

NOTES

SCIENCE, LAW, AND TRUTH: DEFINING THE SCOPE OF THE *DAUBERT* TRILOGY

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INTRODUCTION

The characteristic goals and the inherent exuberance of science generate a natural tendency toward progress and expansion.¹ That tendency finds particular expression in today's courtroom, where science offers insight into a wider array of legal disputes than at any time in the past. Experts testify "on blood, bullets, bite-marks, battered wives; on PCBs, paternity, poisons, post-traumatic stress; on radon, recovered memories, rape trauma syndrome, random-match probabilities; on psychosis, asbestosis, silicosis"²—and the list goes on. Scientific experts may comment on both civil and criminal matters, they may offer empirical or theoretical explanations, and they may speak from established or inchoate fields of inquiry. An unprecedented *quantity* of scientific evidence is available for use in American courtrooms and the *complexity* of available scientific information easily

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1 See MARIANO ARTIGAS, *KNOWING THINGS FOR SURE* 159–82 (Alan McCone Jr., trans., 2006) (seeking an explanation and description for the progress of science and concluding that both the external and internal goals of science lead to new objectifications and the extension of science to new objects of inquiry, which constitutes progress); F.A. HAYEK, *THE COUNTER-REVOLUTION OF SCIENCE* 105–16 (1952) (discussing scientific philosophy during the French Enlightenment and the material and intellectual conquest of nature which generated a spirit of scientific exuberance that has influenced generations of scientists); cf. ARTIGAS, *supra*, at 222 (asserting that scientism—a theory that claims that the methods of the physical sciences are applicable to all fields—is not dead).

2 Susan Haack, *What's Wrong with Litigation-Driven Science? An Essay in Legal Epistemology*, 38 *SETON HALL L. REV.* 1053, 1054 (2008).

exceeds the expertise that may be expected of any single individual. As a result, the assessment of scientific evidence in the courtroom has become, not surprisingly, a controversial subject in American law.

The *Daubert* trilogy³ attempts to give judges a methodology for evaluating scientific claims in the legal context. The trilogy is a series of three cases decided by the Supreme Court in the 1990s, each case dealing with some aspect of admissibility determinations for scientific evidence.⁴ The *Daubert* trilogy presents guidelines for judges to apply when determining whether scientific evidence is admissible in federal court according to the parameters set by Rule 702 of the Federal Rules of Evidence. Importantly, these cases assign the role of gatekeeper primarily to judges rather than juries when it comes to scientific evidence and testimony.⁵

The *Daubert* decisions became the subject of intense intellectual discourse from the moment they were handed down. Since that time, scholars have written extensively on the application of the *Daubert* holdings to various types of scientific and technological evidence, including historian testimony,⁶ behavioral science,⁷ forensic evidence,⁸ proof of injury in toxic tort litigation,⁹ and valuations by experts in bankruptcy proceedings.¹⁰ Some professors have directly criticized the *Daubert* decisions themselves.¹¹ Others have analyzed the integration of the trilogy with hallmarks of American justice—for example, the jury trial¹² and the adversarial process.¹³ Still other

3 *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); *Joiner v. Gen. Electric Co.*, 522 U.S. 136 (1997); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

4 See *infra* Part I (discussing the *Daubert* trilogy of cases and their holdings).

5 See *infra* note 22 for a discussion of the choice to grant the judge the authority to exclude scientific evidence from the consideration of a jury.

6 See, e.g., Maxine D. Goodman, *Slipping Through the Gate: Trusting Daubert and Trial Procedures to Reveal the 'Pseudo-Historian' Expert Witness and to Enable the Reliable Historian Expert Witness—Troubling Lessons from Holocaust-Related Trials*, 60 BAYLOR L. REV. 824, 836–39 (2008).

7 See, e.g., Mark S. Brodin, *Behavioral Science Evidence in the Age of Daubert: Reflections of a Skeptic*, 73 U. CIN. L. REV. 867, 871–97 (2005).

8 See, e.g., Paul C. Giannelli, *Ake v. Oklahoma: The Right to Expert Assistance in a Post-Daubert, Post-DNA World*, 89 CORNELL L. REV. 1305, 1316–18 (2004).

9 See, e.g., CARL F. CRANOR, TOXIC TORTS 337–70 (2006).

10 See, e.g., Stan Bernstein et al., *Squaring Bankruptcy Valuation Practice with Daubert Demands*, 16 AM. BANK. INST. L. REV. 161, 167–68, 263–65 (2008).

11 See, e.g., Andrew E. Taslitz, *Daubert's Guide to the Federal Rules of Evidence: A Not-So-Plain-Meaning Jurisprudence*, 32 HARV. J. ON LEGIS. 3, 53–56, 76–77 (1995).

12 See, e.g., Allan Kanner & M. Ryan Casey, *Daubert and the Disappearing Jury Trial*, 69 U. PITT. L. REV. 281, 291–92, 306–08 (2007).

13 See, e.g., David E. Bernstein, *Expert Witnesses, Adversarial Bias, and the (Partial) Failure of the Daubert Revolution*, 93 IOWA L. REV. 451, 487–89 (2008).

scholars have offered predictions for the future of the judiciary after *Daubert* and have advocated an expansion of independent judicial research.¹⁴

An additional dimension of the *Daubert* holdings, however, has emerged in the past five years as the *Daubert* guidelines have become influential outside of the admissibility context in which they were developed. Judges facing cases with scientific import have used *Daubert* and its progeny to establish a jurisprudential foundation for resolving science and law questions even when the admissibility context has not been specifically at issue. This expansion of the *Daubert* guidelines outside of their initial domain presents significant questions about the reach and relevance of the *Daubert* standards. Scholars have yet to debate this aspect of the *Daubert* holdings fully.

This Note will analyze the *Daubert* holdings and their recent applications in contexts outside of pure admissibility decisions. Part I will outline the *Daubert* trilogy holdings. Part II will consider the philosophical distinctions between science and law and will illustrate how these fields resist integration and must be balanced against one another in holdings like those of the *Daubert* trilogy. Parts III and IV will examine two fields into which the use of the *Daubert* holdings has expanded beyond the traditional admissibility questions that the cases themselves decided: first, the Federal Vaccine Court's recent holdings concerning a possible scientific link between autism and childhood vaccinations;¹⁵ and second, the *Kitzmiller* decision¹⁶ at the district court level, which held that creationism could not be science, based in part on criteria set forth in the *Daubert* holdings.

This Note will conclude by recommending to future courts that the *Daubert* criteria be applied only where judges must necessarily balance the weight of competing scientific claims in order to resolve a particularized legal question; the vaccine-autism cases, like *Cedillo*, provide an example of such a situation. Future courts should avoid using the *Daubert* criteria to make nonessential evaluations concerning the philosophy of science, which should appropriately be left to experts and individuals as a matter of public opinion and the democratic process. Unlike the court in *Kitzmiller*, judges should confine their role to determining distinct questions of law that are explicitly relevant to discrete legal matters.

14 See, e.g., Edward K. Cheng, *Independent Judicial Research in the Daubert Age*, 56 DUKE L.J. 1263, 1265–68 (2007).

15 *Cedillo v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010).

16 *Kitzmiller v. Dover Area Sch. Dist.*, 400 F. Supp. 2d 707, 735–36 (M.D. Pa. 2005).

I. UNDERSTANDING THE *DAUBERT* TRILOGY

The *Daubert* trilogy provides the fundamental legal framework for considering the admissibility of scientific and other technical evidence in federal courts. Understanding the law both before and after *Daubert* is essential to beginning any discussion about the scope of the *Daubert* holdings and the ways in which the application of these holdings should be expanded or limited.

A. *The Law Before Daubert*

Before the holdings in the *Daubert* trilogy of cases, federal courts in the United States had considered the admissibility of scientific evidence under the “*Frye* standard,” derived from a brief, citation-free opinion issued in 1923.¹⁷ In *Frye v. United States*,¹⁸ the U.S. Court of Appeals for the D.C. Circuit considered the admissibility of scientific testimony supporting the use of a “systolic blood pressure deception test,”¹⁹ known more commonly today as a lie detector test. At that time, the admission of systolic blood pressure tests had yet to be supported by any court.²⁰

The *Frye* case directly confronted the nebulous question of how courts should determine the accuracy and validity of scientific evidence and to what extent expert opinions should be guarded by judges and to what extent they should be available to juries. In settling this issue, the court articulated what would come to be known as the *Frye* standard, stating:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.²¹

This standard of “general acceptance” required judges to look to the scientific community as a whole in order to assess the validity of scientific evidence. Evidence was deemed to be inappropriate for juries if

17 See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 585 (1993).

18 293 F. 1013 (D.C. Cir. 1923).

19 *Id.* at 1013.

20 *Id.* at 1014.

21 *Id.*

it was not the subject of general acceptance among scientific professionals.²²

The *Frye* standard of general acceptance survived for over seventy years as the dominant, though not the only, standard for the admissibility of scientific evidence in federal courts.²³ The *Frye* standard was not without critique, however, and resistance to the standard grew over time, particularly because the test was difficult to apply and frequently generated anomalous results.²⁴ Though the *Frye* test appeared to require only a single, simple level of inquiry—that of determining “general acceptance”—in reality, the test required multiple steps of evaluation, each fraught with its own difficulties.²⁵ Courts needed to determine the proper scientific field in which to look for general acceptance.²⁶ Courts also needed to decide exactly what part of the evidence required general acceptance; was it the explanatory

22 See *id.* It is important to note that vesting oversight power in judges is not an inevitable conclusion. American law has historically struggled to allocate power between judges (who are a highly educated and professionalized class) and juries (who tend to be more representative of the majority of citizens). See John H. Langbein, *Chancellor Kent and the History of Legal Literature*, 93 COLUM. L. REV. 547, 566 (1993). Although the power differential between judges and juries is beyond the scope of this Note, it is a highly controversial subject that has divided many scholars and experts. For a critique of judicial oversight of scientific evidence, see Daniel W. Shuman & Anthony Champagne, *Removing the People from the Legal Process: The Rhetoric and Research on Judicial Selection and Juries*, 3 PSYCHOL. PUB. POL'Y & L. 242, 254–56 (1997), affirming the competency of juries for determining the reliability of expert testimony and criticizing elitist reformers who suggest that judges should perform this task. But see Andrew W. Jurs, *Science Court: Past Proposals, Current Considerations, and a Suggested Structure*, 15 VA. J.L. & TECH. 1, 28–35 (2010) (advocating the formation of a specialized science court featuring expert judges who would ensure that juries hear only the “best, legally admissible and vetted scientific evidence”).

23 *Daubert v. Merrell Dow Pharm., Inc.* 509 U.S. 579, 585 (1983). Some jurisdictions did not adopt the *Frye* test, but adhered to a “relevance test” instead. See Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 COLUM. L. REV. 1197, 1203 (1980). Under this test, only evidence deemed *relevant* to the particular case could be admitted at trial. *Id.* In practice, the relevance standard differed little from the *Frye* general acceptance standard because only information that was substantively linked to the question before the court could be deemed relevant. The determination of a valid, substantive link was largely a matter of general acceptance in the scientific community. See *id.* Said differently, “[u]nder the relevancy approach, novel scientific evidence is treated the same as other kinds of evidence. Thus, if an expert testifies that an innovative technique is valid, a court could find that evidence derived from that technique is probative.” *Id.* at 1204.

24 See Giannelli, *supra* note 23, at 1207–08.

25 See *id.* at 1208–23 (discussing the underlying decisions required in applying the *Frye* test).

26 *Id.* at 1207–10.

scientific theory behind a particular technique or merely the technique itself?²⁷ And finally, courts had to choose which type of evidence to use to determine general acceptance—expert testimony, scientific literature, judicial opinions, or some combination thereof.²⁸

By the 1970s, attacks on the *Frye* test had emerged from both courts and commentators.²⁹ Some critics said the test was too conservative because it kept out reliable scientific information that was simply too new to be generally disseminated and accepted within the scientific community.³⁰ Such an exclusion amounted to a requirement for “cultural lag” in judicial decisions, forcing courts to operate at a distance from current scientific thought and to prefer older information simply because it had been discovered earlier.³¹ The adoption of the Federal Rules of Evidence, which became effective in 1975, further challenged the *Frye* test by leading courts to question whether the new Rules required modifications to the general acceptance standard.³² Rule 702 addressed the admission of expert testimony but did not employ the phrase “general acceptance,” thereby prompting concerns over whether or not the *Frye* test had survived the passage of the Rules.³³ By 1980, the *Frye* test had splintered into several alternative interpretations applicable in different jurisdictions.³⁴ At that time, rejection of the *Frye* test became an open discussion and courts and commentators began exploring new ways to approach the admission of scientific evidence in the courtroom.³⁵

27 *Id.* at 1210–15.

28 *Id.* at 1215–19.

29 *See id.* at 1223–28 (discussing objections to the *Frye* standard).

30 *See* Steven M. Garrett, Note, *People v. Murtishaw: Applying the Frye Test to Psychiatric Predictions of Dangerousness in Capital Cases*, 70 CALIF. L. REV. 1069, 1085 (1982) (discussing critics who call the *Frye* test too conservative).

31 *See* Giannelli, *supra* note 23, at 1223–24.

32 *Id.* at 1228–29.

33 FED. R. EVID. 702 (“If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.”). The portion of the Rule following the word “otherwise” reflects post-*Daubert* amendments that codified the *Daubert* trilogy rulings; at the time of the *Daubert* decision, Rule 702 would have concluded with the word “otherwise.” *Id.* R. 702 advisory committee’s note (2000 amend.).

34 *See* Giannelli, *supra* note 23, at 1228.

35 *See id.* at 1231 (introducing a discussion of alternative proposals to the *Frye* test).

B. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*³⁶ the Court resolved the tension between the Federal Rules of Evidence and the *Frye* test by finding that the Rules had superseded *Frye*, resulting in a more inclusive and permissive standard for the admission of scientific evidence in federal court.³⁷ The *Daubert* plaintiffs were a pair of minor children born with serious birth defects who alleged through their parents in California state court that their mothers' ingestion of the drug Bendectin during pregnancy had caused their deformities.³⁸ Bendectin was a prescription anti nausea drug being marketed by Merrell Dow Pharmaceuticals, the defendant, at the time of the suit.³⁹

At the time of the suit, no scientific literature existed to suggest that Bendectin was a teratogen (an agent capable of disrupting the development of human fetuses). In fact, thirty published studies of more than 130,000 patients had found that there was no risk of birth defects from exposure to Bendectin in the womb.⁴⁰ Petitioners did not dispute this assessment but instead countered the defense's expert testimony with eight experts of their own, all of whom had concluded that Bendectin could cause human birth defects.⁴¹

In *Daubert*, the U.S. Supreme Court accepted the petitioners' assertion that the Federal Rules of Evidence had superseded the *Frye* standard that had been employed by the lower courts.⁴² Justice Blackmun, writing for the Court, characterized the backdrop of the Federal Rules of Evidence as a "permissive" one in contrast to the *Frye* rule, which he described as an "austere standard, absent from, and incompatible with, the Federal Rules of Evidence."⁴³ Despite its preference for a more liberal standard than that of the *Frye* case, Justice Blackmun's opinion nevertheless retained a significant role for the judge—that of the gatekeeper, ensuring that scientific evidence admitted in court is not only relevant, but also reliable.⁴⁴ Having made this assertion, however, Justice Blackmun offered little in the way of concrete guidance, preferring instead to outline a series of "general observa-

36 509 U.S. 579 (1993).

37 *Id.* at 589.

38 *Id.* at 582.

39 *Id.*

40 *Id.*

41 *Id.* at 583.

42 *Id.* at 587.

43 *Id.* at 589.

44 *See id.*

tions” regarding the appropriate factors that a judge may consider in determining admissibility.⁴⁵

Justice Blackmun provided a nonexhaustive list of four factors that judges may consider when deciding on the admissibility of scientific evidence: (1) whether the evidence can be and has been tested (known as falsifiability or refutability); (2) whether the evidence has been subjected to peer review and publication; (3) the known or potential rate of error for the technique or evidence seeking to be admitted; and (4) the general acceptance of the technique or evidence in the scientific community.⁴⁶ Notably, the *Frye* standard reappears in the fourth criterion. Blackmun explained that “general acceptance” is still an appropriate inquiry (though not the exclusive inquiry) because widespread acceptance in the scientific community can be indicative of reliability and because a known technique that has attracted only minimal support can be rightly viewed with skepticism.⁴⁷ Overall, the Court in *Daubert* envisioned a flexible inquiry based upon principles and methodology without regard to the particular conclusions that may be generated by scientific evidence.⁴⁸

C. General Electric Co. v. Joiner

In *General Electric Co. v. Joiner*⁴⁹ the Supreme Court addressed the question of the standard of appellate review for admissibility decisions made by courts under the new *Daubert* standard.⁵⁰ The case concerned Robert Joiner, an electrician whose work often required him to place his hands and arms into dielectric fluid that had been contaminated with polychlorinated biphenyls (PCBs), an illegal substance that was generally “considered to be hazardous to human health.”⁵¹ In 1991, Joiner was diagnosed with small-cell lung cancer and he sued the petitioners, the manufacturers of the contaminated dielectric fluid.⁵²

45 See *id.* at 593. Justice Blackmun introduced these factors by saying, “[w]e are confident that federal judges possess the capacity to undertake this review [of scientific evidence]. Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.” *Id.*

46 *Id.* at 593–94.

47 *Id.* at 594 (citing *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985)).

48 *Id.* at 594–95.

49 522 U.S. 136 (1997).

50 See *id.* at 139.

51 *Id.*

52 *Id.* The petitioners here were several corporations, though for simplicity’s sake only General Electric will be referenced in the case discussion.

Joiner conceded that he had been a smoker and had a family history of lung cancer, but he alleged that his exposure to PCBs had “promoted” his cancer, causing him to develop cancer sooner than he otherwise would have, if he would have developed it at all.⁵³ Although Joiner provided expert testimony that supported his theory of cancer “promotion” through PCB exposure, the district court ruled that the expert testimony was inadmissible, having failed to rise above the level of “subjective belief or unsupported speculation.”⁵⁴

The Eleventh Circuit Court of Appeals reversed, stating that “[b]ecause the Federal Rules of Evidence governing expert testimony display a preference for admissibility, we apply a particularly stringent standard of review to the trial judge’s exclusion of expert testimony.”⁵⁵

At the Supreme Court, both sides agreed that the standard of review for *Daubert* admissibility decisions should be abuse of discretion, but they disagreed over whether a “particularly stringent” standard of review was the same as “abuse of discretion.”⁵⁶ The Supreme Court in *Joiner* held that the appellate court had in fact applied a more stringent standard than abuse of discretion and had therefore failed to grant the trial court the deference that evidentiary decisions require.⁵⁷ The Court went on to apply the deferential abuse of discretion standard to the district court’s decision and found that the district court had been within its discretion in determining that Joiner’s expert testimony was inadmissible.⁵⁸

D. Kumho Tire Co. v. Carmichael

In 1999, the Supreme Court added again to its *Daubert* jurisprudence with a third case, *Kumho Tire Co. v. Carmichael*.⁵⁹

Patrick Carmichael initiated suit against Kumho Tire after the right rear tire of his minivan blew out while he was driving, killing one of his passengers and severely injuring others in the vehicle.⁶⁰ Carmichael claimed that the tire malfunction occurred as the result of a

53 *Id.* at 139–40.

54 *Joiner v. Gen. Electric Co.*, 864 F. Supp. 1310, 1326 (N.D. Ga. 1994), *rev’d*, 78 F.3d 524 (11th Cir. 1996), *rev’d*, 522 U.S. 136.

55 *Joiner*, 78 F.3d 524, *rev’d*, 522 U.S. 136.

56 *Joiner*, 522 U.S. at 141. The admissibility decision was outcome determinative in this case because the district court’s exclusion of Joiner’s expert testimony resulted in a grant of summary judgment to General Electric. *Id.* at 140.

57 *Id.* at 143.

58 *Id.* at 143–47.

59 526 U.S. 137 (1999).

60 *Id.* at 142.

manufacturing defect and he offered supporting testimony from an expert in tire failure, Dennis Carlson, Jr.⁶¹ Carlson conceded that the tire in question had been poorly cared for and should have been taken out of service,⁶² but he nevertheless concluded that the tire's malfunction had been caused by a manufacturing defect because it exhibited only one sign of abuse; under Carlson's visual/tactile rubric, two such signs were necessary to conclude that abuse had been responsible for the tire's failure.⁶³ Carmichael contended that Carlson's method of tire analysis was a reliable method, as evidenced by its use by other experts and by Carlson's long experience as a tire failure expert.⁶⁴ The district court agreed with Kumho, however, and excluded Carlson's testimony, relying on the *Daubert* factors to decide that Carlson's testimony was insufficiently reliable for drawing conclusions in the case.⁶⁵

The U.S. Court of Appeals for the Eleventh Circuit reversed, finding that *Daubert* only covered "scientific" evidence, not technical or specialized knowledge, and that Carlson's testimony was experiential rather than scientific within the meaning of *Daubert*.⁶⁶

In his opinion for the Supreme Court, Justice Breyer conceded that the *Daubert* opinion only referred to "scientific" knowledge.⁶⁷ He denied, however, that this limiting language served to prevent the *Daubert* criteria from being applied to other types of technical or specialized knowledge. Distinguishing between scientific and technical knowledge would be an impossible task in many instances, given that science frequently overlaps with other fields, including engineering.⁶⁸ The Court held that *Daubert's* general principles apply to all expert matters indicated by Federal Rule of Evidence 702, and wherever the

61 *Id.*

62 *See id.* at 154. The Court explained Carlson's concessions as follows:

The tire in question, the expert conceded, had traveled far enough so that some of the tread had been worn bald; it should have been taken out of service; it had been repaired (inadequately) for punctures; and it bore some of the very marks that the expert said indicated, not a defect, but abuse through overdeflection.

Id.

63 *Id.*

64 *Id.* at 156.

65 *Carmichael v. Samyang Tires, Inc.*, 923 F. Supp. 1514 (S.D. Ala. 1996), *rev'd*, 131 F.3d 1433 (11th Cir. 1997), *rev'd sub nom. Kumho Tire*, 526 U.S. 137.

66 *Carmichael*, 131 F.3d at 1435–36.

67 *Kumho Tire*, 526 U.S. at 147–48.

68 *Id.* at 148.

methods, data, principles, or application of expert testimony is called into question, the *Daubert* analysis should freely apply.⁶⁹

Although the *Kumho* decision expanded the reach of the *Daubert* guidelines, it simultaneously backed away from the *Daubert* opinion by rendering the four *Daubert* factors to a less definitive and more discretionary role.⁷⁰ Justice Breyer explained that “[*Daubert*’s] list of factors was meant to be helpful, not definitive. Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged.”⁷¹

E. Summarizing the *Daubert* Trilogy

Taken together, the three cases of the *Daubert* trilogy⁷² generated a new body of law surrounding the admission of expert testimony in federal court by replacing the old *Frye* test with a new standard derived from Rule 702. They preserved the role of judges as gatekeepers and affirmed that judicial decisions were reviewable only for abuse of discretion.⁷³ The trilogy outlined four criteria for judges to consider, but also confirmed that judges may determine how to apply these criteria by using all, some, or none of the factors listed.⁷⁴

In 2000, the *Daubert* trilogy holdings were incorporated into Rule 702 of the Federal Rules of Evidence through the following addition, shown in italics:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, *if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.*⁷⁵

II. SCIENCE V. LAW: SITUATING *DAUBERT*

Science and law are dissimilar fields that require skillful mediation in order to coexist. Understanding the friction between science

69 *Id.* at 149.

70 *See id.* at 151; Susan Haack, *Of Truth, in Science and in Law*, 73 BROOK. L. REV. 985, 990–91 (2008).

71 *Kumho Tire*, 526 U.S. at 151.

72 *Kumho Tire*, 526 U.S. 137; *Joiner v. Gen. Electric Co.*, 522 U.S. 139 (1997); *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 578 (1993).

73 *Kumho Tire*, 526 U.S. at 158; *Daubert*, 509 U.S. at 593.

74 *See* Haack, *supra* note 70, at 991.

75 FED. R. EVID. 702 (emphasis added).

and law is essential for understanding the necessity of holdings like *Daubert* for directing the resolution of legal disputes that implicate scientific ideas.

Philosophies of law and philosophies of science agree that both fields seek after a goal of truth in some form. Each field, however, approaches questions of truth differently and prioritizes the importance of truth in different ways.⁷⁶ Science searches out and makes claims about truth in the physical processes, structures, and phenomena of the natural world.⁷⁷ Science's most important goal—that which orders all other goals in the field—is to find true answers in response to questions.⁷⁸ Scientific truths in their purest form are objective and are not socially constructed; a claim possessing scientific validity will be true regardless of what the subjective beliefs of human beings might say to the contrary.⁷⁹ Science is not a time-bound field and maintains a willingness to reconsider old questions at all times.⁸⁰ And as for the foundations that produce scientific truth, these can be understood as entirely external to the process of scientific inquiry itself. Science observes and tests the natural world and attempts to discern the truth of the structures and processes that already exist

76 In an increasingly relativistic and politically correct society, the use of the word truth may make many readers squeamish. For a discussion of why the word truth should be applied to the context of this discussion and why “scare quotes” are unnecessary, see Haack, *supra* note 70, at 992–96.

77 *Id.* at 995; see also ARTIGAS, *supra* note 1, at 10 (defining experimental science as “a human activity in which we seek knowledge of nature to obtain controlled domination over it” (emphasis omitted)).

78 Haack, *supra* note 70, at 994. Despite popular portrayals, the search for scientific truth is not endless in its possibilities. See ARTIGAS, *supra* note 1, at 14 (noting that the possible truths to be uncovered by scientific inquiry fall on a spectrum ranging from near certainty with regard to observable phenomena to “mere experimental *plausibility* (as in the case of the ‘Big Bang’ model)” (emphasis added)). Nevertheless, the concept of a single law governing the entire universe is a recurring theme among philosophers of science. Compare HAYEK, *supra* note 1, at 112 (discussing the discrediting of Pierre-Simon Laplace’s world formula, which embraced the idea of a single formula capable of explaining all worldly phenomena), with EDWARD O. WILSON, CONSCIENCE 11 (1998) (urging trust in the consilience of science because the momentum of the natural world is toward conceptual unity).

79 ARTIGAS, *supra* note 1, at 111; see Haack, *supra* note 70, at 995.

80 See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596–97 (1993). This proposition should not be overstated, however, because new scientific discoveries rarely lead to the wholesale abandonment of previous theories. See ARTIGAS, *supra* note 1, at 171–72 (showing that scientific progress is accumulative rather than linear, meaning that scientific progress does not build continuously but maintains old ideas alongside new ideas even when complete reconciliation between old and new is not possible).

there, themselves operating independently from any outside scrutiny.⁸¹

Realistically, however, science is incapable of achieving the robust objectivity to which it aspires. After all, *subjective* scientists necessarily conduct the search for *objective* scientific truths.⁸² Scientists are influenced by external factors that, at the very least, direct the progress of scientific inquiry by favoring some scientific investigations over others⁸³—consider the decisive impact of government funding benefiting military defense research. Evidence is rarely available in perfect form, both because evidence can be imprecise, incomplete, and difficult to analyze, and also because evidence gathering generally relies on the use of other imperfect instruments, including outside scientists with varying degrees of integrity conducting work at great distances.⁸⁴ Because evidence rarely establishes a proposition definitely, scientists must rely on consensus as a measure of a claim's validity,⁸⁵ but "consensus," like "acceptance," is a sociological concept indicating scientists' agreement; it is a measure of objective scientific correctness filtered through the subjective evaluations of individual scientists.⁸⁶ Most importantly, science cannot be divorced from the philosophical assumptions that constitute its foundation. For example, the assumption that nature can be rationally understood is essen-

81 See Haack, *supra* note 70, at 995 ("To be sure, scientific claims and theories come into being as the result of scientists' intellectual work . . . , [b]ut it is not scientists' intellectual work, but the nature of the phenomena and events in the world that those claims and theories describe, that makes those scientific truths *true*."). Some scholars have argued even more radically for divorcing the study of science from any internal controls that might be imposed by human beings. See, e.g., PAUL FEYERABEND, *AGAINST METHOD* 17–22 (1975) (introducing his argument in favor of "epistemological anarchism" in the sciences and advocating the abandonment of theoretical strictures imposed on scientific investigation—including the strictures imposed by the scientific method—so as to promote freedom of inquiry and the humanitarian goals of liberty in the sciences).

82 See Haack, *supra* note 70, at 995.

83 See ARTIGAS, *supra* note 1, at 9 (discussing externalism, the sociological understanding that science is affected by social, economic, and political circumstances).

84 See Haack, *supra* note 70, at 996; see also ARTIGAS, *supra* note 1, at 94–96 (discussing the essential role of experimental laws to the process of evidence gathering, but noting that experimental laws themselves contain theoretical terms and are not exact translations of the laws of nature).

85 Haack, *supra* note 70, at 997.

86 ARTIGAS, *supra* note 1, at 124–26 (discussing John Ziman's theories of the social dimensions of science and noting the importance of the scientific community in filtering information toward the establishment of a consensus of rational opinion).

tial to the pursuit of scientific knowledge, but is not a universally accepted proposition.⁸⁷

The law, like science, concerns itself with the pursuit of true answers, but it does so according to a different set of priorities and foundational authorities.⁸⁸ The law will frequently prioritize other considerations above the notion of pure factual truth. For example, judges may employ outright legal fictions in order to avoid factual realities.⁸⁹ Similarly, the desire to determine the truth of a defendant's transgression is regularly subordinated to the preservation of that defendant's constitutional rights.⁹⁰ And unlike science, which looks to external evidence to determine truth, the law determines truth partly according to its own foundational assertions of what the truth is or ought to be. Laws establish the parameters of truth for legal decision-making, but they do so only for a particular time and place; laws can be changed, creating a new legal truth that applies to a new time and place.⁹¹ A similar situation arises when courts are

87 Historically, cultures that do not accept this fundamental premise that nature behaves rationally have been incapable of, or at least disinterested in, supporting a robust scientific field. See *id.* at 177 (discussing the “still-births” of science in other cultures). It is important to note here that the law also proceeds from philosophical foundations. *E.g.*, ARISTOTLE, POLITICS bk. 4, pt. 11 (Benjamin Jowett trans., Oxford Univ. Press 1905) (n.d.) (discussing the best governance system for reconciling opposing social classes); THE FEDERALIST NO. 10, at 44 (James Madison) (George W. Carey & James McClellan eds., 2001) (stating that the principle task of modern legislation is to regulate various factions, including factions based on property ownership).

88 Objectivity is not the exclusive domain of science—it is also a foundational priority of the American legal system. THE FEDERALIST NO. 10, *supra* note 87, at 44 (James Madison) (“No man is allowed to be a judge in his own cause; because his interest would certainly bias his judgment, and, not improbably, corrupt his integrity.”).

89 *Cf.* *Summers v. Tice*, 199 P.2d 1, 3 (Cal. 1948) (“[W]here a group of persons are . . . engaged in the use of firearms, and two of them are negligent in firing in the direction of a third person who is injured thereby, both of those firing are liable for the injury suffered by the third person, although the negligence of only one of them could have caused the injury.”).

90 *Cf.* *Mapp v. Ohio*, 367 U.S. 643 (1961) (holding that the exclusionary rule, which prohibits the use of evidence obtained in violation of a defendant's constitutional rights, applies to the states through the Due Process Clause of the Fourteenth Amendment).

91 For example, it is true that in Ohio any person “recklessly caus[ing] the death of another or the unlawful termination of another's pregnancy” is guilty of a third degree felony. OHIO REV. CODE ANN. § 2903.041 (LexisNexis 2004). This is not true because of some independent and observable process, but because the Ohio state legislature has acted to set this definition and thereby make it true. This definition is true within the jurisdiction of Ohio at the present time, but its truth could be modified by the legislature at a later date, thereby altering the truth of the law through

bound to follow prior decisions—judges participate in the creation and clarification of legal truths that will govern subsequent matters, thereby altering the truth of the legal landscape according to their inquiry.⁹²

All of this is not to say that truth does not matter to the law; in fact, the law wants something more than simple, speedy resolutions. The law seeks *just* resolutions and “substantial justice requires factual truth.”⁹³ The law relies on scientific and technical experts to shed light on the factual truths behind legal disputes. Unfortunately, the adversarial system tends to have the perverse effect of encouraging lawyers to seek radical experts who are willing to assert the most confident conclusions based on the least convincing evidence.⁹⁴ Expert testimony is essential, but determining how to use such testimony is fraught with difficulty.⁹⁵

The *Daubert* guidelines attempt to reconcile the divergent priorities and foundations of science and law by generating the balance contemplated by those Federal Rules of Evidence, “designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.”⁹⁶ Still, the *Daubert* trilogy itself admits that the guidelines are flexible lines of inquiry and not firmly established principles by which all scientific testimony can be evalu-

legal action so that a new truth would prevail. See Haack, *supra* note 70, at 1005 (“[L]egal truths are not exactly like, say, the truths of physics, but are more like social-scientific truths. Truths to the effect that the law is thus and so have to be understood to be specific to a jurisdiction and to a time And what makes it true that the law in such-and-such a jurisdiction at such-and-such a time is thus and so is what legislators and courts do.”).

92 See 1 WILLIAM BLACKSTONE, COMMENTARIES *69 (“For it is an established rule to abide by former precedents, where the same points come again in litigation . . . as also because the law in that case being solemnly declared and determined, what before was uncertain, and perhaps indifferent, is now become a permanent rule, which it is not in the breast of any subsequent judge to alter or vary from, according to his private sentiments: he being sworn to determine, not according to his own private judgment, but according to the known laws and customs of the land; not delegated to pronounce a new law, but to maintain and expound the old one.”).

93 Haack, *supra* note 70, at 986.

94 *Id.* at 1002 (“[T]he legal process can sometimes create spurious, artificial scientific certainty, and spurious, artificial scientific doubt.”). For a related conclusion drawn from an analysis of popular film portrayals of scientific evidence in the courtroom, see David S. Caudill, *Idealized Images of Science in Law: The Expert Witness in Trial Movies*, 82 ST. JOHN’S L. REV. 921, 949 (2008), which states, “Judges and jurors who do not recognize the limitations on the cultural authority of science may alternatively accept the unreliable testimony of experts who claim certainty, and reject the reliable testimony of experts who concede their uncertainties.”

95 See Haack, *supra* note 70, at 986–87.

96 *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

ated.⁹⁷ District court judges are not responsible for arriving at indisputably accurate decisions, but only for rendering decisions within the realm of their judicial discretion.⁹⁸ This situation does little to shed light on when and how the *Daubert* guidelines should be applied. The two case studies that follow will illustrate the limits of the *Daubert* guidelines and the appropriate circumstances in which those guidelines should apply.

III. THE FEDERAL VACCINE COURT AND THE *DAUBERT* GUIDELINES

In 1986, Congress passed the National Vaccine Injury Compensation Act,⁹⁹ which created the National Childhood Vaccine Injury Compensation Program (VICP),¹⁰⁰ a distinct adjudicative system to handle claims against vaccine manufacturers for injuries allegedly resulting from vaccinations. Initially, the VICP covered vaccinations for seven diseases,¹⁰¹ but coverage has since been extended to cover vaccinations for an additional eight diseases.¹⁰² Under the VICP, all claims against the manufacturers of vaccines for the covered diseases must be filed with the U.S. Court of Federal Claims, where the Office of Special Masters (created by the VICP) will appoint a Special Master to function as a trial judge over the vaccine injury proceedings.¹⁰³ Petitions are also served upon the Secretary for Health and Human Services, who then replaces the vaccine manufacturer as the defendant in the case.¹⁰⁴ Proceedings decided by the Special Master can be appealed to the U.S. Court of Appeals for the Federal Circuit and ultimately to the U.S. Supreme Court.¹⁰⁵

97 See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999) (applying the abuse of discretion standard for appellate review of admissibility decisions by a lower court).

98 See *Joiner v. Gen. Electric Co.*, 522 U.S. 136, 143 (1997).

99 Pub. Law No. 99-660, 100 Stat. 3755 (1986) (codified as amended in scattered sections of 42 U.S.C.).

100 *Id.* § 2110, 100 Stat. at 3758–84 (codified as amended at 42 U.S.C. § 300aa-10 (2006)).

101 These diseases are diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio. Office of Special Masters, *Vaccine Program Background*, U.S. C. OF FED. CLAIMS [hereinafter *Vaccine Program Background*], <http://www.uscfc.uscourts.gov/sites/default/files/vaccine.background.2010.pdf> (last visited May 26, 2011).

102 The additional diseases are hepatitis B, hemophilum influenza type b (Hib), varicella (chicken pox), rotavirus, human papillomavirus (HPV), hepatitis A (HAV), meningococcal vaccines (MCV4 and MPSV4), and pneumococcal conjugate (PCV7). *Id.* at 1.

103 *Id.*

104 *Id.*

105 *Id.* at 2.

The VICP streamlines the normal process for determining causation in tort claims by providing two ways for a petitioner to prove causation of a vaccine injury. The first method allows a petitioner to use the Vaccine Injury Table to prove causation.¹⁰⁶ Establishing the conditions required by the Vaccine Injury Table creates a *rebuttable* presumption of causation; the respondent can still present evidence proving that the injury in a particular case was more probably the result of a nonvaccination factor.¹⁰⁷ If the petitioner's injury does not appear on the Vaccine Injury Table or if the circumstances of the injury differ from those indicated in the Table, the petitioner may nonetheless pursue the claim, although the petitioner will have to establish actual causation in such a case.¹⁰⁸

The VICP funds its administration and its awards through an excise tax, established by the Act and imposed on each dosage of vaccine sold. The proceeds from the tax are held in trust to pay for the administration of the VICP and to pay awards for successful injury claims.¹⁰⁹ The VICP allows for calculations of damages that include past and future medical treatment, rehabilitation, therapies, special education, and lost earnings. Compensation for pain and suffering is capped at \$250,000 and vaccine-related deaths receive a \$250,000 award.¹¹⁰ The largest award granted to date totaled \$9.1 million.¹¹¹

In 1998, British scientist Dr. Andrew Wakefield published a report in the scientific journal *The Lancet* presenting evidence that suggested a link between autism and the measles, mumps, and rubella (MMR) vaccination.¹¹² Wakefield's article sparked a persistent controversy over the existence of a link between autism and the MMR vaccine and led to a precipitous decline in the number of parents choosing to vaccinate their children for MMR.¹¹³ Although subse-

106 *Id.* ("The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed period of time following vaccination, create a rebuttable presumption of causation.").

107 *Id.*

108 *Id.*

109 *Id.*

110 *Id.*

111 *Id.*

112 A.J. Wakefield et al., *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 LANCET 637 (1998).

113 Brian Deer, *Hidden Records Show MMR Truth*, SUNDAY TIMES (LONDON), Feb. 8, 2009, http://www.timesonline.co.uk/tol/life_and_style/health/article5683643.ece ("[Wakefield's] paper triggered a public health crisis. In Britain, immunisation rates collapsed from 92% before the Lancet paper was published, to 80% at the peak of Britain's alarm."); see also Arthur Allen, *In Your Eye, Jenny McCarthy*, SLATE (Feb. 12, 2009), <http://www.slate.com/id/2211156> ("An outbreak of 135 cases of measles

quent scientific studies failed to corroborate Wakefield's findings and although Wakefield's work came under fire for being methodologically and ethically problematic, the parental concerns induced by the paper were difficult to overcome.¹¹⁴ Concerns over the potential link between vaccines and autism prompted thousands of families to file suit under VICP. As of March 2010, 13,330 cases had been filed with the U.S. Court of Special Claims, Office of Special Masters; 5,617 of those claims concerned vaccination links with autism.¹¹⁵

In order to proceed with the resolution of the overwhelming number of autism-related claims (referred to collectively as the Omnibus Autism Proceeding),¹¹⁶ the Office of Special Masters (OSM) conducted a series of meetings with the Petitioners' Steering Committee (PSC), a body composed of counsel representatives for many VICP petitioners bringing autism-related claims.¹¹⁷ The PSC presented three theories of autism causation to the OSM,¹¹⁸ which then requested the PSC to designate three "test cases" for each theory of autism causation (nine test cases in total).¹¹⁹ The OSM appointed a special master to hear each case and render a decision on the particular theory being advanced in support of an autism-vaccination link.¹²⁰

around the United States [in 2008]—the biggest in a decade—began in unvaccinated children.”).

114 Deer, *supra* note 113; see also Liza Gross, *A Broken Trust: Lessons from the Vaccine-Autism Wars*, PLOS BIOLOGY, 7 (2009), <http://www.pubget.com/paper/19478850> (discussing the work of Susan Kaufman, a medical anthropologist who has conducted research investigating why parents persistently believe in the autism-vaccine link despite contrary scientific evidence).

115 *Vaccine Program Background*, *supra* note 101, at 2.

116 For a summary of the history of the Omnibus Autism Proceeding, see *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *8–9 (Fed. Cl. Feb. 12, 2009).

117 See Autism General Order #1 at 1–2, *In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder*, Autism Master File (Fed. Cl. July 3, 2002), [hereinafter Autism General Order #1], available at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf>; Office of Special Masters, *The Autism Proceedings*, U.S. Ct. FED. CLAIMS, 1, http://www.uscfc.uscourts.gov/sites/default/files/autism.background.2010_0.pdf (last visited May 10, 2011) [hereinafter *The Autism Proceedings*].

118 The Office of Special Masters described the three theories of “general causation” as follows: “(1) that MMR vaccines and thimerosal-containing vaccines can combine to cause autism; (2) that thimerosal-containing vaccines can alone cause autism; and, (3) that MMR vaccines alone can cause autism.” *The Autism Proceedings*, *supra* note 117, at 1. The PSC dropped the third theory of general causation after the evidence supporting it was largely presented at the first hearing for the first theory of general causation. *Id.*

119 *Id.*

120 *Id.*

The hearings concerning the PSC's first theory of general causation took place in 2007.¹²¹ The special masters issued decisions in these cases in February 2009 and all three cases were either affirmed or denied review by the U.S. Court of Federal Claims.¹²² Hearings have taken place in the three test cases representing the second theory of autism causation, but decisions in those cases are still pending.¹²³

The three autism test cases, *Cedillo v. Secretary of Health & Human Services*,¹²⁴ *Hazlehurst v. Secretary of Health & Human Services*,¹²⁵ and *Snyder v. Secretary of Health & Human Services*,¹²⁶ respectively, present ideal opportunities for the application of the *Daubert* criteria because the central issue in all three cases is one centered solely on the reliability of scientific evidence.¹²⁷ Although admissibility standards are not specifically at issue in the autism cases, the legal inquiry essentially serves the same purpose; the special masters heard scientific evidence and had to determine the reliability of that evidence in order to weigh the likelihood of a scientific link between vaccines and autism.¹²⁸ The *Daubert* guidelines assist judges in determining the relevance and reli-

121 *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332258 (Fed. Cl. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), *review denied*, 88 Fed. Cl. 706 (2009).

122 *See supra* note 118 (indicating subsequent history of Special Masters' decisions).

123 The three test cases for the second theory of autism causation are *King v. Health & Human Servs.*, No. 03-589V, *Mead v. Health & Human Servs.*, No. 03-215V, and *Dwyer v. Health & Human Servs.*, No. 03-1202V. *The Autism Proceedings, supra* note 117, at 2.

124 2009 WL 331968.

125 2009 WL 332258.

126 2009 WL 332044.

127 Joëlle Anne Moreno, *It's Just a Shot Away: MMR Vaccines and Autism and the End of the Daubertista Revolution*, 35 WM. MITCHELL L. REV. 1511, 1517-18 (2009) ("The new Federal Vaccine Court cases raise 'science and law' concerns because the special masters evaluated complex and competing scientific claims and resolved science-based questions of global significance.").

128 *See id.* at 1514-15 (discussing the amount and the nature of the scientific evidence heard by the special masters in the autism cases).

ability of scientific evidence;¹²⁹ these were the central tasks confronting the special masters in *Cedillo*, *Hazlehurst*, and *Snyder*.¹³⁰

The three vaccine-autism cases considered a vast amount of scientific information, far more than what would normally be included in a case litigated under the VICP. The *Cedillo* case alone included 658 medical articles admitted as evidence.¹³¹ The three cases together included 939 medical articles, 5,000 pages of transcript, 700 pages of post-hearing briefs, fifty expert reports, and twenty-eight separate testimonies of expert witnesses.¹³² The volume of information, the complexity of claims, and the scope of the decisions in these cases is too vast to permit an examination of each one here; *Cedillo* will represent the three test cases for purposes of this discussion.¹³³

Michelle Cedillo was born on August 30, 1994 and showed generally normal patterns of development throughout the first sixteen months of her life.¹³⁴ Michelle received all of the recommended childhood vaccinations during those sixteen months, including several containing the mercury-based preservative called *thimerosal*.¹³⁵ On December 20, 1995, Michelle received her MMR vaccination during a pediatric appointment.¹³⁶ Records from her next pediatric visit about three weeks later indicated that Michelle had been experiencing a series of symptoms since the December visit.¹³⁷ Her eighteenth-month “well check” records indicate no major health problems, but noted that Michelle had been speaking less since having been ill in January.¹³⁸ Michelle’s next appointment was in early 1997. By that time, her development was clearly abnormal and in July she received a

129 *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993) (“[U]nder the [Federal] Rules [of Evidence] the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”).

130 *Moreno*, *supra* note 127, at 1526–27 (“In each of the three cases, the special masters carefully considered a vast quantity of complex scientific information and the resulting lengthy discussions are replete with detailed assessments of the scientific validity of each competing theory and claim.”).

131 *The Autism Proceedings*, *supra* note 117, at 1. The general causation testimony in *Cedillo* was applied to *Hazlehurst* and *Snyder*, thus explaining the larger number of articles considered in that case.

132 *Id.*

133 *Cedillo* is an obvious choice because it was more extensively litigated, serving as a reference point for general causation issues raised in both *Hazlehurst* and *Snyder*.

134 *Cedillo v. Sec’y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968, at *4 (Fed. Cl. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010).

135 *Id.*

136 *Id.*

137 *Id.* at *5.

138 *Id.*

diagnosis of “autism disorder.”¹³⁹ Michelle also struggled with chronic gastrointestinal problems, for which she received several diagnoses of various problems at different times.¹⁴⁰

Michelle’s parents, petitioners in the case, did not allege that Michelle had suffered a “Table Injury” but contended instead that Michelle’s gastrointestinal problems and her autism were the result of thimerosal-containing vaccines and the MMR vaccine, all of which Michelle received in the first two years of her life.¹⁴¹ The special master in the case summarized the petitioners’ causation theory as follows:

- (1) The thimerosal-containing vaccines that Michelle received during her first 16 months of life weakened her immune system.
- (2) That weakening of the immune system allowed the measles virus contained in the MMR vaccine to persist within Michelle’s body.
- (3) The persisting vaccine-strain measles virus damaged Michelle’s digestive system, causing her gastrointestinal difficulties.
- (4) The persisting vaccine-strain measles virus also damaged Michelle’s brain, causing her autism, mental retardation, and seizures.¹⁴²

Before discussing the various scientific claims put forward by either side through medical articles and expert testimony, the special master in *Cedillo* offered a discussion of the *Daubert* case and the guidelines it offered for determining the reliability of scientific evidence.¹⁴³ Specifically, the special master asserted that utilizing the *Daubert* factors as an evaluative framework would be appropriate in the case.¹⁴⁴ In particular, the “peer review and publication” factor and the “general acceptance” factor received explicit attention.¹⁴⁵

The first scientific assertion in the *Cedillo* case is that thimerosal-containing vaccines damage infants’ immune systems. To support this assertion, the petitioners relied on Dr. H. Vasken Aposhian, who testified that mercury can be toxic to humans, that the mercury in thimerosal-containing vaccines could cause immune system problems in humans, and that the mercury in Michelle’s vaccines “could be a substantial contributing factor to the onset of [her] immune dysfunction.”¹⁴⁶ Dr. Aposhian also offered testimony seeming to support a

139 *Id.* at *5–6.

140 *Id.*

141 *Id.* at *15.

142 *Id.*

143 *Id.* at *3.

144 *Id.* (citing *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

145 *Id.*

146 *Id.* at *17.

theory of “genetic hypersusceptibility,” which means that some individuals may be genetically predisposed to immune system damage from ethylmercury.¹⁴⁷ Dr. Aposhian’s testimony additionally supported the notion of a “mercury efflux disorder,” a possible condition in which a child is unable to excrete mercury as efficiently as most children do.¹⁴⁸

The respondent offered the testimony of Dr. Jeffrey Brent as a rebuttal to Dr. Aposhian. Dr. Brent, whose credentials were more substantial and more relevant than Dr. Aposhian’s,¹⁴⁹ refuted Dr. Aposhian’s testimony at every turn by pointing out flaws in his understanding of mercury as it behaves within the human body and by supplying scientific studies that tended to disprove Dr. Aposhian’s assertions.¹⁵⁰ After considering the reliability of the scientific literature offered by both Dr. Aposhian and Dr. Brent, the special master concluded that Dr. Brent’s scientific testimony was more persuasive and that Dr. Aposhian’s testimony failed to rise above the level of speculation.¹⁵¹

After similarly considering the opposing testimonies of other expert witnesses concerning other scientific points, the special master addressed the reliability of evidence obtained by the Unigenetics laboratory, which claimed to have found persisting measles virus in Michelle’s intestinal tissue.¹⁵² The special master considered experts from both sides who testified regarding the validity of the Unigenetics results. The petitioners’ two expert witnesses on this issue, Dr. Karen Hepner and Dr. Ronald Kennedy, testified that the Unigenetics test results were reliable, even despite the inability of other scientists to subsequently replicate the results.¹⁵³ The respondent’s four expert witnesses exposed numerous flaws in the Unigenetics results, ranging

147 *Id.* at *20–21.

148 *Id.* at *17.

149 Dr. Brent was one of approximately 250 board-certified medical toxicologists in the United States while Dr. Aposhian was only a professor of toxicology and not even a medical doctor. *Id.* at *17–18.

150 *Id.* at *18–23.

151 *Id.* at *24 (“In short, I find that the evidence falls far short of demonstrating that it is ‘more probable than not’ that thimerosal-containing vaccines can damage infants’ immune system.”).

152 *Id.* at *29. Unigenetics was the for-profit laboratory that conducted the tests on intestinal tissue that Dr. Andrew Wakefield relied upon in his later-discredited article for the *Lancet*. *Id.* at *30. The two doctors who founded Unigenetics were also authors of the *Lancet* article. Their establishment of the laboratory appeared to have been “for the purpose of providing testing of claimants in certain British litigation in which it was alleged the MMR vaccine can cause autism.” *Id.*

153 *Id.* at *33–34.

from methodological problems of technique¹⁵⁴ to suspiciously altered laboratory notebooks.¹⁵⁵ The special master concluded that the Unigenetics laboratory results were *not* reliable. In making this determination, the special master relied heavily on considerations that corresponded to two of the *Daubert* factors. First, subsequent attempts to replicate the Unigenetics results were unsuccessful; this is an element of the testability or falsifiability factor from *Daubert*. Second, the only study that may possibly have replicated the Unigenetics results was never published; peer review and publication is another of the *Daubert* factors.¹⁵⁶

The *Cedillo* case continued through a litany of other scientific assertions by the petitioners, all of which were refuted by the more reliable and more persuasive expert testimony presented by the respondent. Altogether, the special master devoted 145 pages of text to explaining each scientific claim, the expert testimony presented by both sides, and the conclusions to be drawn from that testimony as a result of reliability determinations.¹⁵⁷ The special master, though sympathetic to the plight of the Cedillo family, found in favor of the respondent, stating:

I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of causation-in-fact evidence, to a listed vaccination. In this case the evidence advanced by the petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the petitioners in this case are not entitled to a Program award on Michelle's behalf.¹⁵⁸

The application of the *Daubert* factors to the *Cedillo* case represents a slight expansion of the *Daubert* holding beyond the boundaries that the original decision expressly contemplated. The *Daubert* trilogy specifically addressed *admissibility* questions, while the *Cedillo* case centered on issues of *reliability*. Typical *Daubert* cases determine only the admissibility of evidence in single, discrete cases—in *Cedillo*, the result was a determinative outcome bearing on thousands of other vaccine-autism cases pending before the court.

154 *Id.* at *36–37 (nothing that Unigenetics failed to perform “reverse-transcription” in its tests and the results showed “discordant replicates,” which are inconsistent with reliable results).

155 *Id.* at *38.

156 *Id.* at *40–41.

157 *Id.*

158 *Id.* at *135.

Still, the utilization of the *Daubert* factors in the *Cedillo* case is appropriate because the root objective of the *Daubert* analysis is to weigh scientific evidence according to its relevance and reliability. *Cedillo*, *Hazlehurst*, and *Snyder* required a judge (here, called a special master) to wade through complex and conflicting scientific testimony in order to arrive at a final decision about scientific fact. For reasons outlined earlier, this is not a comfortable position for courts and judges because the law must impose an unnatural finality on scientific claims that are otherwise open to revision according to the dictates of scientific methodology.¹⁵⁹ Nevertheless, substantial justice requires that a judge come to the best possible conclusion of fact given only the available scientific evidence. Since such decisions are inevitable, judges need guidelines for assessing scientific testimony; the *Daubert* factors fill this need and as *Cedillo* shows, where scientific truths are the only issues to be settled, *Daubert's* guidelines for analyzing scientific evidence will be helpful in resolving complex claims.

IV. *KITZMILLER* AND THE LIMITATIONS OF THE *DAUBERT* FACTORS

*Kitzmiller v. Dover Area School District*¹⁶⁰ considers a very different science and law question from that at issue in the autism-vaccination cases. *Kitzmiller* required the U.S. District Court for the Middle District of Pennsylvania to enter an emotionally charged and highly controversial debate over the boundaries of science and religion in public life. On October 18, 2004, the Dover Area School Board of Directors passed a resolution requiring that students be made aware of problems with the Darwinian theory of evolution;¹⁶¹ on November 19, 2004, this resolution took concrete shape as a press release from the school board indicating that as of January 2005, all ninth grade biology students in the district would hear the following statement read in their classrooms:

The Pennsylvania Academic Standards require students to learn about Darwin's Theory of Evolution and eventually to take a standardized test of which evolution is a part.

Because Darwin's Theory is a theory, it continues to be tested as new evidence is discovered. The Theory is not a fact. Gaps in the Theory exist for which there is no evidence. A theory is defined as a well-tested explanation that unifies a broad range of observations.

Intelligent Design is an explanation of the origin of life that differs from Darwin's view. The reference book, *Of Pandas and*

159 See *supra* notes 86–90, 92 and accompanying text.

160 400 F. Supp. 2d 707 (M.D. Pa. 2005).

161 *Id.* at 708.

People, is available for students who might be interested in gaining an understanding of what Intelligent Design actually involves.

With respect to any theory, students are encouraged to keep an open mind. The school leaves the discussion of the Origins of Life to individual students and their families. As a Standards-driven district, class instruction focuses upon preparing students to achieve proficiency on Standards-based assessments.¹⁶²

A group of parents whose children attended school in the district filed suit alleging that the school board's policy on intelligent design (ID) instruction violated the Establishment Clause of the First Amendment.¹⁶³

District Court Judge Jones agreed with the petitioners and found that the Dover School Board's policy violated the constitutional rights of students in the district and their parents.¹⁶⁴ In arriving at this decision, Judge Jones engaged in a number of different inquiries, including whether average students in the classroom would see the ID statement as advancing religion (he found that they would) and whether average adults in the community would see the ID statement as advancing religion (again, they would).¹⁶⁵ These two conclusions were enough in themselves to resolve the case under Establishment Clause jurisprudence; in fact, either conclusion on its own would have been sufficient to resolve the case on Establishment Clause grounds.¹⁶⁶ Judge Jones gave a third independent reason for finding that the ID policy violated the Constitution—the fact that the school board's purpose in enacting the new ID policy was to promote religion in the district's schools.¹⁶⁷ But after establishing the unconstitutionality of the ID policy on three independent grounds, Judge Jones undertook a fourth level of inquiry, asking whether intelligent design could correctly be considered *science*.¹⁶⁸

Judge Jones found that intelligent design theory could not be science and outlined three reasons for reaching this determination:

(1) ID violates the centuries-old ground rules of science by invoking and permitting supernatural causation; (2) the argument of irreducible complexity, central to ID, employs the same flawed and

162 *Id.* at 708–09.

163 *Id.* at 709.

164 *Id.*

165 *Id.* at 724, 734.

166 Jay D. Wexler, *Kitzmiller and the "Is It Science" Question*, 5 *FIRST AMENDMENT L. REV.* 90, 99–100 (2006); *see also* Moreno, *supra* note 127, at 1535.

167 *Kitzmiller*, 400 F. Supp. 2d at 746–63 (finding that the ID policy failed the *Lemon* test (citing *Lemon v. Kurtzman*, 403 U.S. 602 (1971))).

168 *Id.* at 734–35.

illogical contrived dualism that doomed creation science in the 1980's; and (3) ID's negative attacks on evolution have been refuted by the scientific community.¹⁶⁹

Judge Jones also added that ID had not been published in peer-reviewed journals and had not been subjected to testing and research, factors that he deemed "important" in determining that ID was not science.¹⁷⁰

In his opinion, Judge Jones did not explicitly cite the *Daubert* criteria or acknowledge their relevance to his discussion.¹⁷¹ Nevertheless, Judge Jones' analysis corresponded closely to several of the *Daubert* factors. He engaged in a discussion of "testability" as an essential aspect of scientific study,¹⁷² emphasized the refutation of the theory of irreducible complexity in peer-reviewed journals,¹⁷³ stressed the nonreplicable nature of the supernatural forces relied upon in ID theory,¹⁷⁴ asserted that ID's failure to be published in scientific journals is a further indication of its nonscientific nature,¹⁷⁵ and noted that ID theory is not generally accepted within the scientific community.¹⁷⁶ Despite the lack of explicit acknowledgment of the *Daubert* factors, many scholars do not hesitate to draw the connection between Judge Jones' analysis and the *Daubert* criteria.¹⁷⁷ In fact, Professor Joelle Anne Moreno uses the *Kitzmiller* case to illustrate the possibilities for

169 *Id.* at 735.

170 *Id.*

171 *See id.* at 735–46 (containing no citations or acknowledgments of *Daubert* or its progeny).

172 *Id.* at 735; *cf.* *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993) (stating that whether a scientific theory can and has been tested is a key question to be answered in determining the admissibility of that theory).

173 *Kitzmiller*, 400 F. Supp. 2d at 741; *cf.* *Daubert*, 509 U.S. at 593–94 (stating that peer review and publication is a relevant consideration in determining scientific validity for admissibility purposes).

174 *Kitzmiller*, 400 F. Supp. 2d at 742–43; *cf.* *Daubert*, 509 U.S. at 593 (establishing refutability as one of the criteria to be considered in determining scientific validity).

175 *Kitzmiller*, 400 F. Supp. 2d at 744–45; *cf.* *Daubert*, 509 U.S. at 593–94 (highlighting publication as an indication of scientific validity).

176 *Kitzmiller*, 400 F. Supp. 2d at 745; *cf.* *Daubert*, 509 U.S. at 596 (giving "general acceptance" as a consideration having bearing on the validity of a scientific theory).

177 *See, e.g.*, Moreno, *supra* note 127, at 1534, 1536 (referring to Judge Jones's discussions of peer-review, publication, and falsifiability as "unattributed nod[s]" to *Daubert* and stating that "[i]t is hard to fathom two more closely related inquiries than Justice Blackmun's effort to identify the attributes of legitimate science in *Daubert* and Judge John E. Jones, III's recent exploration of the scientific underpinnings of Intelligent Design Theory in *Kitzmiller v. Dover Area School District*"); Wexler, *supra* note 166, at 105 (discussing the fact that judges typically engage in the questions Judge Jones addresses in the context of *Daubert* evaluation).

science and law jurisprudence that have emerged as a result of the *Daubert* trilogy decisions.¹⁷⁸

Whether he stated it directly or not, there can be little question that Judge Jones applies the *Daubert* criteria to his discussion of whether ID is science. Such an application of the *Daubert* guidelines, however, falls outside of the admissibility context in which the *Daubert* cases were decided. This application is not a beneficial expansion of the *Daubert* rulings. Rather, it reflects a mistaken understanding of *Daubert's* capabilities.

Determining whether ID could be considered science was absolutely nonessential to resolving the Establishment Clause issue in the *Kitzmiller* case.¹⁷⁹ Judge Jones himself acknowledged as much in his opinion when, just before initiating his discussion on the “is it science” question, he stated, “[w]e have now found that both an objective student and an objective adult member of the Dover community would perceive Defendants’ conduct to be a strong endorsement of religion pursuant to the endorsement test.”¹⁸⁰

Aside from the opinion’s negative implications for judicial restraint, the determination that ID is not science does not logically lead to the conclusion that ID cannot therefore be taught in public schools; such an inference, which Judge Jones implies, suggests that science and religion exist in a dichotomous relationship of opposition. In fact, determining that ID *is not* science does not mean that ID *is* religion—it could just as easily be philosophy or ideology.¹⁸¹ And in any event, the Constitution says nothing about teaching science in public classrooms; the Constitution regulates the establishment of religion, but makes no requirements regarding scientific instruction by public institutions.¹⁸² There is no requirement that scientific study

178 See Moreno, *supra* note 127, at 1534–39 (discussing why the *Kitzmiller* case should be placed within the *Daubert* science and law canon, creating a more inclusive and transdisciplinary approach to science and law).

179 Wexler, *supra* note 166, at 99–100.

180 *Kitzmiller*, 400 F. Supp. 2d at 734.

181 Wexler, *supra* note 166, at 97. Wexler additionally points out that simply because an idea can be considered “science” does not mean that it will be constitutional to teach that idea in public schools. See *id.* For example, scientific studies may suggest that people who pray are healthier and recover from illnesses more quickly than those who do not pray, but the scientific basis of these studies will not allow a school to constitutionally teach students to pray or lead them in prayer in schools. *Id.* at 97–99.

182 *Id.* at 100; see also Jay D. Wexler, *Intelligent Design and Judicial Minimalism: Further Thoughts on the “Is it Science?” Question*, 4 U. ST. THOMAS J.L. & PUB. POL’Y 30, 32 (2009) (emphasizing that the Constitution does not prohibit public schools from teaching subjects that are not science).

in public schools be divorced from related subjects, including the history, sociology, or philosophy of science.¹⁸³

Defining “science” for the purpose of classifying ID theory was a judicial inquiry without any connection to a legal question or point of law.¹⁸⁴ In the context of the *Kitzmiller* decision, “science” is a nonlegal term; it does not appear in any statute or binding precedent that controls the legal inquiry in the case.¹⁸⁵ By interpreting the word “science” in his decision, Judge Jones stepped outside of the role assigned to the judiciary, which is limited to determining questions of *law*.¹⁸⁶ Judges are not philosophers of science and they do not possess the education or professional background to define a term like “science” successfully when that term is unconnected to a legal context.¹⁸⁷ It is true that the *Daubert* holdings provide assistance to judges interpreting the notion of “science” (or perhaps, more accurately, the notion of good versus bad science).¹⁸⁸ But importantly, the *Daubert* holdings serve to interpret the word “scientific” *in the context of* Rule 702 of the Federal Rules of Evidence.¹⁸⁹ This means that the *Daubert* criteria address a specifically legal question—one of statutory interpretation. Such a connection is essential because it preserves checks on judicial authority; if Congress disagrees with the judiciary’s interpretation of Rule 702’s “scientific” language, then Congress can amend the rule or alter its wording.¹⁹⁰

Using the *Daubert* criteria to resolve a nonessential, nonlegal, philosophical question is an unjustifiable expansion of the *Daubert* holdings. Indeed, such an expansion violates the language of the *Daubert* decision itself, which was intended to strike the balance required by the Federal Rules, “designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.”¹⁹¹ *Kitzmiller*’s “is it science” question was unconnected to

183 Wexler, *supra* note 166, at 100.

184 *Id.* at 103, 105–06.

185 *Id.* at 100–01.

186 *Id.*; see also ANTONIN SCALIA, A MATTER OF INTERPRETATION 13–14 (1997) (discussing the modern age as an age of legislation and affirming the responsibility of judges to interpret statutory texts strictly because judges who use texts to develop evolving doctrines are frustrating the purpose of written laws).

187 Wexler, *supra* note 166, at 103.

188 See *id.* at 106 (noting that it is not clear whether *Daubert* and Rule 702 require judges to distinguish between “science” and “non-science” or simply between good science and bad or unsuccessful science).

189 *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993); Wexler, *supra* note 166, at 105–06.

190 Wexler, *supra* note 166, at 105–06.

191 *Daubert*, 509 U.S. at 597.

any particularized legal dispute; applying *Daubert* in that case, even implicitly, constitutes an inappropriate extension of the *Daubert* trilogy holdings.

CONCLUSION

The *Daubert* trilogy holdings established criteria for judges to consider when making determinations about the admissibility of scientific evidence and expert testimony in federal court. Since their publication, however, the *Daubert* holdings have gained some traction in other types of legal conflicts involving science and law. Two such conflicts include the vaccine-autism test cases heard in Federal Vaccine Court and the *Kitzmiller* decision regarding intelligent design theory and the Establishment Clause.

As these two examples illustrate, the *Daubert* criteria cannot simply be applied to any discussion merely because that discussion implicates science and law topics. Rather, the *Daubert* guidelines come to bear in a reliability context, where scientific evidence must be weighed to determine relative authority, whether for purposes of admissibility or for rendering a judicial decision in the face of competing scientific claims. This is the essential task required to bring science into the courtroom because it reconciles the contrary aims of the fields of science and law. The *Cedillo* case provides an example of a nonadmissibility context in which *Daubert* can be applied by a judge to assist in the resolution of a legal dispute.

The *Daubert* criteria do not provide a helpful framework for judges making nonessential philosophical determinations that implicate scientific topics, as was the case in the *Kitzmiller* context. That case did not require a reliability assessment of competing scientific claims because the legal dispute concerned only the unconstitutional advancement of religion under the Establishment Clause. Applying the *Daubert* criteria to cases like *Kitzmiller* invites judges into science and law conflicts that are beyond the scope of legal inquiry and judicial determination. The law is not concerned with the internal philosophical underpinnings of the scientific field; judges should confine their role to determining distinct questions of law with explicit relevance to discrete legal matters.

