decisions must have the resources and sophistication to mount such a campaign.¹⁹⁷ Second, those attempting to insert their own science into the agency record would likewise be subject to the requirements of *Daubert*, preventing regulated parties from sneaking in “junk science” of their own.

The concerns about interested parties pursuing “junk science” of their own underscores a fundamental misconception of regulatory *Daubert*, namely, that its proponents are primarily interested in raising a rhetorical “junk science” battle cry to challenge agency determinations of risk. Indeed, one of the benefits of regulatory *Daubert* would be to preclude over-reliance on “junk science” in the decision-making process, whether it was offered by the agency in question or inserted into the record by an interested party. Other benefits of regulatory *Daubert*, including increased transparency and accountability, and decreased substantive bias, are just as compelling as the struggle against bad science. The discussion over regulatory *Daubert* has to move beyond the constraints of the “junk science” debate if its full benefits and drawbacks are to be unearthed.

C. Potential Impairment of Public Policy?

In a similar vein to concerns of impaired administrative efficiency, opponents of regulatory *Daubert* cry foul over potential degradations of public policy.¹⁹⁸

195. See *supra* note 93 and accompanying text.

196. See, e.g., Kelly, *supra* note 96, at 165 (“There is a danger that *Daubert* can undermine administrative law by fostering an attitude of skepticism of agency action based upon science and creating a rhetorical weapon with which to attack agency policy-making.”).

197. See Wagner, *supra* note 193, at 102-03.

The good-science reforms offer new procedural tools for regulatory overseers (loosely referred to as “the public”) to challenge the science underlying regulation; yet because these tools require considerable expertise from users, they are effectively available to only a small set of attentive regulatory participants. The resources needed to employ these tools, in terms of both scientific expertise and resources, will exclude most attentive regulatory participants.

Id. (footnotes omitted).

198. Cf. McGarity, *supra* note 184, at 224 (“Daubertizing judicial review of agency risk assessment will pervert the process of health and environmental risk assessment by encouraging lawyer-dominated attempts to bend science to the will of regulated industry.”); Wagner, *supra* note 193, at 88-89.

This criticism reflects apprehension that litigation will drive agency decisions, thereby interfering with the agency's task of implementing statutory mandates.¹⁹⁹

With regard to this concern, recall that the current statutory mandate of the ESA is that agencies use the "best available science" in listing determinations.²⁰⁰ The flexible standards of *Daubert*,²⁰¹ implementing quality scientific methodologies,²⁰² should have an animating effect on what is currently a lackluster and impotent interpretation of the congressional mandate to use the "best available science."²⁰³ Because the courts have been unwilling to give effect to the ESA's science standard independent of the APA, adding *Daubert* to the equation is a very sensible way to breathe life into the ESA's listing standard. Procuring the "best available science" is indispensable, for it provides the very justification for the abridgement of personal liberties which come as an unavoidable effect of the ESA.²⁰⁴

The most devastating result of the good-science reforms is their potential for converting science from the agencies' friend to their enemy. Agency risk assessments that rely on cutting-edge studies will be rewarded with bothersome Data Quality Act complaints, requests for data access, and potential challenges under regulatory *Daubert*. Agencies might find that incorporating or even publicizing recent scientific discoveries in the course of their regulatory duties is a losing proposition since it opens them up to unending attack under the good-science laws. As a result, the dissemination and use of cutting-edge science might itself become 'ossified' in the administrative process. Scientists might also be reluctant to share the results of path-breaking studies with agencies for fear of having their research tarnished by good-science complaints.

Id. (footnotes omitted); McGarity, *supra* note 192, at 935-36.

[S]cience-based reforms will probably harm the delicate process of generating policy-relevant science. Once procedures are available for challenging the quality of scientific information, risk-producing industries are likely to engage in illegitimate science-bending strategies in an effort to persuade decisionmakers to 'exclude' from agency consideration or public discussion scientific studies that are damaging to their interests. Companies already have a great incentive to do whatever they can to deconstruct adverse scientific studies and to launch ad hominem attacks on the scientists that produce those studies. Creating fora specifically for the purpose of entertaining attempts to bend science will only reward well-coordinated and vicious attacks on science and scientists. This in turn will discourage scientists from engaging in policy-relevant research.

Id. (footnote omitted).

199. See, e.g., Wagner, *supra* note 193, at 100 ("By imposing new procedural requirements on agency use of scientific evidence, the reforms might conflict, either directly or indirectly, with agencies' statutory mandates that they act expeditiously and err on the side of health and the environment."); McGarity, *supra* note 184, at 156 ("[T]he 'Daubertization' of agency risk assessments would have a predictable impact on regulatory policy running directly counter to the precautionary policies animating most health, safety, and environmental statutes.").

200. See *supra* notes 29-40 and accompanying text.

201. See *Daubert v. Merrell Dow Pharm., Inc.* 509 U.S. 579, 594 (1993) ("The inquiry envisioned by [Federal] Rule [of Evidence] 702 is, we emphasize, a flexible one.").

202. See *supra* notes 59-60 and accompanying text.

203. See *supra* notes 120-21 and accompanying text.

204. See Raul & Dwyer, *supra* note 94, at 7-8.

Indeed, if private litigants are entitled to rules requiring sound science to protect parochial interests, certainly the public should be equally assured that good science is the foundation for national action. The regulatory science used to justify agency decisions that commit society's public resources and allocate social priorities should be no less rigorous than the litigation science that is currently tested according to the methods and procedures prescribed in *Daubert*.

There is no evidence that litigation will drive agency decision-making under *Daubert* any more than the current scheme. Indeed, the opposite scenario seems likely. If *Daubert* can succeed in separating the current agency jambalaya of science and policy into more distinct groups of scientific information and policy information, this should lead to a more respectful appreciation of the merits of agencies' decisions. If current attacks on agency science are indeed a shadow regime for challenging agency policy, as the critics contend,²⁰⁵ then providing for the segregation of the underlying science and policy will eliminate that avenue of attack, presumably leading to less litigation.

Much of the debate over regulatory *Daubert's* effect on agency policy is preoccupied with the continuing validity of the "precautionary principle."²⁰⁶ In the view of some commentators, *Daubert* in the administrative law context would portend a new attitude of skepticism toward agency action,²⁰⁷ which would have deleterious effects on what are perceived to be precautionary policies implicit in environmental statutes like the ESA.²⁰⁸ This view rests on a false assumption that

Id.; cf. Doremus, *supra* note 95, at 255.

Science is a politically appealing justification because it promises objective, rational decisions. It is supposed to be free of emotion. That characteristic may look especially important to those championing protection of environmental features that lack obvious utilitarian value. The semblance of scientific objectivity helps them avoid uncomfortable and difficult debates over underlying values. Without the cover of science, they might face the difficult prospect of defending public implementation of what appears to be nothing more than their (perhaps quirky) taste for environmentalism. Science also promises decisions free of the corrupting influences of politics and money. Science-based decisions are far less likely to appear tied to the interests of a narrow special-interest group than decisions openly based on economics. Probably because they are seen as above the ordinary political fray, scientists enjoy a high level of public trust. Decisions that can be presented as scientific therefore instantly gain a level of respectability that other decisions do not have.

Id. (footnotes omitted).

205. Cf. Kelly, *supra* note 96, at 165 ("There is a danger that *Daubert* can undermine administrative law by fostering an attitude of skepticism of agency action based upon science and creating a rhetorical weapon with which to attack agency policy-making.").

206. The short definition of the "precautionary principle" has been stated as "the notion that, where scientific evidence is uncertain, society should err on the side of overprotection." Doremus, *supra* note 95, at 296. This Comment is not intended as a comprehensive exploration of the "precautionary principle"; however, a few thoughts are worth mentioning. Consider the ramifications of a policy that eschews waiting for solid evidence of the need for national action in favor of a "cautious" approach. This rationale would justify a hasty U.S. invasion of Iraq, based on inconclusive or speculative evidence of the presence of weapons of mass destruction, simply in the name of being "safe" where the truth is unknown. Similarly, states or the federal government might be justified in completely outlawing abortion procedures because the science is inconclusive on whether life begins at conception. Since life does *potentially* begin at conception, then legislators would be well justified in outlawing the termination of any pregnancy, just to be "safe." Of course, these are extreme examples; however, they do present the problem with predicating any broad action *on a lack of evidence of the need*. These problems exist in environmental law as well as other contexts.

207. See Kelly, *supra* note 96, at 165 ("There is a danger that *Daubert* can undermine administrative law by fostering an attitude of skepticism of agency action based upon science and creating a rhetorical weapon with which to attack agency policy-making.").

208. Cf. Wagner, *supra* note 193, at 100 ("By imposing new procedural requirements on agency use of scientific evidence, the reforms might conflict, either directly or indirectly, with agencies' statutory mandates that they act expeditiously and err on the side of health and the environment."); McGarity, *supra* note 184, at

Daubert is intended solely as a weapon to attack regulation.²⁰⁹ In fact, regulatory *Daubert* takes no view on the precautionary principle, which is properly understood as a policy concern.²¹⁰ Once the separation of policy and science has been effectuated, *Daubert* has no relevance and no application to policy choices properly within the discretion of the agency.

It would seem that the real motivation of the regulatory *Daubert* critics lies elsewhere. For instance, one commentator has noted that “judges who come to the task [of reviewing agency actions] with an anti-government ideological perspective are not always as concerned with the quality of agency decisions as they are with ensuring that agencies do not encroach too deeply upon private markets.”²¹¹ Of course, this pendulum swings both ways. Judges with an ideological agenda favoring more regulation might be less concerned with litigants’ legitimate economic, property, and liberty interests and the actual scientific merit for a regulation than they are with ensuring that nothing stands in the way of “protecting” a species—regardless of whether the species actually needs protection. It should raise no controversy to recognize that this risk is inherent in all litigation of all stripes and can cut both ways.

VI. CONCLUSION

Regulatory *Daubert* has much to offer the ESA’s “best available science” standard. By instituting a new framework for judicial review of the methodologies behind agency science, regulatory *Daubert* will help agencies effect a needed separation between policy and science. This will result in a lower risk of substantive bias, greater accountability, and greater transparency.

Less substantive bias should result in more accurate species assessment and better application of limited conservation resources. Increased accountability will help allow the public and Congress to maintain effective checks on federal agencies that wield immense power over the day-to-day lives of American citizens. Better transparency will help improve congressionally mandated opportunities for public involvement and participation in the rulemaking process and national species policy development. More transparency will also lead to

156 (“[T]he ‘Daubertization’ of agency risk assessments would have a predictable impact on regulatory policy running directly counter to the precautionary policies animating most health, safety, and environmental statutes.”).

209. Cf. McGarity, *supra* note 184, at 156.

The proponents of strict judicial risk-assessment scrutiny have a clear, normative agenda in mind. Having failed during the 104th Congress to reign in federal regulatory agencies by enacting sometimes draconian regulatory-reform legislation, regulatory reformers are now attempting to gain regulatory relief in the courts by subtly assigning a more activist role to judges, who are perceived to be more sympathetic to their goals than Congress.

Id. (footnotes omitted).

210. See *supra* notes 83-84 and accompanying text.

211. McGarity, *supra* note 184, at 223.

increased public faith in the regulatory process, which in turn should lead to less litigation and increased willingness to shoulder the burdens imposed by national species policy.

Regulatory *Daubert* can clarify the judicial role in existing administrative law doctrines by providing judges with a familiar framework to assess scientific evidence and by clarifying the protocol and procedure for engaging in searching, “hard look” review, while maintaining appropriate deference to well-defined policy choices. This would have the added benefit of providing some independent significance to the “best available science” standard apart from the APA’s “arbitrary and capricious” standard, which would help realize the congressional intent to pursue species policy grounded in science, not speculation.

Congressional action and judicial adoption are unlikely avenues to realize regulatory *Daubert* at this time. For this reason, agencies enforcing the ESA would be well-advised to adopt a regulatory *Daubert* scheme via informal rulemaking.