WHAT TO DO ABOUT FEDERAL AGENCY SCIENCE:
SOME DOUBTS ABOUT REGULATORY DAUBERT

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INTRODUCTION

Federal statutes, as elaborated upon by Supreme Court decisions, require federal courts to defer to agency decision making, regardless of whether the agency engaged in “formal” or “informal” rulemaking.1 In Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.,2 the Supreme Court added that deference is strongest when “[an agency] is making predictions, within its area of special expertise, at the frontiers of science[,] . . . as opposed to simple findings of fact.”3 Since that case was decided, the Court has consistently deferred to agency decisions involving technical expertise, though it has not elaborated on what one scholar refers to as Baltimore Gas’s “super deference”4 standard.5

When the Court issued Baltimore Gas in 1983, federal courts also applied a very liberal standard to the admissibility of expert testimony in civil

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1 Section 706(2)(A) of the Administrative Procedure Act lets judges intervene when a federal agency makes a decision via informal rulemaking only when a court finds that the underlying agency decision was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A) (2012). Subpart (E) adds that when an agency engages in formal rulemaking, courts may overturn its decisions only if they were not supported by substantial evidence. In practice, courts use the arbitrary and capricious standard in this context as well. Id. § 706(2)(E); Emily Hammond Meazell, Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science, 109 Mich. L. Rev. 733, 740 (2011) (“[I]n practice the two standards are largely indistinguishable for purposes of judicial review.”).


3 Id. at 103. See also Massachusetts v. NRC, 924 F.2d 311, 324 (D.C. Cir. 1991); Envtl. Def. Fund v. NRC, 902 F.2d 785, 788-89 (10th Cir. 1990); Citizens for Fair Util. Regulation v. NRC, 898 F.2d 51, 54 (5th Cir. 1990); Natural Res. Def. Council, Inc. v. EPA, 865 F.2d 1420, 1430 (9th Cir. 1988); Nat’l Wildlife Fed’n v. Hodel, 839 F.2d 694, 761 n.107 (D.C. Cir. 1988); Ohio v. NRC, 814 F.2d 258, 264-65 (6th Cir. 1987). Courts have been especially likely to rely on Baltimore Gas in cases that, like Baltimore Gas itself, involved regulatory decisions regarding nuclear power.

4 Meazell, supra note 1, at 734 (internal quotation marks omitted).

and criminal cases. Almost any qualified expert could testify on almost any subject matter within his expertise without his testimony being subject to any significant judicial scrutiny. Beginning in 1993, however, the Supreme Court, interpreting the original version of Rule 702 of the Federal Rules of Evidence, issued a series of three rulings, popularly known as the “Daubert trilogy”—Daubert v. Merrell Dow Pharmaceuticals, Inc., General Electric Co. v. Joiner, and Kumho Tire Co. v. Carmichael—each of which enunciated a reliability test for expert testimony and tightened the standards for the admissibility of expert testimony.

In 2000, an amendment to Rule 702 codified a test that allows experts to testify only when their opinions meet a stringent reliability test. The amendment states,

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
(b) the testimony is based on sufficient facts or data;
(c) the testimony is the product of reliable principles and methods; and
(d) the expert has reliably applied the principles and methods to the facts of the case.

In short, Rule 702 requires courts to subject all expert testimony in civil and criminal cases to a stringent reliability test. And the test must be applied not just to the general methodology used by the expert, but to how the expert applied his “principles and methods reliably to the facts of the case.”

Since Daubert was decided, a chorus of voices, primarily coming from attorneys who represent the interests of corporate clients, have argued that courts should apply a similarly stringent reliability test to judicial review of administrative agency actions that rely on the agency’s understanding of the relevant scientific evidence. Applying Rule 702’s standard when an ad-
ministrative agency’s reliance on science in the regulatory process is disputed in court is known by the shorthand “regulatory Daubert.”

Those who favor regulatory Daubert argue, in essence, that good science is good science, regardless of the context. Courts don’t permit plaintiffs to rely on speculative and unreliable expert scientific testimony in a toxic tort case, so courts should not allow administrative agencies to rely on similarly dubious scientific evidence in making administrative decisions. As Alan Charles Raul and Julie Zampa Dwyer, authors of the leading article advocating regulatory Daubert, put it,

[T]he same “good science” rationale [of the Daubert line of cases] 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.

Opponents of regulatory Daubert, meanwhile, object to the extension of the reliability test. Some object, at least in part, because they think judges should not apply the reliability test in any context. These critics believe that judges are not sufficiently competent to apply the test—which makes one wonder why the critics think that the next line of decision makers, lay jurors, are more competent—or that a reliability test is designed to stifle proper measures to protect the public from injuries caused by corpora-

requirements that a federal litigant is already subjected to.”); Charles D. Weller & David B. Graham, New Approaches to Environmental Law and Agency Regulation: The Daubert Litigation Approach, 30 ENVTL. L. REP. 10557 (2000) (“As a matter of policy and statutory interpretation, the Daubert reliability standard should apply to federal environmental agencies in rulemaking and adjudication.”); Andrew Trask, Comment, Daubert and the EPA: An Evidentiary Approach to Reviewing Agency Determinations of Risk, 1997 U. CHI. LEGAL F. 569, 586 (“Applying the Daubert gatekeeping function therefore allows courts to check the validity of the agency’s reasoning while maintaining the proper amount of deference to the agency’s rulemaking and adjudicative powers.”); John Dale Dunn & Steve Milloy, A Strategy to Stop EPA Science Abuse, AM. THINKER (Apr. 11, 2012), http://www.americanthinker.com/articles/2012/04/a_strategy_to_stop_epa_science_abuse.html (“There is a way to stop the EPA’s abuse of science and prevent their continued aggressive regulatory activity that destroys the economy and causes harm to Americans. . . . The method that will work is a well-established judicial and legal demand for good scientific evidence as described in the Daubert [S]upreme [C]ourt opinion . . . .”).

15 Meazell, supra note 1, at 753-54.
16 See FED. R. EVID. 702.
17 Raul & Dwyer, supra note 14, at 7.
18 Thomas O. McGarity, On the Prospect of “Daubertizing” Judicial Review of Risk Assessment, 66 LAW & CONTEMP. PROBS. 155, 156 (2003) (“Assigning a Daubert-like gatekeeper role to courts engaged in judicial review of agency risk assessments is a profoundly bad idea.”). As noted below, infra note 19, McGarity is no fan of Daubert more generally.
19 McGarity, supra note 18, at 156 (“Judges’ limited competence in areas involving scientific data and analysis, complex modeling exercises, and large uncertainties is well recognized in administrative law and has been effectively demonstrated by the courts themselves in post-Daubert toxic torts opinions.”); Wendy E. Wagner, Importing Daubert to Administrative Agencies Through the Information Quality Act, 12 J.L. & Pol.’Y 589, 599-600 (2004).
tions by making it unduly difficult for toxic tort plaintiffs to succeed. Critics also argue that regulatory *Daubert* would have an unwelcome deregulatory impact, done stealthily through judicial decision rather than as a result of legislation subject to public debate.

So, like the proponents of regulatory *Daubert*, many opponents think the courts should use the same test for reviewing agency actions based on scientific evidence as they do for the admissibility of scientific testimony in tort cases. Unlike proponents of regulatory *Daubert*, these opponents think this test should be quite lenient.

Opponents of regulatory *Daubert* have had the upper hand in judicial decisions. Courts have consistently rejected the notion that Rule 702 standards apply to judicial review of agency decision making. Likewise, federal agencies have rejected appeals to implement *Daubert*-like standards when reviewing scientific evidence. On the other hand, a few decisions, mostly from the Seventh Circuit, have invoked the *Daubert* reliability test as informing their review of agency determinations, even while acknowledging that *Daubert* itself is not binding. The Seventh Circuit decisions, however, were in the immigration and black lung context. These cases involve individualized litigation that much more closely resembles traditional common

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20 McGarity, supra note 18, at 171 (“[J]udicial adoption of regulatory *Daubert* will likely result in unconstrained regulatory policymaking by unaccountable and scientifically illiterate judges and in a much higher incidence of judicial remand of important regulations.”).

21 Id.

22 See Thomas O. McGarity & Sidney A. Shapiro, *Regulatory Science in Rulemaking and Tort: Unifying the Weight of the Evidence Approach*, 3 WAKE FOREST J.L. & POL’Y 65, 96 (2013) (“The jury is still out, so to speak, on whether the federal courts will apply divergent approaches to the evaluation of scientific evidence in regulatory and tort cases. We see no grounds for any such divergence.”).

23 Id.

24 E.g., Lobsters, Inc. v. Evans, 346 F. Supp. 2d 340, 344 (D. Mass. 2004) (“*Daubert* and its progeny interpret the Federal Rules of Evidence, however, and the federal rules of evidence do not apply to NOAA hearings.”); Stewart v. Potts, 996 F. Supp. 668, 678 n.8 (S.D. Tex. 1998) (“[Daubert] does not apply to APA review of agency action. . . . The agency in this case is the factfinder, and the Court must give a high degree of deference to its expertise.”). Another explanation stems from separation-of-powers values. See, e.g., Sierra Club v. Marita, 46 F.3d 606, 622 (7th Cir. 1995) (“While such a proposal might assure better documentation of an agency’s scientific decisions, we think that forcing an agency to make such a showing as a general rule is intrusive, undeferential, and not required.”).


26 Pasha v. Gonzales, 433 F.3d 530, 535 (7th Cir. 2005) (concluding expert should not have been permitted to testify); Rodriguez Galicia v. Gonzales, 422 F.3d 529, 539 (7th Cir. 2005) (invoking the “spirit” of *Daubert* to reason that nothing in experts’ curricula vitae indicated that they were unqualified); Niam v. Ashcroft, 354 F.3d 652, 660 (7th Cir. 2004) (“[T]he spirit of *Daubert*. . . . does apply to administrative proceedings. . . . ‘Junk science’ has no more place in administrative proceedings than in judicial ones.”); Peabody Coal Co. v. McCandless, 255 F.3d 465, 469 (7th Cir. 2001) (“An agency must *act* like an expert if it expects the judiciary to treat it as one.”); McElmurray v. U.S. Dep’t of Agric., 535 F. Supp. 2d 1318, 1325 (S.D. Ga. 2008) (“While *Daubert* does not apply to agency decisions in any formal respect, the principles underlying that decision do apply.” (citing *Pasha*, 433 F.3d at 535)).
law toxic tort litigation than the broad regulatory controversies that proponents of regulatory Daubert have in mind.

This Article sides with regulatory Daubert’s opponents, but for different reasons than the ones articulated above. Part I of this Article explains that the Daubert trilogy and Rule 702 created special rules for expert testimony to address the problem of adversarial bias—a form of witness bias that arises due to the use of adversarial experts procured and paid by the parties. A party to litigation will only present experts who that party knows in advance will support the particular positions that party is litigating. Given that expert opinion often relies to some degree on judgment rather than objective fact, there is often no way for the fact finder, a lay jury, to distinguish between sound and unsound expert testimony. The choice facing the judicial system is to let jurors unwittingly rely on testimony that may have no firmer basis than an expert witness’s say-so, or to require some objective support for expert testimony before permitting the jury to rely on it.

Part I also provides several reasons why the Daubert/Rule 702 reliability test should not be applied to judicial review of agency actions. First, requiring inexpert judges to police regulatory science as used by expert agencies is very different from requiring inexpert judges to police the testimony of adversarial experts who present their testimony to randomly selected lay fact finders—that is, jurors.

Second, “risk assessment is not a purely scientific enterprise.” A agencies are charged by Congress not only with creating and interpreting scientific evidence, but in many cases with determining what the relevant standard of proof should be. Unlike bad science, bad policy is not a Daubert issue. Judicial interference in scientific decision making by agencies risks having judges making not just evidentiary determinations about the quality of evidence presented, but intertwined policy decisions outside the scope of judicial authority.

Third, and perhaps most important, regulatory decision making has a very different context than expert witness testimony in litigation. In the latter context, the fact finder is attempting to discern what actually happened, by a preponderance of the evidence (or, in the criminal context, beyond a reasonable doubt). It makes sense in that context to ensure that decisions are based only on reliable evidence.

By contrast, in the regulatory context agencies are often asked to anticipate and preempt risks that may present themselves in the future. Undertaking a risk assessment to determine whether and to what extent to regulate a potentially harmful substance about which little is known is a far different task than trying to determine, as the tort system does, whether a specific plaintiff’s injury was caused by exposure to a particular substance. It would be inappropriate to apply Rule 702 or a similarly stringent reliability test to

27 McGarity, supra note 18, at 156.
28 Id.
agency risk assessments and other endeavors geared toward regulating prospective risks. Trying to determine the scope of a prospective risk typically requires a fair amount of speculation, and so it makes little sense to apply a test that, as we shall see, was created precisely to undermine courtroom speculation.

Part II discusses ways that we could encourage better scientific decision making without resorting to the blunt tool of regulatory Daubert. First, courts should ensure that statutes that require agencies to rely on the “best available science” are being adhered to by the agencies. Second, courts, without reviewing the substance of an agency’s decision, should require the agency to explicitly separate its policy judgments from its scientific determinations. Such transparency would have a variety of positive implications, as will be discussed below. Third, Congress could require more agency scientific determinations to be reviewed by non-agency panels and other forms of peer review. Fourth, even though regulatory Daubert should be a non-starter, Daubert-like standards should apply to expert evidence presented in administrative hearings that mimic toxic tort cases. This Article explores the latter argument through the example of causation hearings under the National Childhood Vaccine Injury Act (“Vaccine Act”).

I. WHY SPECIAL RULES FOR EXPERT TESTIMONY?

Before one discusses the desirability of applying Daubert to judicial review of agency action, one must answer the critics of regulatory Daubert who are critical of Daubert, period. As one critic poses the question, “Courts give questions to the jury if reasonable people could find for either side. Why should disagreement among scientists be the one sphere of human inquiry in which we do not let a fact-finder resolve the dispute as applied to a particular set of facts?”

Neither the Supreme Court in the Daubert trilogy nor the authors of amended Rule 702 explained the underlying rationale for the vast shift in the law of expert testimony from “let it all in” to a stringent admissibility test. In particular, they did not explain why expert testimony should be subject to a reliability test, but no other potentially dubious testimony should face the same prerequisite. The Court explicitly relied only on a rather wooden interpretation of the language of Rule 702, and the advisory

30 Until Bendectin and other “toxic tort” cases became a major issue in the mid-to-late 1980s, federal courts typically applied the Frye general acceptance only to a narrow category of forensic evidence, and beyond that had a virtually open door to any purportedly expert testimony presented by a qualified individual, with qualifications defined quite forgivingly.
committee in turn relied on the *Daubert* trilogy and follow-up opinions from lower courts.\textsuperscript{32}

I have argued that the implicit rationale for the modern special rules for expert testimony, but not for lay witnesses, is to combat “adversarial bias.”\textsuperscript{33} Adversarial bias refers to witness bias that arises because experts are retained to advance the cause of one party to an adversarial proceeding. Adversarial bias has at least three sources: (1) conscious bias; (2) unconscious bias; and (3) selection bias.\textsuperscript{34}

The problem of conscious bias is presented by “hired guns” who will adapt their opinions to the needs of the attorney who hires them. Unlike with regard to ordinary fact witnesses, attorneys can shop from an almost unlimited pool of expert witnesses. Lay witnesses can be discredited, or have their credibility challenged, by pointing out the source of their bias (such as a financial stake in the litigation, or a relationship with a party). By contrast, opposing counsel will inevitably find it extremely difficult to discredit a hired-gun expert for taking money for his testimony. After all, opposing counsel will have his own expert on his payroll. Therefore, even the conscious bias of a hired gun will likely not be brought out effectively on cross-examination.

The second type of adversarial bias is unconscious bias. As Sir George Jessel pointed out in an English judicial opinion over a century ago, “[T]here is a natural bias to do something serviceable for those who employ you and adequately remunerate you.”\textsuperscript{35}

The third type of adversarial bias is selection bias. Selection bias means that the experts retained by a party will not represent a random sampling of expert opinion. Rather, they will represent the perspective of the at-
torney wants to present at trial. Even if an attorney chooses not to solicit a venal hired gun (or can’t find one), selection bias will allow attorneys to shop for outlier experts, who because of idiosyncrasy or incompetence have views well outside those of the median expert in his field on the particular issue at hand. An issue on which there would be a strong consensus among non-adversarial experts can thus be made to appear to be a close one.

In some circumstances, the jury may not hear from any expert whose views represent mainstream expert opinion. If the range of possibilities for a question presented to the court is represented by one to one hundred, and non-partisan experts would cluster around forty-eight, the jury may only hear from one side’s experts who argue that the correct answer is between one and five, and the other side’s experts who argue that the correct answer is between ninety-five and one hundred. To the extent that the experts’ views are based on subjective opinion divorced from any objective indicia of reliability, the jury will have no way of recognizing that both sides’ experts are outliers.

The obvious solution to the problem of adversarial bias would be to replace experts chosen by adversarial parties with experts chosen by a nonadversarial party, most likely the judge. But despite recurring suggestions that the American legal system limit or even eliminate expert witnesses selected by parties to litigation, court-appointed experts have been and remain rare.

Instead, federal evidence rules evolved to demand an objective basis for opinion testimony to deal with the problems attendant to adversarial bias. As the Federal Rules of Evidence Advisory Committee Notes to amended Rule 702 state, “The trial court’s gatekeeping function requires more than simply ‘taking the expert’s word for it.’” Applying this to the context of toxic tort litigation, the language of Rule 702 requires district courts to reject expert causation testimony based on the expert’s “best guess,” because speculation is not objectively reliable. Courts regularly do exclude such evidence, though not universally; some courts express their displeasure with the trend toward strict scrutiny of expert testimony by ignoring or downplaying the rules, while others rely on cases decided before

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36 See BRUCE D. SALES & DANIEL W. SHUMAN, EXPERTS IN COURT: RECONCILING LAW, SCIENCE, AND PROFESSIONAL KNOWLEDGE 6 (2005) (“[M]any commentators have observed that lawyers often have a sufficient number of available expert witnesses to allow them to select one that will best represent a client’s partisan interests.”); Joseph Sanders, From Science to Evidence: The Testimony on Causation in the Bendectin Cases, 46 STAN. L. REV. 1, 26 n.130 (1993).

37 See generally KAYE ET AL., supra note 6, at § 11.2. (“[F]rom the later part of the nineteenth century to the present, the dominant proposed solution to the problems of adversarial experts has been to call for the use of non-adversarial experts, in order to create a nonpartisan source of expert knowledge.”).

38 Id. at § 11.2.3 (“[B]y all accounts judges exercise these powers infrequently.”).

39 FED. R. EVID. 702 advisory committee’s note.

40 Id.
Rule 702 was amended, or even cases decided before some or all of the Daubert trilogy cases were decided.  

Explaining the rationale for Rule 702/Daubert leaves open the question of whether, as advocates of a regulatory Daubert claim, one should similarly apply a reliability test to regulatory science.

Proponents of regulatory Daubert seem to believe that the basis for Rule 702 is solely or primarily a function of the desire to improve the quality of legal decision making, based on expert scientific testimony, to avoid the proliferation of so-called junk science in tort cases. Given that the legal system has determined that applying Daubert/Rule 702 will improve the quality of science used in civil tort litigation, applying a similarly strict standard to agency science would improve the quality of science utilized by agencies.

The proliferation of junk science in toxic torts and pharmaceutical cases brought the issue of expert testimony to widespread public and judicial attention, but, as discussed previously, the junk science issue cannot explain what eventually emerged. The Daubert trilogy and Rule 702 are not aimed at improving the quality of scientific evidence for tort cases in particular. Rather, they strive to ensure the reliability of all expert testimony, scientific and non-scientific, in criminal and civil cases, to deal with the issue of adversarial bias.

Proponents of regulatory Daubert would likely respond that while administrative agencies do not typically rely on adversarial expert witnesses, they have their own biases. While some scholars argue that agencies are pretty good at handling purely scientific issues, even when those issues have controversial policy implications, others believe that agencies are “captured” in a variety of ways by anti-corporate, pro-regulatory interests and skew their science to promote the ends of those interests.

Contrariwise, some scholars believe that agencies are routinely captured by the industries they are supposed to regulate. As a result, their use

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41 See Bernstein, Judicial Resistance, supra note 33, at 28.
43 See Bernstein, Expert Witnesses, supra note 33, at 463.
44 See Wendy E. Wagner, The “Bad Science” Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation, 66 LAW & CONTEMP. PROBS. 63, 72 (2003) (“[D]espite the thousands of public health and safety regulations promulgated annually, there are surprisingly few examples of EPA using unreliable science or using science inappropriately to support a final regulation.” (footnote omitted)).
of science is therefore skewed to the benefit of corporations seeking to be free from regulation, for example by choosing to rely on dubious scientific evidence presented by industry. 46 Meanwhile, some critiques of agency science focus on systematic deficits that may create random errors that do not inherently favor more or less regulation. 47

It’s not clear which of these perspectives—views that are typically based on anecdotal evidence, on a very limited set of observations that may not be generalizable, or on theoretical constructs of unknown validity—most accurately describes our regulatory process. The extent to which agency science is objective and high quality may also vary significantly from agency to agency. Indeed, it might be that objectivity and quality can vary significantly within agencies, depending on the individual scientists and administrators involved, and whether the underlying issue is a mundane one of little general interest, or one that raises ideological and political hackles.

But assume, arguendo, the scenario most helpful to advocates of regulatory Daubert—that bias in regulatory science used by agencies is pervasive, and that it overwhelmingly takes the form of agencies relying on unreliable scientific evidence to support new or stricter inefficient regulation of business. Even if so, regulatory agencies are nevertheless not subject to the specific problem addressed by Rule 702 and Daubert: having a randomly selected group of twelve inexpert, and often innumerate, lay people determine which set of adversarial experts’ testimony should be credited.

However, if regulatory Daubert were adopted, courtroom challenges to agency science under regulatory Daubert would inevitably involve adversarial experts chosen by each side. These experts are as likely to obfuscate matters further as to assist the court, and would bring all of the problems attendant to adversarial bias into judicial review of agency output.

Moreover, while judicial scrutiny of expert testimony is preferable to simply dumping a matter on a jury, there’s little reason to think that judges will make better scientific decisions than agencies. Judges may lack the institutional competence, and sufficient insulation from the political debate over the proper scope of the regulatory state, to be sound adjudicators of controversial and contested scientific conclusions arising from the regulatory process.

Another problem with regulatory Daubert is that it assumes that the underlying problem that needs to be addressed with agency decision making is with the unreliable science utilized by the agency, rather than with the


regulatory standards established by the agency. In fact, the latter is often the source of discontent with agency decision making based on science, and regulatory Daubert, construed as applying a Rule 702-like standard to judicial review of agency science, does not address the issue of the underlying regulatory standard.

Imagine, for example, if, in the toxic tort context, the jury was responsible for deciding not only whether a plaintiff met his burden of proof, but what that burden should be. Imagine, further, that many juries decided that the correct standard in toxic tort cases is that the plaintiff need only show that a not-unreasonable scientist could plausibly believe that exposure to a substance may have caused, contributed to, or aggravated a plaintiff’s condition. Complaints that these juries were relying on bad science would largely be beside the point, given that the relevant burden of proof the juries adopted virtually invites—and indeed depends on—plaintiffs to present speculation and guesswork by their experts.

Federal agencies, analogously, are charged by legislation with the responsibility to determine what level of risk needs to be shown before regulation is appropriate. As in the context of toxic tort litigation, if the decision maker, in this case the agency, has decided as a matter of policy to act on the basis of a very low standard of proof, no judicial intervention on behalf of science will be effective. As one scholar has noted, “A risk analyst can always draw a larger circle in space and time, postulate new pathways for release, measure contamination at lower levels, and raise concerns about smaller, longer-term effects among larger groups of people.”

Regulatory Daubert could lead to the exclusion of some speculative scientific information supporting a strict regulatory symptom, but could also open the door to courts second-guessing policy choices made by the agencies in the guise of seeking better science. This scenario “raises serious institutional issues not present in Daubert-style review of expert testimony in private tort litigation.”

Additionally, and contrary to the hopes of advocates of regulatory Daubert, judicial second-guessing could lead to judicial intervention causing more (or worse), rather than less (or better), regulation. It is worth remembering that judicial deference to agency decision making has long been advocated by conservatives because they perceived that liberal judges in the 1960s and 70s were unfairly second-guessing agencies to promote a liberal regulatory agenda.

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49 McGarity, supra note 18, at 156; see also SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 49-50 (1990) (stating that regulatory issues not resolvable by science itself are left to politically accountable agencies acting within the scope of their missions).
Ideological issues aside, greater judicial involvement would not necessarily improve regulatory outcomes. Thirty years ago, Peter Huber, without whitewashing the failings of agencies, made the classic case against entrusting the courts with public risk management:

The legal system has no special competence to assess and compare public risks, and the legal process is not designed or equipped to conduct the broad-ranging, aggregative inquiries on which sensible public-risk choices are built. Expert administrative agencies, troubled and erratic though they may be, remain best able to regulate public risks in a manner calculated to advance the public health and welfare.\(^\text{51}\)

The third, and likely most important, problem with applying \textit{Daubert}/Rule 702 to reviews of administrative proceedings is that administrative agencies often serve a quite different function than does the judicial system. Applying a much more lenient standard for decision making based on scientific evidence used in regulatory determinations, as opposed to causation determinations in toxic tort cases and other litigation, rests on the differing contexts. In the former, agencies seek to protect the public from potential risks that \textit{may} turn out to harm public health, while in the latter the plaintiff has the burden of showing that, in regards to a particular risk, first that a substance \textit{can} cause human harm (general causation)\(^\text{52}\) and that it \textit{did} in fact cause harm to that particular individual (specific causation).\(^\text{53}\) Otherwise, the system runs the risk of depriving someone of his or her liberty, or redistributing a defendant’s property to a plaintiff, without a sound basis for doing so.

By contrast, a substance may be classified and regulated as a carcinogen even though everyone agrees that it presents only a small, hypothetical risk to humans from chronic exposure to large amounts of the substance. Not only are administrative agencies charged with protecting the public from future risk in the face of scientific uncertainty,\(^\text{54}\) they are often explicitly required by statute to utilize a conservative standard for assessing that risk.\(^\text{55}\)

\(^\text{52}\) \textit{See}, e.g., \textit{In re} Hanford Nuclear Reservation Litigation, 292 F.3d 1124, 1133 (9th Cir. 2002) (General or generic causation involves “whether the substance at issue had the capacity to cause the harm alleged”).
\(^\text{53}\) \textit{See}, e.g., \textit{In re} Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 524 F. Supp. 2d 1166, 1172 (N.D. Cal. 2007) (“Specific causation refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance.”).
\(^\text{54}\) \textit{See} Wagner, \textit{supra} note 19, at 590 (“Regulators generally err on the side of protecting the public health and environment when crafting protective regulatory standards and do not require vigorous gate-keeping of scientific evidence . . . .”)
\(^\text{55}\) \textit{E.g.}, \textit{id.} at 594 (“Because Congress demands that EPA err on the side of protection in most statutes, EPA is legally justified, if not compelled, to place lower demands on scientific developments
In thinking about the difference between the regulatory and common-law-toxic-tort contexts, consider the issue of scientists relying on the “weight of the evidence” in making a determination of the toxicity of a substance. Of course, the act of inferring “B” from “A” while trying to reach the correct conclusion must mean that one has weighed the evidence and reached that conclusion. Utilizing weight of the evidence is only scientifically valid when a transparent and detailed explanation of exactly how each element in the body of evidence was weighed, and that explanation is grounded in a proper theory of why each element was given a particular weight.

In practice, and despite some judicial rulings to the contrary,\(^56\) this means that expert testimony based on weight of the evidence should typically be inadmissible in toxic tort litigation. Rule 702 requires exclusion of speculative testimony even when it is based on the best available evidence, and experts relying on a weight of the evidence methodology rarely, if ever, explain in detail how and why the evidence at hand leads to a conclusion of causation, beyond asking the judge to trust their judgment based on their expertise. Rule 702 is especially demanding for toxic tort experts because they must present evidence not simply that a substance may be harmful to human health, and not just that it does present a risk to human health, but that the substance in fact was more likely than not the cause of a particular plaintiff’s injury.

In the risk assessment context, meanwhile, weight of the evidence is used as shorthand for extrapolating conclusions from limited but varied data.\(^57\) Agencies relying on weight of the evidence often do not do a particularly thorough job of explaining why they reached the conclusions they did based on the available data.\(^58\) In some contexts, this may even rise to the

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\(^{56}\) E.g., Milward v. Acuity Special Prods. Group, Inc., 639 F.3d 11, 18 (1st Cir. 2011).

\(^{57}\) The EPA, for example, explains:
Judgment about the weight of evidence involves considerations of the quality and adequacy of data and consistency of responses induced by the agent in question. The weight of evidence judgment requires combined input of relevant disciplines. . . . Generally, no single weighing factor on either side determines the overall weight. The factors are not scored mechanically by adding pluses and minuses; they are judged in combination. Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,981 (Apr. 23, 1996).

\(^{58}\) See Douglas L. Weed, Weight of Evidence: A Review of Concept and Methods, 25 RISK ANALYSIS 1545, 1546–51 (2005); see also Virginia H. Dale et al., Enhancing the Ecological Risk Assessment Process, 4 INTEGRATED ENVTL. ASSESSMENT & MGMT. 306, 306 (2008) (“An approach to interpreting lines of evidence and weight of evidence is critically needed for complex assessments, and it would be useful to develop case studies and/or standards of practice for interpreting lines of evidence.”); Glenn W. Suter II & Susan M. Cormier, Why and How to Combine Evidence in Environmental Assessments: Weighing Evidence and Building Cases, 409 SCI. TOTAL ENV’T 1406, 1406 (2011) (noting that weight of the evidence evaluations are prone to arbitrariness and subjectivity). Nevertheless, federal agencies have their strong defenders with regard to their use of science. See, e.g., Stephen M. Johnson, Junking the “Junk Science” Law: Reforming the Information Quality Act, 58 ADMIN. L. REV. 37, 78
level of resulting in arbitrary and capricious rulemaking. However, to ask an agency to give specific weightings to different types of evidence and to justify those weightings as scientifically valid would often require the agency to go well beyond its knowledge.

An agency often has no choice but to rely on a certain amount of speculation based on limited data; indeed, agencies are often legally required to do so to fulfill their regulatory mandates. So long as an agency is doing the best it can with the available data, it is acting lawfully. In other words, a plausible but highly uncertain hypothesis based on the weight of the evidence is not enough to get past Daubert/Rule 702 in the toxic tort context, but it can be enough to justify agency action.

Similarly, regulatory agencies such as the EPA rely on high-dose animal studies in formulating proactive regulations, even though such testimony is regularly rejected as evidence of causation in toxic tort cases. The regulatory agencies do so not because such studies are particularly reliable, but because such studies are often the best—and perhaps the only—
evidence of human toxicity the agencies have. They are therefore willing to either adopt standards that give significant weight to animal studies, or to let experts make their best guess as to whether the animal studies speak to the safety of the agent.

Indeed, applying a strict reliability test to the science backing prospective risk regulation would practically put many agencies out of business. Courts, wary of their institutional role and the separation of powers, are highly unlikely to be that aggressive. Therefore, if courts were to adopt regulatory Daubert, it would often be applied more liberally in toxic tort cases than Rule 702 allows. These would then become “Daubert precedents” that would inevitably infiltrate toxic tort and other Rule 702 contexts as well. Ironically, then, adopting regulatory Daubert raises the substantial risk that it would not improve agency science, and it would also weaken courts’ resolve to exclude speculative science in toxic tort cases. Given that some courts have consistently looked for excuses or rationales to ignore or


64 See Robert M. Sussman, Science and EPA Decision-Making, 12 J.L. & POL’y 573, 584 (2004). The FDA, however, has recently taken a more restrictive view toward the usefulness of animal studies, at least for the purpose of evaluating health claims. Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims—Final, FOOD & DRUG ADMIN. (Jan. 2009), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm073332.htm (“FDA intends to use animal and in vitro studies as background information regarding mechanisms that might be involved in any relationship between the substance and disease. The physiology of animals is different than that of humans. In vitro studies are conducted in an artificial environment and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism that affect how humans respond to the consumption of foods and dietary substances. Animal and in vitro studies can be used to generate hypotheses, investigate biological plausibility of hypotheses, or to explore a mechanism of action of a specific food component through controlled animal diets; however, these studies do not provide information from which scientific conclusions can be drawn regarding a relationship between the substance and disease in humans.” (citation omitted)).
evade *Daubert’s* reliability test, it would be foolish for those concerned with sound science to give them a new mechanism for doing so.

II. ALTERNATIVES TO REGULATORY *DAUBERT*

   Even if regulatory *Daubert* is a dubious proposal, courts do not necessarily need to continue to engage in super-deference to agency decision making that relies on scientific and technical considerations. Below are some suggestions for alternative reforms that can be implemented or enforced by judges.

   A. Require Agencies to Rely on Truly Scientific Evidence When Required by Statute

   While agencies need not and cannot have “perfect knowledge” before they regulate, a series of federal environmental statutes, including the Clean Water Act and Clear Air Act, require that agency decisions be based on the “latest scientific knowledge” or similar language. Courts have allowed agencies to rely on deeply flawed studies when no other data are available, but “they have either ignored or overlooked the fact that such data must be ‘scientific.’” Courts could require an agency to acknowledge when it has no legitimately “scientific” data to rely upon, and figure out what the statute mandates under such circumstances. Or courts could force the agency to wait until such data are brought into existence before it acts. Regardless, enforcing the requirement that the data agencies rely on be “scientific” would be a way of improving the basis for agency decision making by relying on the requirements of the underlying statutes, rather than inappropriately importing *Daubert.*

   B. Require Agencies to Separate Their Policy Judgments from Their Scientific Judgments

   Courts should only defer to agency decision making if the agency explicitly separates its policy judgments from its scientific determinations,

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65 See generally Bernstein, *Judicial Resistance*, supra note 33 (discussing this phenomenon in great detail).
69 Suggestions for how agencies can ensure they are following scientific protocol can be found in Conrad, *supra* note 45, at 152-53.
something that agencies often fail to do.\textsuperscript{70} Informal rulemaking, in particular, allows agencies to “disguise policy determination as ‘technical’ judgments.”\textsuperscript{71} One way courts could encourage the formal separation of policy judgment from scientific determinations would be for the judiciary, led by the Supreme Court, to reverse a decades-long trend and promote formal rulemaking in place of informal rulemaking.\textsuperscript{72}

Incentivizing agencies to do so would have several positive effects. First, it would increase transparency, allowing for better oversight by Congress, and a greater ability of interested citizens to follow and potentially critique agency regulation, or lack thereof.\textsuperscript{73} Second, it would allow courts to review separately the agency’s scientific determinations and its policy decisions. Agencies are given broad discretion to interpret statutes and their own regulations, but this discretion is not unlimited. A statute that requires a relatively high level of scientific proof before regulating may not lawfully be undermined by an agency that chooses to pursue a different policy.\textsuperscript{74} Contrariwise, a statute that requires a very low threshold to trigger regulation may not be undermined by an agency that decides that the regulation fails a cost-benefit analysis when that criterion is not found in the statute.\textsuperscript{75} Segregating policy considerations would allow courts to ensure agency compliance with statutes and regulations, even while continuing to defer to the agencies on purely technical and scientific judgments.\textsuperscript{76}

\textsuperscript{70} See, e.g., BIPARTISAN POLICY CTR., IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY (2009); Nicholas A. Ashford et al., A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking, 7 HARV. ENVTL. L. REV. 297, 342 (1983) (“EPA’s formaldehyde deliberations powerfully illustrate the ease with which matters of policy may be confused with matters of science.”); Raul & Dwyer, supra note 14, at 32 (concluding that agencies should, inter alia, fully disclose their policy choices and default assumptions). For skepticism of whether such a separation can be effectively achieved with regard to the Endangered Species Act, see Katrina Miriam Wyman, Politics and Science in Endangered Species Act Listing Decisions, in INSTITUTIONS AND INCENTIVES IN REGULATORY SCIENCE, supra note 45, at 99.


\textsuperscript{72} See generally id. (advocating increased formal rulemaking, but noting that the Supreme Court has disfavored it and that no scholar has meaningfully defended it in decades).

\textsuperscript{73} See U.S. GENERAL ACCOUNTING OFFICE, GAO-01-810, CHEMICAL RISK ASSESSMENT 19 (2001) (reporting “concerns about whether the 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”); Wendy E. Wagner, The Science Charade in Toxic Risk Regulation, 95 COLUM. L. REV. 1613, 1617 (1995) (accusing agencies of exaggerating the scientific basis for their regulatory decisions to avoid accountability).


\textsuperscript{76} Of course, the risk would remain that courts would be tempted to reverse permissible policy judgments by agencies, rather than simply requiring agencies to stay within the boundaries allowed by the relevant law. See Richard J. Pierce, Jr., Two Problems in Administrative Law: Political Polarity on
Third, failing to distinguish scientific judgment from policy decisions leads to the ossification of regulatory standards. An agency banning or regulating a substance may be making a statutorily required or permitted choice to use an extremely conservative, “precautionary principle”-type standard. In such instances, in the absence of very strong affirmative evidence of safety, the regulation or ban is incontrovertible. In other cases, however, the agency may find a particular study suggesting possible human harm from exposure sufficiently troubling to require a ban or regulation. If made explicit, future developments in the scientific literature exonerating the substance could persuade the agency to change its mind.77 Relatedly, Pascual, Wagner, and Fisher have recently argued that judges can go a long way toward ensuring that agency judgments are scientifically based by requiring agencies to answer “two deceptively simple questions: (1) have the agency’s inferential methods been identified? and (2) does the agency explain how its methods are appropriate to the information on hand and how the methods support the agency’s inferences?”78

C. Require Agencies to Rely More Frequently on Outside Advice

Courts are already more likely to defer to an agency when agency outputs “have been reviewed and endorsed by science advisory panels.”79 Congress could require more agency scientific determinations to be reviewed by non-agency panels and other forms of peer review and collaborative decision making, or the president could mandate this via executive order.80 This may ultimately be of limited efficacy,81 as the special interest battle might simply move from trying to influence the agency regulatory process to trying to influence the composition and outlook of the reviewers. Nevertheless, to the extent critics are correct that certain agencies, including their scientists and policymakers, have been captured by either pro-regulatory environmental and consumer groups, or by anti-regulatory business groups, requiring more review outside of the agency would likely have at least a temporary salutary effect on the quality of the science relied upon, and sci-

the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 DUKE L.J. 300, 311 (suggesting that courts are too eager to overrule agency policy choices when they’re explicitly revealed).

77 Cf. Conrad, supra note 45, at 156-57 (criticizing agencies for making final regulations before the science is settled).

78 Pasky Pascual, Wendy Wagner & Elizabeth Fisher, Making Method Visible: Improving the Quality of Science-Based Regulation, 2 MICH. J. ENVTL. & ADMIN. L. 429, 429 (2013). A much fuller (and valuable) discussion can be found in this article.

79 Id. at 457.

80 Conrad, supra note 45, at 153-54.

81 But see BIPARTISAN POLICY CTR., supra note 70 (suggesting, inter alia, ways to improve scientific advisory boards).
entific reasoning used, by agencies. Perhaps “super-deference” could be reserved only for situations in which the agency is not serving as the only judge of its own scientific determinations.

D. Apply a Rule 702-Like Reliability Test in Circumstances that Mimic Common Law Trials

Given Rule 702’s basis in the problem of adversarial bias, one would expect that Rule 702’s standards would be most helpful to federal courts when reviewing an ALJ’s or special master’s ruling on causation of individual injury in a hearing with adversarial experts. Perhaps the clearest such situation involves claims brought under the Vaccine Act.82

Congress passed the Vaccine Act in 1986 to avert a crisis in vaccine availability in the United States.83 Thanks to personal injury lawsuits, some relying on dubious scientific evidence, and some collecting punitive damages for dubious reasons, the market for vaccines had become unstable. Many manufacturers dropped out due to an inability to obtain liability insurance.84 At the time the Vaccine Act was enacted, the United States had only one manufacturer of the polio vaccine; one manufacturer of the measles, mumps, and rubella (“MMR”) vaccine; and two manufacturers of the diphtheria, pertussis, and tetanus (“DPT”) vaccine.85 Research and development of new vaccines had virtually stopped.86

The Vaccine Act set up an administrative system, meant to streamline the adjudication and compensation process for claimants allegedly injured by vaccines, limit punitive and emotional distress damages to set predictable limits on liability, and create a compensation system funded by the industry as a whole. Not least, the Act also tried to restore some sanity and predictability to vaccine claims by taking the claims out of the common law process, where they were subject to the largely unreviewable whims of juries, and lodging them in the Department of Health and Human Services (“HHS”) through administrative proceedings.

As we have seen, when the Vaccine Act was passed, the standard evidentiary rule for expert testimony was still “let it all in.” As a result, the

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82 National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa1-300aa34 (2012). Another example is federal black lung cases. See U.S. Steel Mining Co. v. Director, Office Workers’ Comp. Programs, U.S. Dep’t of Labor, 187 F.3d 384, 388-90 (4th Cir. 1999) (holding that ALJs must ensure that evidence as “reliable, probative, and substantial” before relying on it in black lung cases (quoting 5 U.S.C. § 556(d)) (internal quotation marks omitted)).


84 Id. at 694.


86 Rutkow et al., supra note 83, at 694-95.
country was in the midst of a series of embarrassingly counter-scientific jury verdicts favoring toxic tort plaintiffs, including in vaccine cases. So moving vaccine cases away from the common law system and into an administrative context to be heard by special masters who would develop expertise in the area must have seemed like an unmitigated boon to vaccine manufacturers. Ironically, however, as the rules for the admissibility of expert testimony became increasingly strict in the common law arena, culminating in the amendments to Rule 702 in 2000, the Federal Circuit has been enforcing laxer causation standards under the Vaccine Act than pertain to evidentiary hearings under Rule 702.

As a commentator points out,

In a traditional toxic tort case, if an expert witness merely makes an educated guess (without supportive empirical data) either that a substance can cause an illness, or that it did cause illness in an individual, the legal system’s response frequently would be to rule against the claimant. The same may not be true under the vaccine compensation program.87

More specifically, federal courts reviewing common law cases “perceive expert testimony based on case reports, animal studies, analogies drawn to similar chemical agents, and differential diagnoses as providing weak support of causation in those cases. But this is exactly the type of proof relied upon in the vaccine compensation fund context to support a showing of causation.”88

The Vaccine Act established two different types of claims. The first is “Table” claims, in which a claimant can rely on a table approved by HHS showing that the injury complained of is caused by the vaccine in question, and that symptoms showed up within the relevant time frame.89 Congress expected most claims to be Table claims, and that they would be dealt with expeditiously, as minimal evidence beyond proof of a proper temporal relationship between the inoculation and the injury would be needed; in other words, Table claims relieve the plaintiff of the burden of proving causation.

As it turns out, however, known, proven side effects of vaccines are few and far between, and the Vaccine Act has primarily been used by claimants to bring more speculative claims. Indeed, 90 percent of the claims brought have been non-Table cases. Non-Table cases proceed similarly to ordinary toxic tort cases, except that the Vaccine Act requires that they be brought before a special master in an administrative proceeding, rather than as a common law case before a federal jury.

88 Id. at 401.
The Vaccine Act is silent on who has the burden of proof in non-Table cases in establishing whether a vaccine caused the injury, and what level of proof is required. In particular, should the lax standard favoring claimants that pertains in Table cases also be applied in non-Table cases, even though the rationale for the lax burden of proof in Table cases is that the causal relationship between the vaccine in question and the injury complained of within a given timeframe has been established scientifically?

For a time, the Court of Federal Claims was bound by a 1991 Federal Circuit opinion concluding that “the findings of the court” need not “meet the standards of the laboratorian,” i.e., need not be scientifically valid. In 2000, however, the chief special master, likely influenced by developments in common law toxic tort cases requiring reliable evidence of causation, issued an influential opinion in Stevens v. Secretary of the Department of Health & Human Services. Consistent with Rule 702’s focus on the importance of an objective basis for expert testimony, Stevens required “[p]roof of confirmation of medical plausibility from the medical community and literature” to establish causation.

The Federal Circuit rejected Stevens four years later in Althen v. Secretary of Health & Human Services. The court instead established a three-prong test for establishing causation, a test meant to be more favorable to the claimant. Under this test, the claimant must show by preponderant evidence that the vaccination brought about her injury by providing:

1. a medical theory causally connecting the vaccination and the injury;
2. a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
3. a showing of a proximate temporal relationship between vaccination and injury.

If [a claimant] satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.

This test, though on its face rather nonsensical, could still have been interpreted in a rigorous way, consistent with the gist of Daubert/Rule 702, if the Federal Circuit had required claimants to present the same quality of evidence common law plaintiffs must establish for causation to satisfy prongs (1) and (2). After all, Althen stated that expert opinion on causation

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92 Id. at *23.
93 418 F.3d 1274 (Fed. Cir. 2005).
must rely on “reputable medical or scientific explanation.” And indeed, some language in Federal Circuit opinions is consistent with such a requirement. The Federal Circuit has held, for example, that “the special master is entitled to require some indicia of reliability to support the assertion of the expert witness,” and that a special master did not err in using Daubert to judge causation.

Nevertheless, Althen “signaled that the special masters should err on the side of compensation and not be bound by traditional tort standards for causal proof.” The problem is that the Federal Circuit held that a speculative opinion by a qualified expert can provide the required “indicia of reliability.” For example, Althen stated that special masters may not require “objective confirmation” in the medical literature, even though this is exactly the sort of thing Rule 702 demands. The court claimed that requiring such proof would “negate the system created by Congress” through the Vaccine Act; apparently, the court concluded that the Vaccine Act was not simply supposed to make legitimate claims quicker, easier, and cheaper to resolve, but to make it easier to pass off speculation presented by an adversarial expert as a legitimate claim.

But given the Vaccine Act’s clear goal of ensuring an adequate vaccine supply by insulating manufacturers from the sort of unpredictable, speculative claims that bedeviled the industry in the 1980s, it defies reason to think that the Act was supposed to make it far

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95 Althen, 418 F.3d at 1278 (quoting Grant v. Sec’y of Dep’t of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)) (internal quotation marks omitted); Knudsen v. Sec’y of the Dep’t of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) (“sound and reliable medical or scientific explanation”).

96 Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010).

97 Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010) (“We see no legal error in the standards applied by the Special Master either in judging causation or in utilizing Daubert.”); see also Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (finding that the special master acted reasonably in using Daubert to evaluate the reliability of expert testimony); Davis v. Sec’y of Health & Human Servs., 94 Fed. Cl. 53, 66 (2010) (describing the Daubert factors as an “acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted . . . by special masters in vaccine cases”).

98 Grey, supra note 87, at 380.

99 See, e.g., Althen, 418 F.3d 1274 at 1279.

100 Id.

101 And, indeed, at least one commentator believes, wrongly, that the primary purpose of the Vaccine Act was to ensure that claimants get compensated without too much muss or fuss, and that Althen actually establishes too strict a causation standard to be consistent with the statute’s purpose. Meredith Daniels, Note, Special Masters in the National Vaccine Injury Compensation Program: Placing a Heightened Burden on Vaccine Program Petitioners by Straying from Precedent and Congressional Intent, 6 J. HEALTH & BIOMEDICAL L. 79, 81 (2010).
easier to win a non-Table claim under the Vaccine Act than it would be to succeed bringing a common law toxic tort claim with evidence of similar quality.

In Capizzano v. Secretary of Health & Human Services,102 meanwhile, the court held that the second prong of the causation test can be satisfied by “medical opinion testimony.”103 This means, in practice, speculative testimony by the claimant’s treating physician based primarily on a temporal relationship between the vaccine administration and symptoms of the injury.104 By contrast, Rule 702 is an especially strong barrier to expert testimony that relies on the post hoc ergo propter hoc (after this, therefore because of this) logical fallacy.105

Capizzano also concluded that the special master in that case had erred in not crediting “the opinions of the treating physicians who concluded that the vaccine was the cause of [the claimant’s] injury.”106 The panel was apparently oblivious to the long history of bogus medical causation claims supported by the testimony of treating physicians, and, for that matter, to the fact that treating physicians are not in an especially good position to resolve causation issues. Worse yet, courts have relied on treating physicians even when those physicians haven’t even concluded that a vaccine caused the injury in question. In at least two cases, the Court of Federal Claims held that the fact that a doctor ordered the cessation of future vaccines was sufficient evidence that the vaccine caused an injury. But the doctors may have issued those orders just in case the patient had been in-

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102 440 F.3d 1317 (Fed. Cir. 2006).
103 Id. at 1326.
104 Id. at 1325-26.
106 Capizzano, 440 F.3d at 1326; see also Zatuchni v. Sec’y of Health & Human Servs., 69 Fed. Cl. 612, 622-23 (2006) (relying heavily on the testimony of treating physicians in concluding that Vaccine Act causation had been established). A treating physician’s testimony regarding causation based on what happened to his specific patient is the equivalent of a case report, and even before the amendment to Rule 702 many common law courts held that case reports were not admissible to prove causation. See, e.g., Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1411 (D. Or. 1996) (“[C]ase reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls.”); Muzzey v. Kerr-McGee Chem. Corp., 921 F. Supp. 511, 519 (N.D. Ill. 1996) (case reports “are not reliable bases to form a scientific opinion about a causal link”); In re TMI Litig. Cases Consol. II, 911 F. Supp. 775, 801 (M.D. Pa. 1996) (excluding testimony relying on a case report and not meeting “the most basic standards of scientific validity”), aff’d, 193 F.3d 613 (3d Cir. 1999); Cavallo v. Star Enter., 892 F. Supp. 756, 765 n.18 (E.D. Va. 1995) (“[C]ase reports are not reliable scientific evidence of causation, because they simply describe[] reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.” (second alteration in original) (quoting Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995)) (internal quotation marks omitted), aff’d in pertinent part, 100 F.3d 1150 (4th Cir. 1996)).
jured by the vaccine and was sensitive to its ingredients, not because they concluded that this is most likely what happened based on sound scientific reasoning.107

To make matters even worse, the Federal Circuit continues to repeat language from a 1994 opinion stating that “determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is ‘logical’ and legally probable, not medically or scientifically certain.”108 Exactly what “legally probable” means is left to the reader’s imagination, but it seems less demanding than “more probable than not, based on objectively reliable evidence.” In fairness, however, some Federal Circuit panels enforce reasonable standards of proof when reviewing vaccine claims.109

On the other hand, some Federal Circuit panels have shown that they would not have known how to apply a reliability standard even if they wanted to. For example, in Andreu ex rel. Andreu v. Secretary of Department of Health & Human Services,110 the Federal Circuit misstated the function of the 95 percent convention used for statistical significance in medical research. The panel was confused, thinking that if a study passes the 95 percent convention that means its results represent a “near certainty.”111 In fact, the 95 percent convention means that there is only a 5 percent chance that a study result that differs from a null hypothesis does so because of random error. A “near certainty” of the absence of random error, however, does not mean that the study is correct, because it does not address the possibility of non-random error—and all observational epidemiological studies are by their nature highly imperfect and therefore have non-random errors. That is why scientists are very reluctant to draw conclusions from just one study, or to pay much heed to statistically significant but small positive results, which may simply be an artifact of undetected non-random error. The 95 percent convention, in short, does not measure whether a study’s results constitute definitive proof of whatever the study purports to show.


109 Snyder v. Sec’y of Health & Human Services, 553 Fed. Appx. 994, 1003 (Fed. Cir. 2014) (referencing Daubert and reversing a Claims Court holding attributing a claimant’s epilepsy to the DPT vaccine); LaLonde, 746 F.3d at 1340 (holding that the special master did not err in requiring the claimant to provide proof of his proposed mechanism of injury from a DPT vaccine).

110 569 F.3d 1367 (Fed. Cir. 2009).

111 Id. at 1380 (emphasis omitted) (quoting Liable v. Sec’y of Health & Human Servs., No. 98–120V, 2000 WL 1517672, at *18 (Fed. Cl. Sept. 7, 2000)) (internal quotation marks omitted).
One could argue that all would be well if Congress would simply amend the Vaccine Act to require that special masters use similar evidentiary standards in determining causation as the federal courts do in determining admissibility under Rule 702. The question is whether the problem is really the language of the Vaccine Act, or a willful opposition to meaningful scientific standards by some of the judges on the Federal Circuit. For example, a Federal Circuit opinion issued in 2006 in a case governed by Rule 702 never cited the text of Rule 702, nor, for that matter, showed an awareness that Rule 702, as amended in 2000, is the governing rule for the admissibility of expert testimony. The court cited Daubert as the last word on the scope of Rule 702, ignoring both the text of amended Rule 702 and Joiner. To justify its ruling, the court cited a pre-Daubert Eighth Circuit opinion for the proposition that inadequacies in expert testimony are a matter of weight, not admissibility. Whether the Federal Circuit’s attitude toward Rule 702 has infected its attitude toward the vaccine litigation, or vice versa, it would likely be wise to simply take non-Table cases away from the administrative process, and return them to common law litigation, where, despite some judicial resistance, Rule 702 generally serves to exclude unreliable causation evidence. Because that doesn’t seem to be in the cards, the Federal Circuit should be encouraged to apply a similarly strict causation standard in Vaccine Act cases as common law courts do to Rule 702 challenges to toxic tort cases.

CONCLUSION

It is tempting to think that because the Daubert/Rule 702 reliability test has improved the quality of expert evidence in toxic tort (and other) cases, applying that test to agency decision making would also improve the quality of scientific evidence relied upon by agencies. As this Article has shown, however, that supposition is likely wrong, because (a) there is little reason to think that courts have more institutional competence to deal with scientific issues than do agencies; (b) much of the criticism of agency reliance on science is based on the regulatory standard the agency is using, which is not a “Daubert” issue; and (c) while Rule 702 requires courts to exclude speculative evidence about past events, the regulatory mission of agencies often requires them to engage in speculation about prospective risk. Courts have other mechanisms they can use to nudge agencies toward better scientific decision making, but “regulatory Daubert” should be a non-starter. There is one major exception: because Rule 702 evolved to deal with the specific problem of adversarial bias by expert witnesses, applying

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112 Liquid Dynamics Corp. v. Vaughan Co., 449 F.3d 1209, 1220 (Fed. Cir. 2006).
113 Id.
114 Id. at 1221.
Rule 702’s reliability standards is appropriate when considering expert evidence of causation of individual injury in a hearing with adversarial experts, as in claims arising under the Vaccine Act.