"REGULATORY *DAUBERT*": A PROPOSAL TO ENHANCE JUDICIAL REVIEW OF AGENCY SCIENCE BY INCORPORATING *DAUBERT* PRINCIPLES INTO ADMINISTRATIVE LAW

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I
INTRODUCTION

In the landmark decision of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[1] the United States Supreme Court empowered federal judges to reject irrelevant or unreliable scientific evidence. *Daubert* has given the judiciary a mandate to foster "good science" in the courtroom and to reject expert testimony not grounded in scientific methods and procedures. Federal agencies—in particular, the Environmental Protection Agency ("EPA")—have been widely criticized for lacking a commitment to sound science. Too often, federal courts have upheld agency decisions that are based on faulty scientific evidence or unsupported assumptions and conclusions. The courts' responsibility to engage in meaningful judicial review of agency action, together with Congress's recent directive calling for agencies to issue data quality guidelines, strongly points to the need for a mechanism to enable more rigorous, consistent review of agency science.

Daubert provides a suitable framework for reviewing the quality of agency science and the soundness of agency decisions consistent with the standards established for review of agency rulemakings under the Administrative Procedure Act ("APA").[2] While the *Daubert* line of cases arises in connection with the admissibility of evidence in litigation governed by the Federal Rules of Evidence, the same "good science" rationale should also apply to judicial review of the science underlying regulatory decisionmaking. 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

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1. 509 U.S. 579 (1993).
2. 5 U.S.C. §§ 551-559, 701-706 (2000).

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*.

To date, two courts have specifically rejected the application of *Daubert* in cases governed by the APA,[3] and no court has directly accepted the proposition that *Daubert* principles should apply in the context of administrative law. In 1999, however, a D.C. Circuit judge on the panel that decided *American Trucking Associations, Inc. v. EPA* cited *Daubert* favorably in his dissenting opinion.[4] In *Daubert* itself, the Supreme Court cited and relied on a scholarly book by a former EPA official discussing regulatory science.[5] One would therefore imagine that the Supreme Court would be receptive to extending *Daubert* principles to review of federal agency science. Indeed, the criteria for judicial review of agency action established in *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Auto Insurance Co.*[6] and its progeny under the APA are substantively consistent with the "relevance" and "reliability" themes of *Daubert*.

This Article argues that *Daubert* principles should apply to the review of agency rulemaking under the APA because these principles are consistent with the APA requirement that agencies engage in reasoned decisionmaking, would assure better documentation of agencies' scientific decisions, and would enhance the rigor and predictability of judicial review of agency action based on scientific evidence. Judges would evaluate the scientific methods and procedures employed by agencies but would not substitute their own policy preferences or conclusions for those chosen by the agencies. The fundamental goal of "regulatory *Daubert*" is, quite simply, to encourage reviewing judges to be less deferential, and thus more probing, of agency science and related administrative justifications for regulatory action.

Incorporating *Daubert* principles into administrative law would improve agency decisionmaking and enhance accountability. Agencies would be compelled to identify the most reliable and relevant scientific evidence for the issue at hand and disclose the default assumptions, policy choices, and factual uncertainties therein. Applying *Daubert* in the administrative context would refine judicial review of agency science, resulting in greater consistency and rigor.

II
REGULATORY ABUSE OF SCIENCE

The federal environmental, health, and safety statutes require administrative agencies to decide how and when to regulate based on scientific, quantita-

3. Sierra Club v. Marita, 46 F.3d 606, 622 (7th Cir. 1995); Stewart v. Potts, 996 F. Supp. 668 (S.D. Tex. 1998).

4. 175 F.3d 1027, 1059 (D.C. Cir. 1999) (Tatel, J., dissenting), *rev'd in part on other grounds*, Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

5. 509 U.S. at 593 (citing SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICYMAKERS 61-76 (1990)).

6. 463 U.S. 29, 43 (1983).

tive, and other technical methods of analysis.[7] 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.

EPA, in particular, has faced attack for its misuse of science in its policies and decisionmaking. It is frequently perceived as adjusting science to fit policy and has itself acknowledged that its treatment of science needs attention. Former EPA Administrator Christine Todd Whitman has publicly stated that "improv[ing] the role of science in decision-making" is one of EPA's top budget priorities.[8] In 1992, EPA's own expert panel issued a report to then-Administrator William K. Reilly on the role of science at EPA, entitled *Safeguarding the Future: Credible Science, Credible Decisions*.[9] In that report, the expert panel stated:

> EPA has not always assured that contrasting, reputable scientific views are well explored and well documented from the beginning to the end of the regulatory process . . . *EPA science is perceived by many people, both inside and outside the Agency, to be adjusted to fit policy.* Such "adjustments" could be made consciously or unconsciously by the scientists or decision-maker.[10]

A. Pervasive Criticisms of EPA Science

Academics and others have criticized EPA for the poor quality of its scientific analyses as well as its practice of obscuring its assumptions by disguising policy-based decisions as scientific ones. Professor E. Donald Elliott, for example, has documented the "decline of science as an important determinant in environmental decisionmaking."[11] There is a consensus among observers that, "[i]n general, scientists have little stature and power within EPA. Instead, those with the power to make and influence decisions tend to have an inclination toward law and politics."[12] Professor Wendy E. Wagner has noted that "camou-

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7. *See, e.g.*, Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (2000); Clean Water Act, 33 U.S.C. § 1251 (2000); Safe Drinking Water Act, 42 U.S.C. § 3005 (2000); Clean Air Act, 42 U.S.C. § 7401 (2000); Public Health Service Act, 42 U.S.C. § 201 (2000).

8. Pat Phibbs, *EPA: IG Staff to Discuss Pending Investigation Into How Science Is Used in EPA Rulemaking*, Daily Rep. for Executives (BNA), No. 165, at A-28 (Aug. 27, 2001); *see also* Pat Phibbs, *Fisher Wants EPA's Top Scientists, Advisors to Focus Together on Most Important Issues*, Daily Rep. for Executives (BNA), No. 230, at A-15 (Dec. 3, 2001) (discussing the deputy administrator of EPA's call for the Science Policy Council to have a more direct role in overseeing EPA science).

9. EXPERT PANEL ON THE ROLE OF SCIENCE, U.S. ENVTL. PROTECTION AGENCY, SAFEGUARDING THE FUTURE: CREDIBLE SCIENCE, CREDIBLE DECISIONS (1992).

10. *Id.* at 36-37 (emphasis added).

11. E. Donald Elliott et al., *Science, Agencies, and the Courts: Is Three a Crowd?*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,125, 10,126 (2001). Professor Elliott remarked that this critique of agency decisionmaking is the subtext of Justice Stephen Breyer's groundbreaking book BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993).

12. *See* MARK R. POWELL, SCIENCE AT EPA: INFORMATION IN THE REGULATORY PROCESS 18 (1999). For further commentary on the flaws in EPA's approach to science, see *Elevating EPA to Cabinet Status: Hearing Before the Subcomm. on Energy Policy, Natural Res. & Regulatory Affairs, House Comm. on Government Reform*, 107th Cong. (2001) (statements of Robert W. Hahn and Randall Lutter) [hereinafter Hahn Testimony] (making several recommendations for improvements in EPA's science); ANGUS MACBETH ET AL., NAT'L LEGAL CTR. FOR THE PUB. INTEREST, CARTOON

flaging controversial policy decisions as science assists the agency in evading various political, legal, and institutional forces."[13]

Congress has also expressed concerns over the inadequacy of EPA science and has taken steps toward addressing the situation.[14] For example, at a July 2000 hearing before the House Government Reform Committee's Subcommittee on Energy and Environment concerning the results of the National Research Council ("NRC") report entitled *Strengthening Science at the U.S. Environmental Protection Agency*, Subcommittee Chairman Ken Calvert expressed concern that "[r]ather than the best science driving regulatory policy at EPA, regulatory policy drives scientific activity and can prejudice scientific conclusions."[15] He said of the NRC's findings:

> The [NRC] notes that science is 'an important part of the basis for many Agency decisions and actions, but has not been the only basis and in many cases, has not even been a major determinant of EPA's decisions.' Frankly, this troubles me. The EPA has gone to great lengths to convince Congress that it is a science agency. This report calls into doubt EPA's commitment to sound science.
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> . . . We found many specific instances where EPA has not conducted adequate research or used readily available research data.[16]

In response to the NRC report, on October 3, 2001, the House Science Committee approved a bill to create a deputy administrator of science and technology at EPA.[17] The bill passed the House of Representatives on April 30,

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SCIENCE: THE STRUGGLE BETWEEN POLITICS AND SCIENCE AT THE ENVIRONMENTAL PROTECTION AGENCY (2002) (documenting EPA's poor use of science through an examination of the agency's regulation of PCBs under the Toxic Substances Control Act and the Clean Water Act).

13. Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1617 (1995); *see also* Allentown Mack Sales & Serv., Inc. v. NLRB, 522 U.S. 359, 376 (1998) ("An agency should not be able to impede judicial review, and indeed even political oversight, by disguising its policy making as fact finding."); Wagner, *supra*, at 1628 ("If policy decisions are to receive appropriate public scrutiny, science–policy decisionmakers must be extremely forthright in distinguishing policy judgments from scientific facts.").

14. The most significant action recently taken by Congress is the provision in a 2001 appropriations bill calling for the creation of new Office of Management and Budget ("OMB") data quality guidelines. *See infra* Part IV.

The U.S. Chamber of Commerce has also considered action to improve agency science. William L. Kovacs, its vice president, recently called upon Congress to require EPA to develop standards for sound science. *See* Pat Phibbs, *Chamber of Commerce Seeks to Develop Consensus Definition of "Sound Science*," 33 Env't Rep. (BNA) 1674 (July 26, 2002). Kovacs has identified sixteen components of a sound science model: that science be documented, rational, comprehensive, factual, reliable, peer reviewed, appropriate, qualified, reproducible, validated, objective, archivable, understandable, communicable, adequate, and responsive. *EPA Cabinet Elevation: Agency and Stakeholder Views: Hearing Before the House Subcomm. on Energy Policy, Natural Res. & Regulatory Affairs*, *Comm. on Gov't Reform*, 107th Cong. 15-18 (2002) (statement of William L. Kovacs, Vice President, U.S. Chamber of Commerce) [hereinafter Kovacs Testimony]. Though Kovacs applauds OMB's data quality guidelines, he urges Congress to go still further to require agencies to use sound science. He urges a legislative mandate directed to EPA that would compel the agency to improve its science.

15. *Strengthening Science at the U.S. Environmental Protection Agency: Hearing Before the Subcomm. on Energy and Env't, House Comm. on Sci.*, 106th Cong. 2 (2000) (statement of Rep. Ken Calvert, Chairman, Subcomm. on Energy & Env't) [hereinafter Calvert Testimony].

16. *Id.* at 1-2.

17. H.R. 64, 107th Cong. § 1(a)(2) (2001); *see also House Committee Approves Bill to Create*

2002,[18] and was referred to the Senate Committee on Environment and Public Works on May 1, 2002.[19] Representative Vernon Ehlers, who introduced the bill, noted that EPA's science has met with criticism from regulated industries and environmental advocates alike.[20] Moreover, according to Ehlers, "Members of Congress and the judiciary do not have confidence that the agency uses science appropriately in its decisions."[21]

The bill provides that the deputy administrator "shall coordinate and oversee the science and technology activities of the agency and ensure that agency decisions are informed by the results of appropriate and relevant research."[22] This authority includes providing advice to the EPA administrator regarding science and technology issues, participating in the development of the agency's science- and technology-based policies, coordinating the acquisition and compilation of relevant science and technology information, establishing guidelines for the dissemination of research results to the public (with particular emphasis on reaching minority and rural communities), and developing guidelines for peer review of science.[23] The Senate failed to take action on the bill before Congress adjourned, however, and the bill has not yet been reintroduced in the 108th Congress.

Through detailed reports and analyses, the General Accounting Office ("GAO") has consistently documented EPA's faulty scientific methods as well as its practice of obscuring the policy-based reasons for some of its decisions.[24] GAO recently noted concern among observers "about whether [EPA and other] agencies' procedures and assumptions are sufficiently transparent, thereby providing decision-makers and the public with adequate information about the scientific and policy bases for agencies' risk estimates as well as the limitations and uncertainties associated with those estimates."[25] GAO has also cited gaps and inaccuracies in EPA data that further compromise the agency's ability to assess risks and set risk-based priorities.[26] These gaps, in part, explain

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Agency Deputy Administrator for Science, Daily Rep. for Executives (BNA) No. 191, at A-16 (Oct. 4, 2001).

18. Act of April 30, 2002, H.R. 64 107th Cong.

19. *See id.*

20. *See Both Sides Are Right: EPA Needs to Improve Science Function*, ENVTL. F., Jan./Feb. 2002, at 30.

21. *Id.*

22. *Id.*

23. *See id.*

24. GAO has "identified several weaknesses in EPA's science programs over the years, including (1) the uneven implementation of peer review procedures for EPA's scientific and technical products, (2) gaps in scientific data, and (3) the lack of performance goals and measures that show the environmental results of EPA's science activities." U.S. GEN. ACCOUNTING OFFICE, PUB. NO. 00-270, GOVERNMENT PERFORMANCE AND RESULTS ACT: INFORMATION ON SCIENCE ISSUES IN EPA'S PERFORMANCE REPORT FOR FISCAL YEAR 1999 AND PERFORMANCE PLANS FOR FISCAL YEARS 2000 AND 2001 (2000) [hereinafter GAO, GOV'T PERFORMANCE & RESULTS ACT].

25. U.S. GEN. ACCOUNTING OFFICE, CHEMICAL RISK ASSESSMENT 19 (2001) [hereinafter GAO, CHEMICAL RISK]

26. *See, e.g.*, U.S. GEN. ACCOUNTING OFFICE, ENVIRONMENTAL INFORMATION: EPA NEEDS BETTER INFORMATION TO MANAGE RISKS AND MEASURE RESULTS 2 (2000); *see also* GAO, GOV'T

EPA's heavy reliance on assumptions.[27]

Although relying on assumptions may be inevitable when scientific knowledge is incomplete, EPA has been criticized for continually and indiscriminately operating from extremely conservative assumptions, enabling misguided regulatory decisionmaking.[28] GAO cautions that "using such precautionary assumptions . . . could produce overly optimistic estimates of the benefits of regulatory actions."[29] EPA's practice of choosing conservative default options is of particular concern when it can be a mechanism for disguising policy choices.[30] GAO has recognized this failing and called for transparency in risk assessments as well as in EPA guidance documents.[31]

PERFORMANCE AND RESULTS ACT, *supra* note 24, at 3 ("EPA lacks fundamental environmental and scientific data about pollutants and their effects on human health and the environment." In an attempt to address such problems, "EPA established the Office of Environmental Information in October 1999.").

27. Indeed, issuing regulations based on inadequate information or policy preferences can be likened to deceptive advertising, which is prohibited by section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2000); both have the capacity to foster misinformation and deceive the public. It is clear from the Federal Trade Commission's approach to deceptive practices that EPA's pattern of disguising policy as science would not pass muster if it were product advertising. The FTC has properly taken an aggressive stance against deception, which includes misrepresentations or omissions. *See* FED. TRADE COMM'N, POLICY STATEMENT ON DECEPTION (1983), *available at* http://www.ftc.gov/bcp/policystmt/ad-decept.htm. Product claims that cannot be supported with sufficient science or other evidence violate the FTC Act's prohibition against unfair or deceptive acts or practices. Information disseminated by federal agencies such as EPA, which are obligated to act in the public interest, can be held to no less high a standard.

28. *E.g.*, U.S. GEN. ACCOUNTING OFFICE, PUB. No. 01-55, ENVIRONMENTAL PROTECTION AGENCY: USE OF PRECAUTIONARY ASSUMPTION IN HEALTH RISK ASSESSMENTS AND BENEFITS ESTIMATES 5 (2000) [hereinafter GAO, PRECAUTIONARY ASSUMPTION]. The precautionary principle encourages regulatory action when a suspected risk cannot be proven with scientific certainty but the risks of inaction might be great. But uncertainty cannot properly be used as a crutch to justify action whenever data are unavailable.

29. *Id.*

30. *See* POWELL, *supra* note 12, at 29-30 (discussing risk assessment at EPA and noting that EPA's risk assessment guidelines "place increasing burdens on EPA decisionmakers to exercise their science and policy judgment and create new opportunities for the exercise of administrative discretion"); *id.* at 81 ("A commonality among [EPA's] regulatory programs . . . has been their reluctance to come to grips with scientific uncertainty in a meaningful way."); Jody Freeman & Laura I. Langbein, *The Time Has Come for Reconsidering the Role of Generic Default Assumptions Based on "Conservative Policy Choice" in Scientific Risk Assessments*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,873, 10,873-74 (2001). *See generally* AM. CROP PROTECTION ASS'N, AN APPROACH FOR ADDRESSING THE PRECAUTIONARY PRINCIPLE (1999).

Of course, EPA is neither unique nor entirely unjustified in subscribing to conservative approaches to regulation. OMB, the regulator of the regulators, has also expressed support for the precautionary principle, when properly applied. John D. Graham, the current director of OMB's regulatory review office, has stated that public concern about perceived risks should play a role in agency science. *See OMB's Graham Concedes Public Concerns, Science Both Relevant to Risk Assessments*, Reg. L. & Econ. (BNA) No. 09, at A-27 (Jan. 14, 2002). Graham contends that even though conservative assumptions may be warranted, the need for caution does not excuse the obligation to use good science. Scientific and procedural safeguards should be used when the precautionary principle is invoked. *See id.*

31. *See* GAO, CHEMICAL RISK, *supra* note 25, at 13, 45; GAO, PRECAUTIONARY ASSUMPTION, *supra* note 28, at 7 ("We are recommending that, in developing its final rule on arsenic, EPA fully disclose and analyze the impact of the key precautionary health assumptions used in its benefits estimate."); *see also* BREYER, *supra* note 11, at 11 (describing the phenomenon of "tunnel vision," whereby agencies promulgate extremely stringent standards that result in high costs with limited addi-

B. Inadequate Extra-judicial Checks on the Regulatory Process

The shortcomings of agency science demonstrate that effective oversight of the regulatory process is imperative. Many of the extra-judicial mechanisms established for ensuring agency accountability unfortunately suffer from deficiencies that render them inadequate by themselves to resolve the pervasiveness of poor quality science.

1. Notice-and-Comment Rulemaking

In 1995, Professor Wendy Wagner published an important article documenting agency abuse of science entitled *The Science Charade of Toxic Risk Regulation*,[32] exposing the "pervasive 'science charade'—in which agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions."[33] Professor Wagner explained that agencies shield themselves behind this charade, couching their proposed rules in hypertechnical terms so as to limit the public's ability to understand and participate in the rulemaking process.[34] Obscuring the true bases for agencies' decisions and overstating the role of science in decision-making limits the public's ability to participate meaningfully in the notice-and-comment process. The "science charade" can thus significantly undercut the effectiveness of public input in agency rulemaking.

2. Peer Review

The peer-review process is designed to provide internal agency checks on science-based decisionmaking.[35] Though peer review is an important component of the scientific process, the nature of peer review and the documented flaws in the peer-review process at EPA render it insufficient to remedy problems with agency science or to ensure reasoned decisionmaking.[36] A recent NRC report highlights the deficiencies in EPA's peer-review policy and demonstrates that the agency's current approach is an inadequate protection against conflicts of interest between its project managers and its peer-review leaders.[37] Moreover, EPA largely views peer review as a bureaucratic requirement, rather than as an integral part of agency culture.[38] GAO has also found that "further improvements are needed to expand the scope of peer reviews [at EPA] and make them more independent,"[39] and that the implementation of EPA's peer-

tional benefits).

32. Wagner, *supra* note 13, at 1613.

33. *Id.* at 1617.

34. *Id.* at 1656-57.

35. *See*, *e.g.*, NAT'L RESEARCH COUNCIL, STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH-MANAGEMENT AND PEER-REVIEW PRACTICE 22 (2000) [hereinafter NRC REPORT].

36. *Id.* at 1-2.

37. *See id.* at 102-08.

38. *Id.* at 103-04.

39. GAO, GOV'T PERFORMANCE & RESULTS ACT, *supra* note 24, at 3.

review policy has been "uneven."[40] Even when the peer-review process functions well, it does not guarantee that agencies will rely upon good science.[41] Peer review is not a replacement for utilizing good science from the inception of the scientific process:

> [I]n many cases, end-of-the-line review cannot repair mistakes or omissions made early in the regulatory development process or fill data gaps. Back-end inspection may be able to identify scientific uncertainties, but rarely can it reduce them. The benefits of regulatory science quality control must also be balanced against the potential for peer reviewers to intrude on the policy domain. If determining whether the data and analysis are adequate for regulatory decisionmaking is the problem, then peer review does not solve the problem. It shifts the problem from decisionmakers to reviewers.[42]

3. Congressional Oversight

Congressional controls such as appropriations and monitoring activities can, to a certain degree, constrain agency actions.[43] The pervasive agency practice of disguising policy judgments as science, however, effectively shields agency officials from intense scrutiny by Congress.[44] Scholars have also questioned the true extent of congressional power over agencies, noting the limited ability of Congress to impose effective, post-decision sanctions against agency action.[45]

4. Congressional Repeal

The Congressional Review Act provides that agencies must submit certain regulations to Congress sixty days before they are scheduled to take effect.[46] Since the Statute's enactment in 1996, however, Congress has passed only one resolution of disapproval.[47] Moreover, the legislature's difficulty in reaching

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40. *Id.*

41. *See* NRC REPORT, *supra* note 35, at 172; *see also Bad Science*, ENVTL. F., Jan./Feb. 2002, at 28 (discussing the deficiencies in EPA's peer review process).

42. POWELL, *supra* note 12, at 139. A stark example of the limits of peer review is found in the recent discovery that a Bell Labs scientist falsified data regarding molecular-scale transistors. Before the data were deemed falsified, the work by that scientist had been touted as a major scientific breakthrough. In discussing why this deception was initially successful, commentators cited the limitations of the peer review process. Peer review screens for scientific errors, but presupposes that the data obtained are honest. *See* Kenneth Chang, *Panel Says Bell Labs Scientist Faked Discoveries*, N.Y. TIMES, Sept. 26, 2002, at A2. Flaws attributable to improperly manipulated data therefore are not likely to be detected by the peer-review process. *See* Peter N. Spotts, *Science Labs, Too, 'Cooking the Books*,' CHRISTIAN SCI. MONITOR, July 19, 2002, at 1.

43. *See* Christopher H. Schroeder & Robert L. Glicksman, Chevron, State Farm *and EPA in the Courts of Appeals During the 1990s*, 31 Envtl. L. Rep. (Envtl. L. Inst.) 10,371, at 10386 (2001).

44. *See* Wagner, *supra* note 13, at 1669-71. In a later, noteworthy article, Professor Wagner discussed the limits Congress faces when it attempts to enact effective environmental legislation. Wendy E. Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181 (1999).

45. *See* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2259 (2001) ("[T]he evidence of dominance is doubtful at best. The empirical work of the public choice theorists, purporting to show that agencies routinely comply with legislative agendas, has come under sharp fire.").

46. 5 U.S.C. § 801(a)(3)(A) (2000).

47. *See* Kagan, *supra* note 45, at 2257 (referring to the repeal of the Ergonomics Program, which had threatened to impose burdensome regulations on employers, without a scientific consensus as to what actually caused ergonomic impairments).

consensus handicaps its ability to respond to agency regulations.[48]

5. OMB Review of Agency Rules

With Executive Order 12,866, President Clinton directed agencies to promulgate regulations only when strictly necessary and to consider the costs and benefits of available regulatory alternatives.[49] Significant regulatory actions are to be submitted to the Office of Information and Regulatory Affairs ("OIRA") for review and comment before publication.[50] Despite this oversight function, OIRA's ultimate impact on agency regulations is necessarily marginal. While executive branch review can rein in and potentially improve regulations at the margin, eleventh-hour review by the small staff at OIRA cannot realistically work significant improvements in complicated regulations developed over months or years, and such review certainly cannot remedy major defects in scientific data or methodology. Moreover, agencies will not always heed executive branch input. EPA, for example, proceeded to issue its proposed Clean Air Act "national ambient air quality standards" ("NAAQS") for ozone despite strong criticism from several executive branch offices that EPA significantly understated the true costs of attainment, conducted insufficient scientific analysis, and failed to support its new standards with adequate data.[51]

6. The Data Quality Guidelines

On January 3, 2002, OMB released its "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies."[52] The Guidelines were issued pursuant to a congressional directive in the Treasury and General Government Appropriations Act for Fiscal Year 2001[53] and evince congressional concern with the quality of agency science. These Guidelines are entirely consistent with the aims of regulatory *Daubert*, and in fact heighten the need for *Daubert*-type review of agency science; courts must ensure that the Guidelines are fully and effectively implemented by compelling agencies to fulfill their new quality-of-information mandate.

The Guidelines are intended to establish greater accountability for the quality of agency data. They require each agency to issue its own guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency."[54] Agen-

48. *See* Jonathan H. Adler, *Free & Green: A New Approach to Environmental Protection*, 24 HARV. J.L. & PUB. POL'Y 664 (2001) (offering reasons for failures in environmental policy).

49. Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), *reprinted as amended in* 5 U.S.C. § 601 (2000).

50. *See id.*

51. *See, e.g.*, Michael Fumento, *Polluted Science*, REASON ONLINE, Aug./Sept. 1997, *at* http://reason.com/9708/fe.fumento.shtml.

52. Office of Mgmt. & Budget, Information Quality Guidelines, 67 Fed. Reg. 369 (Jan. 3, 2002), *reissued with corrections*, 67 Fed. Reg. 8452 (Feb. 22, 2002).

53. Pub. L. No. 106-554, § 515 (2002).

54. Information Quality Guidelines, *supra* note 52.

cies are directed to adopt a basic standard of quality, one akin to the "best available science" standard of the Safe Drinking Water Act ("SDWA"),[55] to review the quality of information before disseminating it.[56] Agencies must also use "sound statistical and research methods" when generating data and developing results.[57] Results must be capable of being substantially reproduced.[58] A primary purpose of the Guidelines—and one that comports with sound public-policy decisionmaking—is to encourage agencies to adopt a good-science foundation before committing to a particular decision.[59] Importantly, the Guidelines request that agencies identify any sources of error that would affect quality, and that they make data and models publicly available.[60]

Agencies are required by the Guidelines to create administrative mechanisms that allow the public to request the correction of information disseminated by agencies, and the agencies have to report to OMB on complaints regarding information quality.[61] These requirements allow access to agency review prior to the issuance of a final regulation. They also suggest that parties may be able to seek federal court review of an agency's refusal to correct information.[62] The Guidelines enhance existing means for affected parties to expose deficiencies in agency science, thereby enabling industry groups to combat excessive deference.[63] Federal courts must be prepared to test the relevance and reliability of agency science; they must aim to ensure that the requirements of quality, objectivity, utility, and integrity are met.

On October 2, 2002, EPA issued its own Data Quality Guidelines.[64] In its guidelines, EPA states that it will address the OMB guidelines by "foster[ing] the continuous improvement of existing information quality activities and programs."[65] According to EPA, it already has "numerous systems and practices in place that address the quality, objectivity, utility, and integrity of information."[66] EPA seemingly intends to rely on its existing mechanisms in lieu of overhauling its current system, while attempting to shelter itself from judicial review.

As soon as EPA's draft guidelines were released, commenters began to

55. *See id.* at 377; 42 U.S.C. § 300f (2000).

56. *See id.*

57. *Id.*

58. *See id.*

59. *See, e.g.*, *OMB Guidelines on Quality of Information Seen as Having Profound Impact on Agencies*, Reg. L. & Econ. (BNA) No. 09, at C-1 (Jan. 14, 2002) [hereinafter *Profound Impact*].

60. *See id.*

61. *See id.* at 376.

62. *See Profound Impact*, *supra* note 59.

63. *See OMB Data-Quality Guidance to Bolster Attacks on EPA Rules*, RISK POLICY REP. (Inside Washington Publishers, Arlington, Va.), Jan. 21, 2002, at 12 (discussing the likely impact of the Guidelines on challenges to agency rulemaking).

64. U.S. ENVTL. PROTECTION AGENCY, GUIDELINES FOR ENSURING AND MAXIMIZING THE QUALITY, OBJECTIVITY, UTILITY, AND INTEGRITY OF INFORMATION DISSEMINATED BY THE ENVIRONMENTAL PROTECTION AGENCY (2002), *available at* http://www.epa.gov/oei/quality/guidelines/EPA-OEI-IQG-FINAL-10-2002.pdf [hereinafter EPA GUIDELINES].

65. *Id.* at 10.

66. *Id.*

express doubt about the fidelity of EPA's guidelines to those of OMB. The final guidelines are substantially the same as the draft version and do not allay those initial misgivings. Of particular concern is that, rather than simply adopting the best-available, peer-reviewed science standard of the SDWA, as recommended in the OMB guidelines, EPA has decided to adapt the quality principles of the SDWA and will use the best science available upon assessment, together with data "collected by accepted methods" or "best available methods."[67] Moreover, EPA will only use these principles "to the extent practicable."[68] EPA thus specifically rejected commenters' recommendations that EPA *adopt* rather than *adapt* the SDWA principles. EPA also created a significant loophole with regard to information-correction requests, as "the Agency may need to weigh the resources needed and the potential delay associated with incorporating additional information in comparison to the value of the new information in terms of its potential to improve the substance and presentation of the assessment."[69]

The EPA guidelines are somewhat encouraging in that, in each document made available to the public, EPA will specify "each significant uncertainty identified in the process of the assessment of risk and studies that would assist in resolving the uncertainty."[70] Due to the other deficiencies, however, on balance, the EPA guidelines dilute the most potentially efficacious aspects of the OMB guidelines. In a letter to Administrator Whitman raising their concerns about EPA's draft guidelines, Congressmen Billy Tauzin and Paul Gillmor asserted that "EPA's proposal would be inconsistent with law and . . . leaves completely open-ended loopholes for EPA not to follow the SDWA principles or *any* principles of objectivity."[71] Among other problems, while the OMB guidelines state that agencies *must* ensure objectivity, EPA has determined that it merely "should" do so.[72] The OMB guidelines contain no justification for attempting compliance only "to the extent practicable,"[73] as EPA has described its own obligations.

EPA has also attempted to circumvent judicial review by characterizing its guidelines as a nonbinding guidance document. EPA states in its guidelines:

> Our Guidelines reflect EPA's best effort to present our goals and commitments for ensuring and maximizing the quality of information we disseminate. As such, they are not a regulation and do not change or substitute for any legal requirements. They provide non-binding policy and procedural guidance, and are therefore not intended

67. *Id.* at 22.

68. *Id.*

69. *Id.* at 23.

70. *Id.* at 23.

71. Letter from W.J. "Billy" Tauzin and Paul E. Gillmor to Christine Todd Whitman, Administrator, U.S. Envtl. Protection Agency 2 (June 7, 2002) (on file with author); *see also* Pat Phibbs, *Environment Regulatory Information Should Be Subject To Correction Mechanism, Industry Tells EPA*, Reg., L. & Econ. (BNA) No. 95, at A-37 (May 16, 2002) [hereinafter *Environment Regulatory Information*] ("On too many margins EPA has provided itself loopholes, provisos, escape clauses, definitional advantages and other artful dodges.") (quoting Richard Belzer, President, Regulatory Checkbook).

72. *See* EPA GUIDELINES, *supra* note 64, at 3.

73. *Id.* at 22.

> to create legal rights, impose legally binding requirements or obligations on EPA or the public when applied in particular situations, or change or impact the status of information we disseminate, nor to contravene any other legal requirements that may apply to particular agency determinations or other actions.[74]

The availability of judicial review of actions taken under the guidelines will undoubtedly be a hotly contested and perhaps a highly litigated subject. The express requirement in the OMB guidelines that agencies establish internal review mechanisms through which affected parties may contest quality-of-information decisions certainly gives rise to a legitimate claim that final agency decisions on such complaints should be subject to further review in the federal courts. Moreover, if a request for information correction relates to information that is already the subject of a public notice-and-comment rulemaking, EPA will generally address the request within the ordinary rulemaking process.[75] Thus, it is inevitable that certain information correction requests will ultimately, if indirectly, be subject to judicial review in the course of challenges to EPA rulemakings. Regardless of the outcome of the prospective judicial review debate, even those courts that are not hearing challenges brought under the guidelines must provide meaningful review that gives effect to explicit congressional intent to heighten the standards for agency science. EPA's apparent measures to resist the most potent aspects of OMB's attempt to reform agency science increase the need for probing judicial review.

7. The Nondelegation Doctrine

The need for effective judicial review is even more imperative in the wake of *Whitman v. American Trucking Ass'ns, Inc.*,[76] in which the Supreme Court held that the Clean Air Act's requirement that EPA set the national ambient air quality standards "requisite to protect the public health" did not effect an unconstitutional delegation of legislative power.[77] *American Trucking* makes it abundantly clear that the nondelegation doctrine is virtually obsolete and that agencies have a free hand to exercise legislative power to fashion regulatory policies.[78] Agencies accordingly have broad power to exercise legislative-type functions.[79] Courts must therefore ensure agency accountability in the exercise of such otherwise unchecked power.

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74. *Id.* at 4.

75. *See id.* at 32. Commenters have criticized EPA for refusing to separately review information correction requests that are also subject to public comment. *See, e.g.*, *Environment Regulatory Information*, *supra* note 71. Concerns about the quality of information incorporated into agency rules served as a major impetus for the OMB guidelines. *See id.* EPA should not be able to evade the review and correction requirement by relegating such problems to the rulemaking process.

76. 531 U.S. 457 (2001).

77. *Id.* at 486.

78. *But cf.* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000) (holding that agencies may not exercise authority to set regulatory policy when Congress has withheld jurisdiction over the matter the agency seeks to regulate).

79. *See American Trucking*, 531 U.S. at 488 (Stevens, J., concurring) ("[I]t would be both wiser and more faithful to what we have actually done in delegation cases to admit that agency rulemaking authority is 'legislative power.'").

C. Federal Courts' Criticisms of the Improper Use of Science

Given their responsibility as the last bulwark of regulatory accountability, federal courts provide a necessary forum for evaluating agency science and scientific decisionmaking. When called upon to review agency decisions, federal courts routinely—though unpredictably—strike down agency actions because of flawed science or methodologies, and in the course of doing so, remark upon the inadequacy of agency science.

In *Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA*,[80] for example, a federal district court rejected EPA's risk assessment classifying secondhand smoke as a Group A carcinogen pursuant to the Radon Research Act.[81] That assessment had appeared in an EPA report that analyzed the effects of secondhand smoke. The court determined that in conducting its assessment, EPA demonstrated a "complete disregard of statutory procedure,"[82] and engineered its methodologies to produce its desired policy outcome.[83] The court denounced EPA for "publicly committ[ing] to a conclusion before research had begun" and "adjust[ing] established procedure and scientific norms to validate the Agency's public conclusion."[84] The court also criticized EPA for "cherry pick[ing]" its data in order to confirm its *a priori* hypothesis.[85]

In *Puerto Rico Sun Oil Co. v. EPA*,[86] another noteworthy decision, the court severely criticized EPA for issuing a pollution discharge permit that did not include a mixing zone analysis. Citing *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Auto Insurance Co.*,[87] the court deemed EPA's decision irrational and discriminatory.[88] The agency's action required an explanation "other than a mechanical desire to reach a rapid conclusion without regard to whether the result is sound."[89]

The persistence of EPA's inadequate methodologies and misguided treatment of science in decisionmaking has given rise to a pervasive sentiment that EPA displays a defiant attitude toward science.[90] In *Chemical Manufacturers Ass'n v. EPA*, the D.C. Circuit struck down a Clean Air Act rule by finding that

80. 4 F. Supp. 2d 435 (M.D.N.C. 1998), *rev'd* 313 F.3d 852 (4th Cir. 2002).

81. 42 U.S.C. § 7401 (2000).

82. 4 F. Supp. 2d at 449.

83. *Id.* at 456.

84. *Id.* at 465-66.

85. *Id.* at 460-62. Four years later, the Fourth Circuit reversed the case on other grounds. Specifically, the court found that the report did not constitute final agency action because it lacked legal and direct consequences. Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852 (4th Cir. 2002). The court therefore found that the agency's action was not reviewable. *Id.* at 862. This decision would appear to conflict with other recent discussions on reviewability. *See* Tozzi v. United States, 271 F.3d 301 (D.C. Cir. 2001); *infra* Part IV.B. (discussing cases). *But see* Thomas O. McGarity, *On the Prospect of "Daubertizing" Judicial Review of Risk Assessment*, 66 LAW & CONTEMP. PROBS. 155 (Autumn 2003).

86. 8 F.3d 73 (1st Cir. 1993).

87. 463 U.S. 29 (1983).

88. 8 F.3d at 78.

89. *Id.* at 79.

90. Chem. Mfrs. Ass'n v. EPA, 28 F.3d 1259, 1266 (D.C. Cir. 1994).

EPA arbitrarily and capriciously designated a chemical as a high-risk air pollutant on the basis of a gas dispersion model that bore no rational relationship to the physical properties of the chemical. Indeed, the chemical was a solid, not a gas, within the relevant temperature range.[91] The court criticized the agency for its speculative factual assertions that "bespeak[ ] a 'let them eat cake' attitude that ill-becomes an administrative agency whose obligation to the public it serves is discharged if only it avoids being arbitrary and capricious."[92] The D.C. Circuit has had repeated occasions to reject EPA's scientific models when they "bea[r] no rational relationship to the reality they purpor[t] to represent."[93]

The above discussion demonstrates that courts are fully capable of, and well-suited to, discovering flaws in agency science and mitigating the consequences by ordering agencies to remedy defects and to engage in more reasoned decisionmaking. This role is entirely consistent with courts' obligation to engage in meaningful judicial review. Moreover, nonjudicial checks on the regulatory process have proven inadequate to reform agency science.

III

APPLYING *DAUBERT* TO JUDICIAL REVIEW OF AGENCY SCIENCE

Probing judicial review is a necessary check on agency discretion. Courts presently lack a consistent or coherent framework for performing this important function. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[94] sets forth several sound principles for review of science that can be usefully extrapolated to the regulatory context.

A. The *Daubert* Decision

In *Daubert*, the Supreme Court articulated the current standard for admitting expert scientific testimony at trial. Before admitting such evidence, the district court must exercise a screening or "gatekeeping"[95] function to ensure that proffered scientific evidence is both relevant and reliable.[96] The inquiry focuses on "whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts at issue."[97] Scientific evidence offered by expert witnesses is "relevant" if it is sufficiently tied to the facts at hand to "fit," be "helpful," or be "scientifically valid" for the purposes for which it is offered.[98] To be deemed "reliable," evidence must also involve scientific knowledge "ground[ed] in the

91. *Id.* at 1264.
92. *Id.* at 1266.
93. Sierra Club v. EPA, 167 F.3d 658, 662 (D.C. Cir. 1999); *see also, e.g.,* Columbia Falls Aluminum Co. v. EPA, 139 F.3d 914, 923 (D.C. Cir. 1998).
94. 509 U.S. 579 (1993).
95. The court's screening function was later referred to as a "gatekeeper" role in *General Electric Co. v. Joiner*, 522 U.S. 136, 139 (1997).
96. *Daubert*, 509 U.S. at 589.
97. *Id.* at 592.
98. *Id.* at 591-93.

methods and procedures of science."[99] Factors pertinent to this analysis include whether the theory or technique under review has been tested or subjected to peer review.[100] The Court emphasized that the inquiry is intended to be a flexible one.[101]

Daubert expressly forbids judges to draw their own scientific conclusions and thus prohibits judges from substituting their conclusions for those of scientists or other experts. Rather, judges scrutinize only "principles and methodology, not . . . the conclusions that they generate."[102]

Supreme Court decisions subsequent to *Daubert* continue to reaffirm its validity and to expand upon its principles. *General Electric Co. v. Joiner*[103] stands for the proposition that a trial judge's decision to admit or to exclude expert testimony can be reversed only for an abuse of discretion. A judge may exercise discretion to exclude evidence when there is "too great an analytical gap between the data" and the opinion or conclusion proffered.[104] The Court in *Kumho Tire Co. v. Carmichael*[105] extended the gatekeeping obligation of *Daubert* to testimony based on technical or other specialized knowledge. In *Weisgram v. Marley Co.*, the Court held that an appellate court may enter judgment as a matter of law when it determines, in applying *Daubert* analysis, that evidence was erroneously admitted at trial, provided that the remaining evidence would be insufficient to support a judgment.[106] After *Daubert*, "parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet."[107]

If *Daubert* were applied in the regulatory context, agency accountability would be increased. Agencies such as EPA would be obligated to rely on science that is scientifically valid for the material issues being decided by the agency, and, at a minimum, would be compelled to state the bases of the scientific assumptions underlying the agency's policy decisions.[108]

Daubert, however, involved the admissibility of scientific evidence under the Federal Rules of Evidence and thus cannot be exported wholesale as controlling authority in the context of agency rulemakings.[109] *Daubert*'s principles of review, though, are directly applicable to and entirely appropriate for review of

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99. *Id.* at 589-90.
100. *See id.* at 593.
101. *Id.* at 594.
102. *Id.* at 595.
103. 522 U.S. 136, 139 (1997).
104. *Id.* at 146.
105. 526 U.S. 137, 141 (1999).
106. 528 U.S. 440, 457 (2000).
107. *Id.* at 455.
108. *Cf.* THE ANNAPOLIS CTR., EPIDEMIOLOGY IN DECISION-MAKING 20 (1999) (noting that *Daubert* could usefully be applied to agency science so as to expose the bases for agency decisions and better inform those who bear the costs of a regulation).
109. This Article is concerned only with review of agency rulemaking. For a discussion of applying *Daubert* to environmental litigation, see Charles O. Weller & David B. Grahame, *New Approaches to Environmental Law and Agency Regulation: The Daubert Litigation Approach*, 30 Envtl. L. Rep. (Envtl. L. Inst.) 10,557 (2000).

agency decisions.[110] Indeed, the APA and decisions rendered under that Act fully endorse the logic and import of *Daubert*. Regulatory *Daubert* therefore supplies an ideal framework for judicial review of administrative actions.

B. *Daubert* Principles and the Administrative Procedure Act

Under the Administrative Procedure Act, courts must set aside agency decisions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," not based on "substantial evidence," or in excess of "statutory jurisdiction, authority, or limitations."[111] Moreover, under the APA, "a sanction may not be imposed or rule or order issued except on consideration of the whole record . . . and supported by and in accordance with . . . reliable, probative, and substantial evidence."[112] The Supreme Court has established rigorous criteria for reviewing agency action under the APA, and for setting aside such action when the explanation offered by an agency "runs counter to the evidence before [it]."[113]

Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Auto Insurance Co.[114] provides a firm basis for importing *Daubert* into judicial review of agency action. There, the Supreme Court reviewed a National Highway Traffic Safety Administration ("NHTSA") decision rescinding the requirement that new motor vehicles be equipped with passive restraints. Finding that the agency had failed to present an adequate basis and explanation for its decision, the Court vacated and remanded the agency's action.[115]

State Farm requires that agencies engage in reasoned decisionmaking by complying with rigorous standards that are strikingly similar to the "relevance and reliability" criteria of *Daubert*. The decision requires every agency to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[116] In reviewing an agency's explanation for its action under the APA, courts must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment."[117]

> Normally, an agency rule would be arbitrary and capricious if the 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

110. For a further explanation of *Daubert*'s utility and relevance in the agency context despite the case's civil litigation origins, see Alan Charles Raul, *Junk Science In, Junk Policy Out: Science and Administrative Law*, *in* SCIENCE, TECHNOLOGY, AND THE LAW 41 (N.Y. Acad. of Sciences ed., 1998).

111. 5 U.S.C. § 706 (2000).

112. *Id.* at § 556(d).

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

114. *Id.*

115. *Id.* at 56.

116. *Id.* at 43 (quotations omitted).

117. *Id.* (quoting Bowman Transp. Inc. v. Arkansas-Best Freight Sys., 419 U.S. 281, 285 (1974)) (quotations omitted).

> ascribed to a difference in view or the product of agency expertise.[118]

As in *Daubert*, in which courts are admonished not to draw their own scientific conclusions, *State Farm* cautioned that "[t]he reviewing court should not attempt itself to make up for such deficiencies."[119] "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency . . . . [The court] may not supply a reasoned basis for the agency's action that the agency itself has not given."[120]

NHTSA's failure to consider or discuss a crucial regulatory option led the Court to invoke analysis from the earlier case of *Burlington Truck Lines v. United States*:[121]

> There are no findings and no analysis here to justify the choice made, no indication of the basis on which the agency exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such . . . practice . . . . Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.
>
> We have frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner, and we reaffirm this principle again today.
>
> . . . .
>
> . . . It is not infrequent that the available data do not settle a regulatory issue, and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion. Recognizing that policymaking in a complex society must account for uncertainty . . . does not imply that it is sufficient for an agency to merely recite the terms 'substantial uncertainty' as a justification for its actions. As previously noted, the agency must explain the evidence which is available, and must offer a "rational connection between the facts found and the choice made."[122]

The Court concluded that, "[b]y failing to analyze the continuous seatbelts option in its own right, the agency has failed to offer the rational connection between facts and judgment required to pass muster under the arbitrary-and-capricious standard."[123] The manner in which the Court exercised its power of review in this case was fully consistent with its earlier pronouncement in *Citizens to Preserve Overton Park v. Volpe*[124] that agency action should not be shielded from a "thorough, probing, in-depth review."[125]

C. Treatment of *Daubert* in the Federal Courts

Despite the clear fit between *Daubert*'s reviewability standards and the

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118. *Id.*

119. *Id.; see also id.* at 52 ("[W]e do not upset the agency's view of the facts, but we do appreciate the limitations of the record in supporting the agency's decision.").

120. *Id.* at 43 (quoting SEC v. Chenery Corp., 332 U.S. 194, 196 (1947)).

121. 371 U.S. 156, 167 (1962).

122. *State Farm*, 463 U.S. at 48-52 (citations and quotations omitted).

123. *Id.* at 56.

124. 401 U.S. 402 (1971), *abrogated in part*, Califano v. Sanders, 430 U.S. 99 (1977).

125. *Id.* at 415.

principles and standards of the APA, no court has yet explicitly invoked *Daubert* in the course of reviewing agency action. In fact, two courts have rejected the application of *Daubert* principles to judicial review of agency action. The U.S. Court of Appeals for the Seventh Circuit rejected *Daubert*'s standards in an environmental case because judicial review under *Daubert* "is intrusive, undeferential, and not required," even though the court conceded it "might assure better documentation of an agency's scientific decisions."[126] The decision provided little analysis of the *Daubert* issues. The case involved judicial review of a Forest Service action under the APA. The appellant merely cited *Daubert* in a footnote in support of a non-controversial proposition that courts are able to review science. An amicus brief in the same case also invoked *Daubert* simply by alluding to a brief it had filed in *Daubert* itself.[127] In short, the litigants did not truly develop the issue.

In *Stewart v. Potts*,[128] the second case to reject the application of *Daubert*, the district court stated that a reviewing court's only role "is to ensure that the agency's decisions are not arbitrary or capricious; it is not to evaluate their scientific methods."[129] *Potts* involved judicial review of an Army Corps of Engineers "wetlands" action. The plaintiff cited *Daubert* extensively, although merely rhetorically, to support the proposition that an agency may not rely on junk science. The government responded that *Daubert* has no role in APA review. The plaintiff did not develop an argument why *Daubert* should (or could) be applied to review under the APA.[130]

Significantly, the Supreme Court, a judge on the D.C. Circuit, and EPA—three key participants in the agency science arena—have acknowledged the potential relevance of *Daubert*-type principles to administrative review. In *Daubert* itself, the Supreme Court recognized that its new "good science" mandate could have application in the context of regulatory science. The Court prominently cited Sheila Jasanoff's book on regulatory science, *The Fifth Branch: Science Advisors as Policymakers*,[131] for its discussion of the role of "peer review and regulatory science." The pages cited by the Court address the relationship between good science and the regulatory decisionmaking process. The Court would not have cited a book focusing exclusively on the role of regulatory science in EPA and Food and Drug Administration ("FDA") decisionmaking if it had not been comfortable with the notion that the new good-science mandate announced in *Daubert* could be extended by analogy to administrative law and judicial review of agency science.

Likewise, Judge Tatel, in his dissent from the majority opinion in the first *American Trucking* decision, cited *Daubert* for the proposition that EPA must

126. Sierra Club v. Marita, 46 F.3d 606, 622 (7th Cir. 1995).
127. *Id.*
128. 996 F. Supp. 668 (S.D. Tex. 1998).
129. *Id.* at 678 n.8 (rejecting application of *Daubert*).
130. *See id.*
131. 509 U.S. at 593 (citing JASANOFF, *supra* note 5, at 61-76).

explain any departures from the recommendations of the Clean Air Scientific Advisory Committee ("CASAC").[132] Judge Tatel thus recognized that *Daubert* principles could promote agency accountability.

EPA has also acknowledged *Daubert*'s relevance to agency science. In its brief in *American Trucking*, on remand before the D.C. Circuit,[133] EPA cited *Daubert* for the proposition that peer review is an important tool for assessing the validity of a scientific technique or methodology.[134]

The rigorous standards the Supreme Court has set for review of agency science and its demonstrated receptiveness to the idea of ensuring "good science" in the regulatory context in *Daubert* itself demonstrate an awareness of the benefits to be gained by applying *Daubert*-type review. In fact, regulatory *Daubert* would raise the standards of agency science, thereby advancing important public policy objectives. *Daubert* gatekeeping principles would significantly enhance the likelihood that regulatory decisions and actions are based on the best available science and sound and objective scientific practices.

D. *Daubert* Application in APA Cases

Sound science objectives are at least as important in the context of government regulation affecting the entire nation as they are in litigation affecting a few private litigants. EPA is responsible for more science-based regulations than any other federal agency. According to a recent article, "[o]f the 137 forthcoming major rules identified by the federal government in October 1999, the EPA accounted for twenty-eight—over twenty percent of the total—and more than any other federal agency."[135] Each of EPA's rules potentially costs society billions of dollars and aims to protect thousands or even millions of people.[136] The vast consequences of EPA rulemaking justify judicial review measures designed to ensure such monumental decisions are firmly supported by available scientific data and well-reasoned analysis.

In *American Lung Ass'n v. EPA*, the D.C. Circuit recognized the public policy benefits of requiring EPA to justify its scientific decisionmaking:

> Where, as here, Congress has delegated to an administrative agency the critical task of assessing the public health and the power to make decisions of national import in which individuals' lives and welfare hang in the balance, that agency has the heaviest of obligations to explain and expose every step of its reasoning.[137]

Accordingly, agency science warrants no greater insulation—and perhaps

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132. Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1059 (D.C. Cir. 1999) (Tatel, J., dissenting from the majority's holding that the provisions of the CAA under review effected an unconstitutional delegation of legislative power).

133. Brief of EPA, Am. Trucking Ass'ns v. EPA, 175 F.3d 1027 (D.C. Cir. 1999) (No. 97-1440) (on file with author). The D.C. Circuit did not refer to this argument in its opinion.

134. *Id.* (citing Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579, 594 (1993)).

135. Adler, *supra* note 48, at 657-58; *see also* Hahn, *supra* note 12, at 2 (discussing the cost of EPA regulations).

136. *See, e.g.*, Elliott et al., *supra* note 11, at 10,131 (remarks of Alan Charles Raul).

137. 134 F.3d 388, 392 (D.C. Cir. 1998); *cf.* Addington v. Texas, 441 U.S. 418, 423 (1979) ("[S]ociety has a minimal concern with the outcome of . . . private suits.").

even less—than other government activity. Courts should recognize that agency science is no more or less sacrosanct than other government activities, and merits scrutiny commensurate with its great public importance.

By requiring agencies to expose the bases for their decisions, including their assumptions and policy-based choices, and to demonstrate that they engage in reasoned decisionmaking based on relevant and reliable evidence, *Daubert* would increase agency documentation of scientific decisions and enhance agency accountability.[138]

Daubert and the APA authorities discussed above lend themselves to a coherent framework for judicial review. To achieve consistency in the review of agency action, courts in every case involving agency science should consider whether:

1. the agency used methodologies and procedures that were reliable and scientifically valid;
2. the scientific evidence relied upon was relevant for the issues before the agency;
3. the agency has set forth the scientific assumptions underlying its policy decisions and exposed any uncertainties;
4. the evidence before the agency supports the conclusion reached;
5. the agency has considered all important factors; and
6. the agency has engaged in reasoned decisionmaking, which includes demonstrating that there is a rational connection between the facts found and the choice made.

Provided the above criteria are met, courts should accord deference to agencies acting within their scientific expertise. Agency decisions that rest upon irrelevant or unreliable scientific evidence should be vacated for an abuse of discretion.

IV

EXCESSIVE JUDICIAL DEFERENCE TO AGENCY SCIENCE

Notwithstanding the call for rigorous review in *State Farm* and other APA cases, many courts accord extreme, almost slavish deference to agency science. Applying conventional notions of administrative law, and over-reading *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,[139] some courts have taken an excessively deferential approach to judicial review. A few such deci-

138. *See, e.g.*, Sierra Club v. Marita, 46 F.3d 606, 622 (7th Cir. 1995) (acknowledging that the use of *Daubert*-type standards "might assure better documentation of an agency's scientific decisions").

139. 467 U.S. 837 (1984). *State Farm* and *Chevron* are logically distinct in their respective areas of application, though those areas may "overlap at the margins," Arent v. Shalala, 70 F.3d 610, 615 (D.C. Cir. 1995), and the precise contours of the overlap are frequently in dispute. While *State Farm* elucidated the appropriate standard to be applied to judicial review of agency fact finding, *Chevron* was concerned with an agency's authority to act and the level of deference owed to an agency's interpretation of a statute under which it is so authorized. On the distinct but sometimes overlapping domains of *Chevron* and *State Farm*, see the majority and concurring opinions by Chief Judge Edwards and Judge Wald in *Arent*, 70 F.3d at 615-16, 619-20.

sions are worthy of brief discussion. It is evident from these cases that a *Daubert*-type approach to judicial review of agency rulemaking is necessary to compel agencies to fulfill their obligations to the public interest.

A. Judicial Deference When an Issue Is Framed as "Science"

Several courts have subjected agency decisions to only "minimal standards of rationality"[140] and stated that "courts necessarily must show considerable deference to an agency's expertise."[141] This overly deferential stance has proven pervasive. In the recent case of *Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*,[142] the Fourth Circuit emphasized that it owed "substantial deference" to the Food and Drug Administration, the agency whose action was under review.[143] At issue was a challenge to the agency's approval of a generic version of the levocarnitine drug. The court ultimately upheld the agency's decision and asserted that its review of an agency's interpretation of its own regulations is even "more deferential than that afforded under *Chevron*."[144] The court thus declined to "ignore the deference due the FDA and impose exacting evidentiary standards on its generic drug approval process."[145] According to the court, "the broad deference due [an] agency is all the more warranted when, as here, the regulation concerns a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns."[146]

Daubert actually demands that courts recognize the agency's expertise and that they not substitute their judgment for that of the agency.[147] This rule strikes an entirely appropriate balance between probing review and judicial deference. Courts too often fail to achieve such a balance, however, instead endowing "technical expertise" or "science" with a talismanic power that commands their retreat from any form of meaningful review. Professor Wagner has commented upon the "tendency of many courts to defer to the agency as an expert when the issue is framed as scientific in nature."[148] Her observation is amply borne out by the case-law.[149]

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140. *See, e.g.*, Envtl. Def. Fund v. EPA, 210 F.3d 396 (D.C. Cir. 2000).

141. *Id.* at 400 (quotations omitted).

142. 288 F.3d 141 (4th Cir. 2002).

143. *Id.* at 146.

144. *Id.* at 146 (quoting Wyo. Outdoor Council v. United States Forest Serv., 165 F.3d 43, 52 (D.C. Cir. 1999)) (quotations omitted).

145. *Id.* at 147.

146. *Id.* at 146.

147. 509 U.S. at 595.

148. Wagner, *supra* note 13, at 1664-65 (citing various cases).

149. *See, e.g.*, United States Air Tour Ass'n v. FAA, 298 F.3d 997, 1008 (D.C. Cir. 2002) ("Ultimately . . . the scientific nature of a model does not easily lend itself to judicial review, and our review proceeds with considerable deference to the agency's expertise.") (quotations omitted); Nat'l Petrochemical & Refiners Ass'n v. EPA, 287 F.3d 1130, 1144 (D.C. Cir. 2002) ("Where, as here, EPA's decision is based on complex scientific or technical analysis, it is entitled to great deference.") (citations omitted); Husqvarna v. EPA, 254 F.3d 195, 199 (D.C. Cir. 2001) (rejecting a challenge to emissions standards under the Clean Air Act and reaffirming the principle that a court "must be 'at its most

In *Texas Oil & Gas Ass'n v. EPA*,[150] for example, the petitioner unsuccessfully argued that EPA's promulgation of zero-discharge limits for pollution was the product of a flawed scientific analysis.[151] Specifically rejecting the argument that no deference is owed when EPA fails to explain its reasoning, the court concluded that extreme deference was due because "the agency's decision rests on an evaluation of complex scientific data within the agency's technical expertise."[152] According to the court, "[a]n agency's choice to proceed on the basis of 'imperfect' information is not arbitrary and capricious unless 'there is simply no rational relationship' between the means used to account for any imperfections and the situation to which those means are applied."[153]

The court in *BP Exploration & Oil, Inc. v. EPA*[154] affirmed EPA's effluent limitations for offshore oil and gas and noted that "[i]n assessing difficult issues of scientific method and laboratory procedure, we must defer to a great extent to the expertise of the EPA."[155] Similarly, in *Environmental Defense Fund v. EPA*,[156] the D.C. Circuit upheld EPA's stringent standards for discharge of PCBs, discounting arguments that the regulations lacked an adequate basis in the record. According to the court, "when an agency must resolve issues 'on the frontiers of scientific knowledge,' the reviewing court will uphold agency conclusions based on policy judgments in lieu of factual determinations."[157] The court found it sufficient that "the evidence in this case is at least suggestive of carcinogenicity."[158] The court all but abdicated its judicial review function entirely, asserting that: "[EPA's] policy decisions are subject to deferential review, and its factual conclusions are upheld although they may not be supported by all the evidence, *or even by most of it*."[159]

The above decisions make evident that many panels defer excessively to any agency action that contains a scientific component. In some instances courts effectively avoid judicial review entirely, preferring instead to defer blindly to an agency's decision regardless of its sometimes even obvious flaws. Such judicial passivity does not enhance democratic accountability. *Chevron* and *Daubert* teach that courts need not—and must not—themselves venture into the merits of competing or complex scientific findings. However, courts must ensure that an agency decision is adequately supported by the record, that the

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deferential' when [the] agency is 'making predictions, within its area of special expertise, at the frontiers of science'") (citations omitted); Int'l Fabricare Inst. v. EPA, 972 F.2d 384, 389 (D.C. Cir. 1992) ("The rationale for deference is particularly strong when the EPA is evaluating scientific data within its technical expertise.").

150. 161 F.3d 923, 933 (5th Cir. 1998).
151. *Id.*
152. *Id.* at 933-34 & n.8.
153. *Id.* at 935 (quoting Am. Iron & Steel Inst. v. EPA, 115 F.3d 979, 1004 (D.C. Cir. 1997)).
154. 66 F.3d 784, 792 (6th Cir. 1995).
155. *Id.* (citations omitted).
156. 598 F.2d 62 (D.C. Cir. 1978).
157. *Id.* at 82 (quoting Am. Iron & Steel Inst. v. OSHA, 577 F.2d 825, 833-34 (3d. Cir. 1978)).
158. *Id.* at 89.
159. *Id.* at 90 (emphasis added).

agency has offered a reasoned explanation for that decision—including exposing any underlying assumptions or uncertainties—and that the agency has followed the proper procedures in reaching its decision. Even when courts have expanded the scope of the agency action that is subject to review, the form of the review itself has often not been rigorous.

B. Broader, but Not Unduly Probing, Review

Several recent cases have explored the issue of finality, and hence reviewability, of agency action. The resulting decisions have tended to find in favor of reviewability, even when agency action has arguably not been "final" according to more conventional notions of administrative law. Nonetheless, even though the scope of judicial review has broadened, the exercise of review itself has not always proven sufficiently probing.

The illustrative case of *Tozzi v. HHS*[160] involved a Department of Health and Human Services ("HHS") decision to upgrade the chemical dioxin from a "reasonably anticipated" to a "known" carcinogen.[161] As mandated by the Public Health Service Act,[162] the listing was published in HHS's biennial *Report on Carcinogens*.[163] The report itself did not give rise to regulation of included substances. The agency accordingly opposed judicial review of the listing, arguing that the report lacked the requisite finality.[164] The D.C. Circuit rejected this argument, holding that the listing or reclassification of a substance is a reviewable agency action.[165] *Tozzi* potentially increased the transparency and reviewability of agency action to a significant degree, in that the court found that an agency decision is reviewable if it triggers regulatory obligations pursuant to the rules of other regulatory bodies, even without further action by the deciding agency.[166] When evaluating the merits, however, the court ultimately

160. 271 F.3d 301 (D.C. Cir. 2001).

161. *Id.*

162. Pub. L. No. 95-622, § 262 (1978) (codified at 42 U.S.C. § 241 (2000)).

163. NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT ON CARCINOGENS (8th ed. 1997).

164. *Tozzi*, 271 F.3d at 310.

165. *Id.* at 310-11.

166. *See id.* at 310. Curiously, the *Tozzi* court did not rely heavily on either of two key Supreme Court reviewability decisions. In *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997), the Supreme Court found reviewable a biological opinion that prescribed legally binding conditions for carrying out a project that would threaten endangered fish. In *American Trucking*, 531 U.S. 457, 477 (2001), the Supreme Court held that an EPA implementation policy described in the preamble of a regulation was reviewable, although EPA had stated the policy was merely preliminary and did not bind the states or the public. *Id.* at 477.

For other recent decisions on reviewability of agency action, see, for example, *Sierra Club v. United States Department of Energy*, 287 F.3d 1256, 1264 (10th Cir. 2002) (reversing a district court finding that a DOE decision to issue a road easement was not ripe); *Alaska v. EPA*, 244 F.3d 748 (9th Cir. 2001) (holding that administrative orders stating EPA's position that a mining facility permit had been improperly issued constituted final agency action even when EPA had not commenced enforcement proceedings); *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000) (finding that an EPA guidance document interpreting certain Clean Air Act regulations was final and reviewable). *But see* Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852 (4th Cir. 2002) (discussed *supra* at note 85); Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726 (1998) (holding that an agency Land and

failed to fully exercise its powers of judicial review.

The plaintiffs alleged that HHS acted arbitrarily and capriciously in relying on mechanistic rather than epidemiological evidence in its decision to classify dioxin as a "known" carcinogen.[167] The court failed to truly probe the agency's decision, instead adopting the "highly deferential" approach to judicial review of agency science and affirming the agency's decision.[168]

A few months after *Tozzi*, the D.C. Circuit considered a similar case in which it reviewed an EPA notice denying an industry group's petition to delete the substance methanol from the Clean Air Act's list of "hazardous air pollutants."[169] The court did not express concerns about finality or its ability to review the agency's action. Paradoxically, the nascent qualities of the agency's action proved to excuse the agency from engaging in and demonstrating a thorough, well-reasoned analysis. In a mere footnote, the court rejected the argument that EPA was required to issue an extensive decision "that includes the factual data on which the rule is based, the methodology used in obtaining and analyzing the data, the major legal interpretations and policy considerations underlying the rule, and a response to comments or criticisms of EPA's proposed action."[170] According to the court, such requirements applied only to formal rulemakings.[171]

Demonstrating extreme deference to the agency, the court affirmed EPA's decision and soundly rejected the petitioners' attacks on the agency's science, including allegations that EPA employed an "unexplained, unacknowledged level of conservatism,"[172] and utilized "an untested, experimental approach."[173] Applying an extremely lenient standard of review, the court asserted that it "may reject an agency's choice of a scientific model 'only when the model bears no rational relationship to the characteristics of the data to which it is applied.'"[174]

C. The Expansion of *Chevron* Deference

The *Chevron* deference applicable to an agency's issuance of rules and regulations might explain the failure by courts to engage in probing review.

Resource Management Plan was not ripe for review because it could be challenged after the plan went into effect); City of San Diego v. Whitman, 242 F.3d 1097 (9th Cir. 2001) (finding that an EPA letter stating which statutory framework the agency would apply to a prospective permit was not final agency action, and therefore not subject to judicial review).

167. *Tozzi*, 271 F.3d at 311.

168. *Id.*

169. Am. Forest & Paper Ass'n v. EPA, 294 F.3d 113, 116 (D.C. Cir. 2002) (citing § 112(b) of the Clean Air Act, 42 U.S.C. § 7412(b) (2000)).

170. *Id.* at 117 n.3 (quoting Petitioner's Brief, at 45) (quotations omitted).

171. *See id.*

172. *Id.* at 121 (quoting Petitioner's Brief, at 22) (quotations omitted).

173. *Id.*

174. *Am. Forest & Paper*, 294 F.3d at 121 (quoting Nat'l Wildlife Fed'n v. EPA, 286 F.3d 554, 562 (D.C. Cir. 2002)).

Although *Christensen v. Harris County*[175] held that *Chevron* deference is ordinarily only accorded to decisions reached after formal adjudication or notice-and-comment rulemaking, the Court recently qualified that statement, explaining that "whether a court should give such deference depends in significant part upon the interpretive method used and the nature of the question at issue."[176] In *United States v. Mead Corp.*,[177] the Court had stated that "the fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position."[178]

In *Barnhart v. Walton*, the Supreme Court appeared to retreat from the implications of *Christiansen* and *Mead* by extending *Chevron* deference to a Social Security Administration position that had been formulated without formal rulemaking.[179] The Court disclaimed any general rule forbidding the application of *Chevron* deference to informal agency action.[180] At the close of its opinion, the Court espoused a fairly expansive form of deference, stating: "The [Social Security Act's] complexity, the vast number of claims that it engenders, and the consequent need for agency expertise and administrative experience lead us to read the statute as delegating to the agency considerable authority to fill in, through interpretation, matters of detail related to its administration."[181] The Court's opinion thus expanded the availability of *Chevron* deference.

Lower federal courts have accordingly proceeded to grant *Chevron* deference to informal agency action.[182] In some such cases, courts have relied on the Supreme Court's recent jurisprudence regarding *Chevron* to give excessive deference to agencies. Specifically, courts have relied on Supreme Court pronouncements regarding the importance of agency expertise to the *Chevron* deference inquiry to justify continuing the practice of excessive deference to agencies on scientific issues.[183] Thus, for example, in *Pronsolino v. Nastri*,[184] the Ninth Circuit accorded *Chevron* deference to an EPA decision to apply "total maximum daily load" ("TMDL") requirements to a particular river.[185] Accord-

175. 529 U.S. 576, 587 (2000).

176. Barnhart v. Walton, 535 U.S. 212, 222 (2002).

177. 533 U.S. 218, 226-27 (2001).

178. *Id.* at 228; *see also id.* at 226-27 ("[A]dministrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.").

179. 535 U.S. 212 (2002).

180. *Id.* at 221.

181. *Id.* at 225.

182. *See, e.g.*, Navajo Nation v. HHS, 285 F.3d 864 (9th Cir. 2002) (according *Chevron* deference to an informal agency adjudication under the Indian Self-Determination and Education Assistance Act, 25 U.S.C. § 450(f) (2000)).

183. *See Barnhart*, 535 U.S. at 225; *Mead*, 533 U.S. at 226-27.

184. 291 F.3d 1123 (9th Cir. 2002)

185. *Id.* at 1125.

ing to the court, the regulation under review "is one of numerous interwoven components that together make up an intricate statutory scheme addressing technically complex environmental issues. Confronted with an issue dependent upon, and the resolution of which will affect, a complicated, science-driven statute for which the EPA has delegated regulatory authority, we consider the EPA's interpretation . . . informative."[186] The court thus simultaneously afforded *Chevron* deference to the agency's interpretation and forewent a probing analysis of the agency's science.

Similarly, in *Robert Wood Johnson University Hospital v. Thompson*,[187] the Third Circuit upheld an HHS interpretation of the Balanced Budget Reform Act after determining that the interpretation was entitled to *Chevron* deference.[188] The court held that "[t]he broad deference of *Chevron* is even more appropriate in cases that involve a complex and highly technical regulatory program . . . which require[s] significant expertise and entail[s] the exercise of judgment grounded in policy concerns."[189] Though the court did devote some analysis to the agency's reasons for its decision, it also relied heavily on *Chevron* deference and on its finding that the statutory scheme at issue was "complex and highly technical" to conclude that the agency's interpretation was permissible.[190]

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. *Daubert* principles could easily and properly inform *Chevron* analysis without eliminating *Chevron* deference. Incorporating *Daubert*-type review would help ensure that *Chevron* is not extended beyond its intended scope.[191]

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.[192] 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.[193] In addition to carrying significant social consequences, excessive def-

186. *Id.* at 1133 (relying on *Mead*, 533 U.S. at 234); *see also id.* at 1134 ("EPA has specialized experience regarding the Clean Water Act which this court lacks.").

187. 297 F.3d 273 (3d Cir. 2002).

188. *Id.* at 282.

189. *Id.* (quotations omitted).

190. *See id.* at 282-85. *Cf.* Am. Corn Growers v. EPA, 291 F.3d 1, 17 (D.C. Cir. 2002) (Garland, J., dissenting) (relying on *Chevron* to conduct an excessively deferential analysis of EPA action and to argue that the group-BART provisions of EPA's Haze Rule were reasonable).

191. *See* discussion *infra* Part V.C. For a good example of how *Chevron* and *State Farm* may be successfully reconciled, see *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484 (D.C. Cir. 1995).

192. *See* Elliott et al., *supra* note 11, at 10,130 (comments of Alan Charles Raul).

193. *See id.* at 10,129 (comments of Alan Charles Raul) (remarking on the "fallacy of the degree of effectiveness of presidential and congressional oversight with regard to agency rulemaking," and noting

erence to agency action is fundamentally incompatible with agencies' recently articulated mandate to ensure the quality of information they disseminate.

V

PROGRESS TOWARD PROBING REVIEW OF AGENCY SCIENCE

Despite the prevailing pattern of excessive deference among the federal courts, certain judicial panels do probe agency science in a manner akin to the regulatory-*Daubert* approach advocated here.[194] The representative cases discussed below demonstrate both that *Daubert*-type review is possible and that *Daubert* principles would not impose a radical change or inject wholly unfamiliar practices into the current form of judicial review. Rather, as these cases demonstrate, regulatory *Daubert* is fully consistent with rigorous review under the APA. Notwithstanding the existing willingness of some panels to delve into science issues, consistency and predictably of review would improve if *Daubert* were incorporated in administrative law.

Although the current judicial approach to agency science has been extremely uneven, even among different panels of the same court, certain decisions have articulated and followed *Daubert*-type principles. In the particularly noteworthy decision of *Chlorine Chemistry Council v. EPA*,[195] the D.C. Circuit ruled against EPA under the SDWA because the agency did not use the best available scientific evidence as required by law.[196] The preamble to the agency's rule made it clear that the scientific evidence supported the establishment of an above-zero "maximum contaminant level goal" ("MCLG") for chloroform.[197] EPA nonetheless proceeded to set a zero threshold for this substance. The court vacated the rule, finding that the agency had acted arbitrarily and capriciously by disregarding its own scientific findings.[198] In effect, EPA's decision was vacated because it was not supported by *Daubert*-defined reliable evidence.

It should be noted that this decision construed the Safe Drinking Water Act, a statute that specifically mandated EPA to use the "best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[199] The agency had also filed a motion with the court stating that it "no longer believed that it should continue to defend its original decision."[200] It is unclear whether the court would have reached the

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that *Chevron* was founded on the assumption that agencies are politically accountable).

194. It should be noted that pre-*Chevron* judicial review of agency action was often intense. The high-water mark of such review was *Ethyl Corp. v. EPA*, 541 F.2d 1, 68 (D.C. Cir. 1976), in which Judge Leventhal asserted: "Congress has been willing to delegate its legislative powers broadly—and courts have upheld such delegation—because there is court review to assure that the agency exercises the delegated power within statutory limits." *Id*. at 86.

195. 206 F.3d 1286 (D.C. Cir. 2000).

196. *Id.*

197. *Id.*

198. *Id.* at 1290.

199. 42 U.S.C. § 300g-1(b)(3)(A) (2000).

200. Motion filed by EPA in *Chlorine Chemistry Council*, 206 F.3d 1286 (D.C. Cir. 2000) (on file with author).

same result had it not been bound to implement the best-available-science standard. Now that the OMB Data Quality Guidelines impose heightened standards for agencies, courts should consistently examine agency decisions with a level of scrutiny that comports with the best-available-science requirement. Such an approach is crucial given the indications that EPA has endeavored to dilute this requirement in its own guidelines.

A. Courts Must Review for Substantial Evidence and Reasoned Decisionmaking

Ensuring that agency decisions are supported by substantial evidence and are the product of reasoned decisionmaking is an effective means of ascertaining whether an agency relied on relevant and reliable science. Thus, in *National Lime Ass'n v. EPA*,[201] the court compelled EPA to demonstrate that the factual basis upon which the agency relied with regard to certain emissions standards was sound: "An agency's action must be upheld, if at all, on the basis articulated by the agency."[202] Agencies must demonstrate the reasonableness of their approach "with substantial evidence, not mere assertions."[203]

Agencies must also engage in reasoned decisionmaking.[204] The D.C. Circuit explicated this requirement in *Appalachian Power Co. v. EPA*,[205] in which it rejected certain growth factors EPA had generated pursuant to the Clean Air Act:

> EPA has not fully explained the bases on which it chose to use one set of growth-rate projections for costs and another for budgets, nor has it addressed what appear to be stark disparities between its projections and real world observations. With its delicate balance of thorough record scrutiny and deference to agency expertise, judicial review can occur only when agencies explain their decisions with precision, for it will not do for a court to be compelled to guess at the theory underlying the agency's action.[206]

In *Corrosion Proof Fittings v. EPA*,[207] the Fifth Circuit struck down EPA's asbestos ban, citing the agency's faulty analysis. EPA had neither considered all of the necessary evidence nor heeded the statutory language requiring the least burdensome regulation, and the agency had failed to consider the alternatives Congress set forth.[208] In light of these defects, EPA's action lacked a rea-

201. 233 F.3d 625, 635 (D.C. Cir. 2000).

202. *Id.* (quoting *State Farm*, 463 U.S. at 50) (quotations omitted).

203. Cement Kiln Recycling Coalition v. EPA, 255 F.3d 855, 866 (D.C. Cir. 2001). The bases for agency action must be both rational and supported by the record. *See* W.R. Grace & Co. v. EPA, 261 F.3d 330, 338 (3d Cir. 2001) (finding that "ordinarily we 'may not uphold the order unless it is sustainable on the agency's findings'" and conclusory findings are insufficient to establish a rational basis).

204. A study of EPA litigation found that the agency has been losing a large number of cases in recent years. EPA's failure to explain its reasoning was a key factor in the agency's losses. *EPA: Agency Loses About Half of Cases in D.C. Circuit in Recent Years*, Daily Env't Rep. (BNA), No. 103, at B-1 (May 26, 2000).

205. 249 F.3d 1032 (D.C. Cir. 2001).

206. *Id.* at 1054-55 (citations omitted).

207. 947 F.2d 1201 (5th Cir. 1991).

208. *Id.*

soned basis.[209]

Reasoned decisionmaking requires that agencies demonstrate a rational link between their decisions and the evidence.[210] In *National Mining Ass'n v. Babbitt*,[211] the D.C. Circuit invalidated as arbitrary and capricious regulations promulgated by the Office of Surface Mining Reclamation and Enforcement. Noting that "we would be obliged to defer to a reasonable agency determination of probabilities—including predictions based on its own expertise and policies—"[212] the court nonetheless found that "the government has failed to justify its presumption . . . . Indeed, the government apparently concedes that it is not supported by available science."[213] The agency itself must supply an explanation for its actions. Thus, "[when] the agency has failed . . . to explain the path that it has taken, we have no choice but to remand for a reasoned explanation for [its] conclusion."[214]

The Ninth Circuit has also struck down a regulation of the National Marine Fisheries Service when the agency failed to use the "best scientific information available," as mandated by the Magnuson-Stevens Act.[215] In *Midwater Trawlers Cooperative v. Department of Commerce*,[216] the court rejected the agency's rule because the justification published in the *Federal Register* was "devoid of any stated scientific rationale."[217] Relying on *State Farm*, the court found the agency's action arbitrary and capricious because it "was a product of pure political compromise, not reasoned scientific endeavor."[218] The court admonished that "the best available politics does not equate to the best available science as required by the Act."[219]

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209. *See id.* at 1224 ("[E]xpertise . . . is not a universal talisman affording the EPA unbridled latitude to act as it chooses."); *id.* at 1227 (commenting that EPA engaged in speculation and displayed a "cavalier attitude toward the use of its own data").

210. *See, e.g.*, Sierra Club v. EPA, 167 F.3d 658, 664 (D.C. Cir. 1999) (rejecting EPA's decision when there were discrepancies between the conclusions suggested by EPA's data and the ultimate agency decision); Am. Lung Ass'n v. EPA, 134 F.3d 388, 392-93 (D.C. Cir. 1998) (remanding due to the agency's failure to explain how the data supported the conclusion reached); Oz Tech. Inc. v. EPA, 129 F.3d 631, 635 (D.C. Cir. 1997).

211. 172 F.3d 906 (D.C. Cir. 1999).

212. *Id.* at 913.

213. *Id.* at 912.

214. Tex Tin Corp. v. EPA, 935 F.2d 1321, 1324 (D.C. Cir. 1991). In *Leather Industries of America v. EPA*, 40 F.3d 392, 400-01 (D.C. Cir. 1994), the court invalidated certain EPA "clean sludge" caps, finding that the caps set were arbitrary and not related to risk. Other caps also lacked a rational basis because the agency had provided no explanation for ignoring the information before it and instead adopting extremely conservative assumptions. *Id.* at 403. EPA "may not engage in sheer guesswork." *Id.* at 408 (citation omitted).

215. 16 U.S.C. § 1851(a)(2) (2000).

216. 282 F.3d 710 (9th Cir. 2002).

217. *Id.* at 720.

218. *Id.*

219. *Id.*

B. Agencies Must Expose Their Assumptions and Use Logically Defensible Models

To be fully accountable for their decisions, agencies must expose their assumptions and rely on logically defensible models and methodologies. The D.C. Circuit recently remanded EPA's electric generating unit growth factors and explained:

> There is no question that agency determinations based upon highly complex and technical matters are entitled to great deference. The EPA has undoubted power to use predictive models, . . . but it must explain the assumptions and methodology used in preparing the model and provide a complete analytic defense should the model be challenged.
>
> . . . The EPA's decision . . . may well have been reasonable . . . . However, there is no way for us to tell because the EPA never offered an explanation.[220]

C. Deference Must Be Balanced Against Probing Judicial Review

Several courts have also deftly articulated the conditions under which *Chevron* deference is due and the appropriate level of deference to be accorded to agency decisions. As one court recognized, "If we are to earn our keep . . . judicial deference to the agency's modeling cannot be utterly boundless."[221] Traditional deference to agency expertise should apply as long as the agency acts within delegated statutory authority, considers all relevant factors, and demonstrates a reasonable connection between the facts in the record and the agency's decision.[222] In *A.L. Pharma, Inc. v. Shalala*,[223] the D.C. Circuit, relying heavily on *State Farm*, recognized that:

> Deferring to an agency's exercise of its discretion, however, is not tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act to set aside agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. To enable us to fulfill our duty, an agency must cogently explain why it has exercised its discretion in a given manner, and that explanation must be sufficient to enable us to conclude that the agency's action was the product of reasoned decisionmaking.[224]

Courts will not simply assume, therefore, that the agency has engaged in reasoned decisionmaking. The agency must provide an explanation sufficient to withstand the court's scrutiny. In *Wyoming v. United States*,[225] for example, the Tenth Circuit found reviewable the United States Fish and Wildlife Service's refusal to allow the state of Wyoming to vaccinate elk against the brucellosis disease. Rejecting the argument that the agency had unbridled discretion to make such decisions, the court quoted a U.S. Department of the Interior opin-

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220. Appalachian Power Co. v. EPA, 251 F.3d 1026, 1035 (D.C. Cir. 2001) (citations and quotations omitted); *see also* Sierra Club v. EPA, 167 F.3d 658, 663 (D.C. Cir. 1999) (requiring EPA to demonstrate that its chosen methodology produced accurate results that supported EPA's conclusion).

221. Chem. Mfrs. Ass'n v. EPA, 28 F.3d 1259, 1265 (D.C. Cir. 1994).

222. Appalachian Power Co. v. EPA, 135 F.3d 791, 801-02 (D.C. Cir. 1998).

223. 62 F.3d 1484 (D.C. Cir. 1995).

224. *Id.* at 1491 (citations and quotations omitted).

225. 279 F.3d 1214 (10th Cir. 2002).

ion requiring that agency action be reasonable and appropriate,[226] and noted that the use of sound professional judgment was required by statute.[227] The court relied on *Overton Park*[228] for the proposition that the agency's decision was subject to "thorough, probing, in-depth review" under the APA.[229] The court could consequently compel the agency to explain the basis for its decision.[230]

The D.C. Circuit, in *NRDC v. Daley*,[231] clarified the role of *Chevron* deference in reviewing agency science when it reversed the district court's decision to uphold a fishing quota established by the National Marine Fisheries Service.[232] The appellants had challenged the Service's faulty analysis in reaching its decision. The district court perceived certain ambiguities in the governing statute, but afforded deference to the Service pursuant to step two of *Chevron*.[233] On appeal, the D.C. Circuit rejected this uncritical deference, finding instead: "This case presents a situation in which the Service's quota for the 1999 summer flounder harvest so completely diverges from any realistic meaning of the Fishery Act that it cannot survive scrutiny under *Chevron* Step Two."[234] The court observed:

> The Service resists this result by suggesting that we owe deference to the agency's scientific judgments. While this may be so, we do not hear cases merely to rubber stamp agency actions. To play that role would be tantamount to abdicating the judiciary's responsibility under the Administrative Procedure Act. The Service cannot rely on reminders that its scientific determinations are entitled to deference in the absence of reasoned analysis to cogently explain why its additional recommended measures satisfied the Fishery Act's requirements. Indeed, we can divine no scientific judgment upon which the Service concluded that its measures would satisfy its statutory mandate.[235]

Agencies cannot merely rely on *Chevron* and on assertions of scientific expertise to evade their responsibility to engage in reasoned decisionmaking.

D. Agencies Must Follow Their Own Precedent and Procedures

Courts engaging in agency science review should ascertain whether agencies have followed their own precedents and procedures. Ensuring consistency in decisions provides a valuable and effective check on the quality of agency science, without requiring judges to draw their own scientific conclusions. Thus, in

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226. *Id.* at 1236.
227. *Id.* at 1237 (citing 16 U.S.C. § 668ee(1) (2000)).
228. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 415 (1971).
229. *Wyoming*, 279 F.3d at 1238.
230. *See id.* at 1240 ("[T]he law requires answers. For instance, the FWS has never explained why the State's proposal would stand as an obstacle to the accomplishment and execution of federal objectives.") (quotations omitted).
231. 209 F.3d 747 (D.C. Cir. 2000).
232. *Id.*
233. *Id.* at 751-52.
234. *Id.* at 753.
235. *Id.* at 755-56 (citations and quotations omitted).

Troy Corp. v. Browner,[236] the D.C. Circuit invalidated as arbitrary and capricious EPA's addition of two chemicals to the Toxic Release Inventory because the listings departed from agency precedent and regulations. Similarly, in *BFI Waste Systems of North America, Inc. v. FAA*,[237] the court vacated a Federal Aviation Administration action because the agency violated its own procedures by conducting an aeronautical study without circulating notice of it and without convening with interested parties to discuss its action.[238] The agency also failed to explain its reasons for declining to follow its procedures. This unexplained failure to comply with the agency's own standards and procedures was arbitrary and capricious under the APA.[239]

VI

THE IMPACT OF REGULATORY *DAUBERT* ON JUDICIAL REVIEW OF AGENCY DECISIONS

The application of *Daubert* principles does not automatically lead to invalidation of agency decisions. Regulatory *Daubert* may actually protect agencies from capricious court rejection of agency actions. The case of *Supreme Beef Processors, Inc. v. USDA*[240] is illustrative. There, the Fifth Circuit invalidated the U.S. Department of Agriculture's ("USDA") performance standard for salmonella bacteria in meat by holding that the relevant statute regulated only the unsanitary conditions of the meat plant itself; contaminants present in raw materials were not within the statute's reach.[241] The USDA sought to bring its regulation within the ambit of the statute by arguing that the presence or absence of salmonella serves as a proxy for adulteration.[242] The court rejected this argument without a probing examination of the agency's science. In a footnote, the court appeared to dismiss the standard based largely on a casual observation that "several equivocal statements about the effectiveness of salmonella levels as a proxy for pathogen controls appear in the final rule."[243] Had the court instead engaged in a careful review of the evidence before the agency and assessed whether the agency demonstrated a rational connection between the facts found and the choice made, the performance standard may have been upheld. By providing consistent standards for judicial review, *Daubert* compels courts to focus on the quality of the agency's science, thus protecting agency decisions from invalidation through arbitrary reliance on isolated statements in an agency rule.

This principle is demonstrated in the recent case of *City of Waukesha v.*

236. 120 F.3d 277, 293 (D.C. Cir. 1997).
237. 293 F.3d 527 (D.C. Cir. 2002).
238. *See id.* at 532.
239. *Id.* at 533. The FAA's action also suffered from the additional defect that the agency's factual conclusions were not supported by substantial evidence.
240. 275 F.3d 432 (5th Cir. 2001).
241. *Id.* at 441-42.
242. *Id.* at 440.
243. *Id.* at 440 n.32.

EPA.[244] The petitioners in that case—various water utility interests—challenged EPA's regulations establishing standards for radionuclide levels in public water systems pursuant to the Safe Drinking Water Act.[245] The petitioners contended, in part, that EPA had failed to use the best available science, as required by the SDWA. The court upheld EPA's actions after engaging in a probing review to ensure that the agency's methodology and conclusions were sound. The court explained that, while deference was owed when matters were within an agency's scientific expertise, "[n]onetheless, our review must ensure that the EPA has examined the relevant data and has articulated an adequate explanation for its actions."[246] The court conducted a searching examination of the record, and found that "the agency adequately explained its reasons" for its actions,[247] "sufficiently justified its choice of model,"[248] and drew logical inferences from the evidence before it.[249] In conducting its analysis, the court did not substitute its own judgment for that of the agency, but rather recognized that when the evidence supported more than one outcome, "[t]he resolution of this contradictory data lies well within EPA's expertise."[250]

Regulatory *Daubert* would not work a radical change in the current approach to review of agency science. Rather, *Daubert* would prompt all courts to follow the lead of the many courts that have already begun to apply rigorous standards of review to agency science. *Daubert* would help overcome "extreme" deference to agency science, and would supply a framework for coherent and consistent judicial review. Regulatory *Daubert* is merely a conceptual framework for emboldening judges to examine methodologies and expose agencies' underlying assumptions and uncertainties. Given the searching review already practiced by numerous courts, regulatory *Daubert* would be a conscious—but relatively modest—effort to unify reviewing standards.

Daubert review comports with the Data Quality Guidelines' call for transparency; *Daubert* review would require agencies to disclose the bases for their decisions, as well as any underlying uncertainties. In fact, various components of the OMB Data Quality Guidelines mirror the relevance and reliability requirements of *Daubert*. OMB has defined "utility" as the usefulness of the information to potential users, and "objectivity" as ensuring that "the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."[251] Applying *Daubert* to agency actions would enable judges to review agencies' compliance with their new good-science mandate. To be effective,

244. 320 F.3d 228 (D.C. Cir. 2003).
245. 42 U.S.C. § 300f (2000).
246. *City of Waukesha*, 320 F.3d at 247 (quotations and citations omitted).
247. *Id.* at 248.
248. *Id.* at 249.
249. *Id.*
250. *Id.* at 252.
251. Information Quality Guidelines, *supra* note 52, at 370. In addition, as in *Daubert*, peer review gives rise to a presumption of objectivity or reliability under the Guidelines. *See id.* at 371.

judicial review must remain in step with evolving agency responsibilities.

A. Judges Would Continue to Defer to Reasoned Decisionmaking

Applying *Daubert* principles in the administrative law context would not empower judges to substitute their conclusions for those of agency scientists or experts. While courts may invalidate agency action that is not the product of reasoned decisionmaking, they may not dictate a conclusion not reached by the agency. In *Appalachian Power Co. v. EPA*,[252] for example, the court explained that "a reasonable prediction deserves our deference notwithstanding that there might also be another reasonable view."[253] Similarly, in *Cement Kiln Recycling Coalition v. EPA*,[254] the court vacated EPA regulations when the agency failed to consider all of the relevant factors, but noted that "it is not our place to dictate to the Agency how to account for [the additional] variables."[255]

Agencies are permitted to make "reasonable extrapolations from some reliable evidence."[256] In *1000 Friends of Maryland v. Browner*,[257] the court upheld EPA's decision that a revised motor vehicle emissions budget was adequate, and explained that, to satisfy the basis-and-purpose requirements of the APA, an agency need only "enable a reviewing court to see what major issues of policy were ventilated . . . and why the agency reacted to them the way it did."[258] When the issues before an agency are relatively concrete, and agency decisions are capable of being supported by objective scientific proof, judicial review should be at its most rigorous. In contrast, when agencies confront issues that are "elusive" or "not easily defined," review should be more deferential.[259]

B. Judges Would Serve Only as "Gatekeepers"

Judges under regulatory *Daubert* would work within the APA to assess the validity of the scientific methodologies and principles employed by agencies to reach their decisions. Under regulatory *Daubert*, it would be appropriate for a court to review the methodology adopted by an underlying scientific study. An agency decision based on a study linking PCBs to skin cancer, for example, could be challenged because of improper statistical techniques or the failure to account for obvious confounding environmental influences.

Courts would not dictate agencies' approaches, however, and would not identify specific, additional methodologies for agencies to employ. In addition, as a recent study conducted by Professors Schroeder and Glicksman analyzing federal courts' treatment of environmental policymaking found, "EPA's deci-

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252. 249 F.3d 1032 (D.C. Cir. 2001).
253. *Id.* at 1053 (quotations and citation omitted).
254. Cement Kiln Recycling Coalition v. EPA, 255 F.3d 855 (D.C. Cir. 2001).
255. *Id.* at 866.
256. Am. Trucking Ass'ns v. EPA, 175 F.3d 1027 (D.C. Cir. 1999), *rev'd in part on other grounds*, Whitman v. American Trucking Ass'ns, 531 U.S. 457 (2001).
257. 265 F.3d 216 (4th Cir. 2001).
258. *Id.* at 238 (citations omitted).
259. *See* Sinclair Broad. Group, Inc. v. FCC, 284 F.3d 148, 159 (D.C. Cir. 2002).

sions to reject data or studies based on flaws identified by the Agency were . . . immune from successful attack."[260]

C. Judges Would Not Make Policy Choices

Daubert obligates judges to scrutinize only scientific "principles and methodology, not . . . the conclusions that they generate."[261] *Daubert* does not allow judges to determine outcomes or to decide on matters of policy; it merely secures minimum standards of scientific validity.

A recent Second Circuit decision scrutinized EPA's science but respected the agency's determination on the appropriate margin of safety for phosphorus levels when limited scientific information was available.[262] The court explained:

> [R]equiring that EPA show a rigorous scientific methodology dictates one course of action as opposed to another and would effectively prevent the agency from acting in situations where action is required in the face of a clear public health or environmental danger but the magnitude of that danger cannot be effectively quantified . . . . [S]imply to reject EPA's efforts to implement the CWA because it must respond to real water quality problems without the guidance of a rigorously precise methodology would essentially nullify the exercise of agency discretion in the form of best professional judgment.[263]

In *Sierra Club v. EPA*,[264] the D.C. Circuit rejected the methodology EPA used to establish performance standards for medical waste incinerators. The court did not substitute its own standard, but instead allowed the agency to either make a new determination or explain its results. As the court explained:

> With these numbers, EPA's method looks hopelessly irrational . . . . EPA has never explained why it made sense to use the highest of its test run data to make up the gap. Nonetheless, we do not vacate the standard. It is possible that EPA may be able to explain it, and the Sierra Club has expressly requested that we leave the current regulations in place during any remand, rather than eliminate any federal control at all. We therefore remand the floor determinations for existing units for further explanation by EPA.[265]

D. Judges Would Not Exercise Scientific and Technical Expertise

Judges would examine the integrity of the scientific process, not perform scientific analyses. Notwithstanding the D.C. Circuit's decision to remand EPA's medical waste incinerator standards in *Sierra Club*, the court noted that "EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to invest resources to conduct the perfect study."[266] The D.C. Circuit has said that courts "will examine each step of EPA's analysis to satisfy ourselves that the agency

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260. Schroeder & Glicksman, *supra* note 43.
261. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 595 (1993).
262. Natural Res. Def. Council v. Muszynski, 268 F.3d 91 (2d Cir. 2001).
263. *Id.* at 103 (citations omitted).
264. Sierra Club v. EPA, 167 F.3d 658 (D.C. Cir. 1999).
265. *Id.* at 664.
266. *Id.* at 662.

has not departed from a rational course, [but] we will not take it upon ourselves, as nonstatisticians, to perform our own statistical analysis—a job more properly left to the agency to which it was delegated."[267]

In *Edison Electric Institute v. EPA*,[268] the court rejected EPA's application of a toxicity test to mineral wastes, as the court was unable to discern the requisite "rational relationship" between the scientific approach and the issue under consideration. When EPA supplied a reasonable explanation for its other actions, however, the court declined to substitute its own judgment in place of the agency's scientific expertise, stating, "[h]appily, it is not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence. Our review aims only to discern whether the Agency's evaluation was rational."[269] Indeed, Professors Schroeder and Glicksman's study of judicial review of EPA science revealed that "[e]ven in cases where courts otherwise took EPA to task, when both petitioners and the EPA produced evidence to support their positions, courts typically deferred to EPA's interpretation of the weight of the evidence rather than deciding that the petitioners' evidence was stronger than that relied on by EPA."[270]

E. Regulatory *Daubert* Would Not Impose New Procedural Obligations on Agencies

In *Vermont Yankee Nuclear Power Corp. v. NRDC*,[271] the Supreme Court held that federal courts may not require agencies to adopt particular procedures. *Daubert* review would not interfere with the procedural aspects of agency action. While courts must ensure that an agency has followed its own procedures,[272] they will not prescribe new procedures for the agency. This is clear from *State Farm*, which provides the basis for incorporating *Daubert* principles into review of agency action. There, the Court made clear that while it was setting forth the appropriate standards for judicial review, it was not imposing any specific procedures for the agency to follow in reaching its decisions.[273]

VII

CONCLUSION

The benefits of bringing *Daubert* principles into administrative law would be numerous, although the impact would not be radical. Given that the APA fully supports *Daubert*-type review, and that many courts have already incorporated the appropriate principles into their judicial review practices, regulatory *Dau-*

267. Appalachian Power Co. v. EPA, 135 F.3d 791, 802 (1998).
268. 2 F.3d 438, 446 (D.C. Cir. 1993).
269. *Id.* at 451 (citations omitted).
270. Schroeder & Glicksman, *supra* note 43.
271. 435 U.S. 519, 524 (1978).
272. *See* BFI Waste Sys. of N. Am., Inc. v. FAA, 293 F.3d 527 (D.C. Cir. 2002) (vacating an action that violated the FAA's own procedures, but not prescribing new procedures for the agency to follow).
273. *State Farm*, 463 U.S. at 50-51 (1983).

bert would introduce relatively modest reforms of the judicial review process. *Daubert*'s benefits would nonetheless be significant and would further the crucial goal of compelling agency accountability.

Junk science hurts the public. Environmental and public health protection is crucial to the well-being of the nation, but so are due process and government integrity. If agencies may justify their policy preferences based on junk science, government accountability, and perhaps even public health, might suffer gravely. Junk science can lead agencies to foist misleading remedial measures on the public, thereby diverting or misdirecting regulatory efforts from more effectively serving the public interest. Bad science is enormously costly. In remarks before the House Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs, William L. Kovacs, vice president of the U.S. Chamber of Commerce, cited examples of EPA programs that imposed billions of dollars of costs on businesses, industry, and state and local governments. After the money had been spent, it was discovered that EPA lacked the data to support the huge costs it had imposed.[274] Poor science results in tremendous misallocation of public resources.

Agencies have a duty to respect good science. If agencies cannot establish a threat to public health or the environment after applying accepted standards of scientific inquiry and evaluating the best available empirical data, they must not be allowed to compensate by manipulating either the data or the process to reach a desired outcome. Even the noblest end does not justify resort to illegitimate means.

Courts must not let agencies continue to rely upon unreliable science. Today, too many district and appellate courts allow federal agencies to base scientific judgments on unreliable or pseudo-scientific evidence because of misguided "extreme" deference to such agencies' scientific expertise. Agencies have exploited such judicial deference to conceal arbitrary judgments and default assumptions, as well as to dress up policy preferences as hard science.

Regulatory *Daubert* would promote greater regulatory accountability. It would empower federal judges to probe the scientific methodologies and principles relied on by agencies. This would require agencies to expose their judgments, assumptions, and policies to judicial scrutiny, as well as to public and congressional accountability.[275] If agencies were aware that their scientific decisionmaking would be more closely scrutinized, they would by necessity improve their decisionmaking, such as by providing better documentation of their findings and the reasons for their actions and by exposing the assumptions and uncertainties underlying their decisions.[276]

Agencies would have to follow best scientific practices. *Daubert* principles

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274. *See* Kovacs Testimony, *supra* note 14, at 11-13.

275. *See* Wagner, *supra* note 13, at 1686 ("An agency's lack of explicitness regarding the areas of scientific uncertainty . . . prevents policymakers and the public from reviewing the agency's policy judgments.").

276. *See* Elliott et al., *supra* note 11, at 10,130 (remarks of Alan Charles Raul).

would deter agencies from relying on outdated, shoddy, or goal-oriented science, such as the assumption that was struck down in *Chlorine Chemistry Council* that every carcinogen, like chloroform in that case, operates in a linear, "non-threshold" fashion.[277] Greater scientific accountability would result from *Daubert*-type scrutiny, thereby improving the quality of federal scientific decisionmaking and assuring that agencies' underlying policy choices are consistent with law and congressional intent.

Daubert would require disclosure of "fudge factors." To survive judicial review under a *Daubert* model, agencies would need to identify the most reliable and relevant science for the issue at hand, explain the reasoning behind their acceptance or rejection of such science, and expose relevant default assumptions, policy judgments, and scientific uncertainties. Professors Schroeder and Glicksman found that courts are best equipped and most willing to invalidate EPA action "in the absence of any supporting evidence [for the agency's scientific reasoning], if EPA completely failed to explain its position, if EPA's reasoning process [wa]s marred by an obvious gap in logic, or if that process [wa]s internally inconsistent or inconsistent with past practice."[278] Once an agency fully and properly disclosed its assumptions, judgments, and uncertainties, its decisions would continue to be entitled to deference. *Daubert* principles would also promote peer review by encouraging agencies to obtain critical and independent scientific evaluation of the evidence on which they intend to rely.

Daubert would promote consistency in judicial review of agency decisions by establishing a more refined, uniform mode of analysis. The current review framework of "extreme" deference that many courts apply conflicts with the more probing scrutiny of other courts. As Professor Wagner has noted in the course of her own call for reform, consistency in judicial review would promote agency efficiency.[279]

A *Daubert* framework would advance the rule of law and sound public policy, both of which are better served by the adoption of a new framework for judicial review of agency science influenced by the standards endorsed by the Supreme Court in *Daubert*, *Joiner*, *Kumho Tire*, and *Weisgram*. Applying *Daubert* principles under the Administrative Procedure Act would sharpen judicial oversight, to the benefit of the nation's regulatory decisionmaking and, therefore, to the benefit of the nation as a whole.

277. Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (D.C. Cir. 2000).
278. Schroeder & Glicksman, *supra* note 43.
279. Wagner, *supra* note 13, at 1716.