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Daubert's Erie Problem

JENNIFER WOLSING*

Introduction

The National Enquirer's headline screamed, "New Thalidomide Scandal—Experts Reveal." The story concerned a new drug described as a "vicious body-twisting crippler" that resulted in "several thousand tragically deformed infants." The paper reported that two infants whose mothers took this drug were born without eyes. Another was born without a brain. The Enquirer was talking about Bendectin, a morning sickness drug marketed by Richardson-Merrell, Inc. Merrell denied any culpability, but the Enquirer quoted two nationally-renowned experts who emphatically agreed that Bendectin caused birth defects. The article also invoked Merrell's previous role in marketing the notorious teratogen thalidomide. Thalidomide's disastrous effects became widely publicized within a few years of its release onto the market.

- * I would like to give very special thanks to Professor John Applegate, Laura Koenig, and the *Indiana Law Journal* Volume 81 Notes and Comments Staff for providing helpful comments, suggestions, and constructive criticism.
- 1. JOSEPH SANDERS, BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION 10–11 (The Univ. of Mich. Press 1998), quoting *New Thalidomide Scandal—Experts Reveal*, NAT'L ENQUIRER, Oct. 1979, at 1. Melvin Belli, the self-proclaimed "king of torts," had contacted the magazine with the potential story.
 - 2. Id.
- 3. The *Enquirer* quoted Alan Done, an expert in drugs' effects on children, and William McBride, a gynecologist who was among the first to recognize the link between birth defects and thalidomide in 1961. McBride's evidence was based on his laboratory tests on rabbits and chicks. Two of eight rabbits receiving higher doses of a chemical similar to Bendectin bore offspring with skeletal and limb defects. *See, e.g.*, William G. McBride, *Teratogenic Effect of Doxylamine Succinate in New Zealand White Rabbits*, 12 IRCS J. of Med. Sci. 536–37 (1984).
- 4. A teratogen is an agent, such as a virus, a drug, or radiation, which causes developmental malformations, particularly of an embryo or fetus. THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1784 (Houghton Mifflin Co. 4th ed. 2000).
- 5. MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS 64 (University of Pennsylvania Press 1996); PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 111-12 (1991); Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation, in* PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 101 (Kenneth R. Foster, David E. Bernstein & Peter W. Huber, eds., The MIT Press 1993).
- 6. The Food and Drug Administration (FDA) warns that even one dose of thalidomide during pregnancy can cause "stunted... growth of fetal limbs (arms, legs, hands, feet). It also puts the fetus at risk of other injuries, including eye and ear defects and severe internal defects of the heart, genitals, kidneys, digestive tract (including lips and mouth), and nervous system." FOOD AND DRUG ADMINISTRATION WEB SITE, THALIDOMIDE: IMPORTANT PATIENT INFORMATION, Sept. 11, 1997, http://www.fda.gov/cder/news/thalidomide.htm.
- 7. "On December 31, 1960 the first English-language published report raised the connection between thalidomide and peripheral neuritis." GREEN, *supra* note 5, at 65. "By March 1962 there was little doubt remaining that thalidomide was . . . teratogenic . . . and

In contrast, the number of Bendectin babies suffering birth defects was not statistically significant. Thus, Bendectin did not receive national attention until one woman, Betty Mekdeci, filed suit against Merrell on behalf of her baby, and the *National Enquirer* picked up the story. Ms. Mekdeci's suit marked the beginning of mass tort litigation against the Bendectin manufacturers. Even with a dearth of evidence demonstrating a causal connection between Bendectin and birth defects, as well as a mounting body of evidence tending to exonerate Merrell Dow Pharmaceuticals, jury verdicts favoring the Bendectin plaintiffs prompted a staggering rise in litigation. 9

The Supreme Court took action for the embattled defendants in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁰ *Daubert* effectively established the federal trial court judge as an "evidentiary gatekeeper." Under this new role, the Ninth and Eleventh Circuits created strict guidelines for the admission of scientific evidence. The new federal guidelines are sometimes more severe than the state standards within their circuits. ¹¹ A federal plaintiff otherwise able to admit evidence of causation in state court is barred from doing so in federal court, which leads to the case's dismissal on summary judgment. This outcome difference encourages eligible defendants to remove to federal courts, thus prejudicing some forum-state plaintiffs.

This Note argues that the outcome differences between the Ninth and Eleventh Circuits and the state courts within their boundaries pose an *Erie* problem in diversity cases where the federal rule is stricter than the state rule. ¹² Part I discusses the history of the Bendectin trials. Part II explains the Supreme Court's response to those trials in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* Part III contrasts the Ninth and Eleventh Circuits' federal standards with the more lenient standards applied by some state courts in those federal circuits. Part IV explains how courts properly conduct an *Erie* analysis. Part V applies Part IV's *Erie* analysis to demonstrate that the discrepancy in practices between state and federal courts constitutes an *Erie* violation. Finally, in Part VI, this Note proposes a solution to the *Erie* problem: federal circuits should always defer to state standards when determining evidence admissibility in diversity cases. ¹³

hideous[ly] toxic[]." Id. at 72.

^{8.} GREEN, supra note 5, at 2-3; Lasagna & Shulman, supra note 5, at 102. Ms. Mekdeci's suit against Merrell was the predecessor to "several thousand claims by children with birth defects and their families"—including the claims raised in Daubert. GREEN, supra note 5, at 3.

^{9.} See infra Part I.

^{10. 509} U.S. 579 (1993).

^{11.} See infra Part III.

^{12.} See infra Parts IV, V.

^{13.} Even when the evidence admissibility decision does not impact summary judgment, the federal circuits privilege defendants' interests over plaintiffs' interests. Therefore, although this Note focuses on evidence that impacts summary judgment decisions, its conclusion applies to all evidentiary decisions.

I. BENDECTIN'S BEGINNINGS

Richardson-Merrell, Inc. marketed Bendectin¹⁴ from the late 1950s until 1983 when Merrell withdrew it from the market.¹⁵ When Betty Mekdeci's case against Merrell went to trial, Merrell's dearth of safety research and apparent efforts to either ignore or misrepresent the warning signs of Bendectin's possible teratogenicity¹⁶ disturbed the jury.¹⁷ Despite the Bendectin plaintiff's increasing problems in proving causation, the jury appeared to focus on Merrell's negligent behavior and returned a verdict for the plaintiff.¹⁸ Several of the other initial Bendectin juries followed suit, ¹⁹ contributing to an "exponential growth" in Bendectin litigation.²⁰ The rapidly increasing litigation and accompanying media coverage encouraged scientists unconnected to the litigation to produce further Bendectin research.²¹ Subsequently, numerous published epidemiological studies demonstrated that taking Bendectin during pregnancy did not "appreciably increase" the risk of birth defects.²² The Food and Drug Administration (FDA) and its Canadian counterpart, Health Canada, also concluded that there was no

- 14. Bendectin is a combination of three ingredients, all of which remain on the market and are generally recognized as being safe. Specifically, Bendectin was the combination of dicyclomine hydrochloride (an antispasmodic, formerly marketed under the name Bentyl), doxylamine succinate (an antinauseant, marketed currently in many over-the-counter products, including Unisom, a sleep aid), and pyridoxine hydrochloride (vitamin B-6). SANDERS, *supra* note 1, at 1.
- 15. Lasagna & Shulman, supra note 5, at 101; SANDERS, supra note 1, at 5; TRIALLAWYERSINC.COM, SAYING NO TO DRUGS 7 (2005), http://www.triallawyersinc.com/healthcare/hc03.html. Bendectin's manufacturer pulled the drug "in the face of \$18 million in annual legal bills—against only \$20 million in total sales," despite the over thirty published studies failing to find a link between Bendectin and birth defects. See id.
- 16. What research Merrell had performed was tainted by "a series of questionable decisions" regarding Bendectin's safety testing and the reporting of those test results to the FDA and members of the medical profession. SANDERS, *supra* note 1, at 8-9.
- 17. See id. at 12–13. In the first Bendectin case, the jury found that the defendant breached no duty, but should pay the plaintiff anyway because of the plaintiff's injury. The jury discussed a small damage award in order to "send a message" to the defendants because of their poor and misleading research. *Id.*
- 18. Lucinda M. Finley, Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules, 49 DEPAUL L. REV. 335, 338 (1999).
 - 19. SANDERS, supra note 1, at 15.
 - 20. Finley, *supra* note 18, at 338.
 - 21. *Id*.
- 22. Id. at 339; SANDERS, supra note 1, at 61–87; see also Allen A. Mitchell, Pamela J. Schwingl, Lynn Rosenberg, Carol Louik & Samuel Shapiro, Birth Defects in Relation to Bendectin Use in Pregnancy: II. Pyloric Stenosis, 147 Am. J. OBSTETRICS & GYNECOLOGY 737 (1983) (supporting the safety of Bendectin in relation to the risk of pyloric stenosis); Joseph Sanders, From Science to Evidence: The Testimony on Causation in the Bendectin Cases, 46 STAN. L. REV. 1 (1993); Sally Zierler & Kenneth J. Rothman, Congenital Heart Disease in Relation to Maternal Use of Bendectin and Other Drugs in Early Pregnancy, 313 NEW ENG. J. MED. 347 (1985) (finding only a weak association between Bendectin and birth defects). For more on determining toxic causation, see GREEN, supra note 5, at 26–34.

link between Bendectin and birth defects.²³ Canada still markets Bendectin as an antinauseant for morning sickness.²⁴

Regardless of the mounting evidence in Merrell's favor on causation, the Bendectin plaintiffs found experts who conducted unpublished re-analyses of the existing studies. Although these experts concluded that Bendectin more than doubled the risk of birth defects, their conclusions remained a minority opinion in both scientific and legal circles. Yet, juries continued to find in favor of the Bendectin plaintiffs. One jury awarded \$19.2 million to a thirteen-year-old boy born with club feet after his mother ingested Bendectin. Another jury assessed \$20 million in compensatory and \$75 million in punitive damages in a single Bendectin case.

Due to the continuing and apparently misguided jury sympathy for plaintiffs, many courts refused to admit any plaintiffs' expert's opinions that attempted to show a causal inference based on anything but "statistically significant, peer reviewed, published epidemiological studies that showed a relative risk above the background risk of two or greater." In other words, the courts required the plaintiffs to present epidemiological evidence concluding that defendant's product, rather than background risks or unexplained causes, was at least fifty percent likely to have caused any particular case of the disease. ²⁹

The *Daubert* trial court was no exception. ³⁰ On appeal from the *Daubert* trial court, the Court of Appeals for the Ninth Circuit supported the district court's stringent

- 23. See generally Sanders, supra note 22, at 10 (explaining that it is implausible to think that the FDA would allow sales of doxylamine succinate, the most suspect ingredient in Bendectin, if it thought doxylamine succinate was teratogenic).
- 24. "In Canada, Bendectin is known as Diclectin and is manufactured and sold by Laboratoire Duchesnay, located in Laval, Quebec." *Id.* at 10 n.30.
- 25. Finley, *supra* note 18, at 339. Verdicts for Bendectin plaintiffs were "regarded as aberrational by many members of the scientific community, the defense bar, some trial judges, and virtually all appellate courts reviewing Bendectin cases." *Id.* In response, many judges issued judgments notwithstanding the verdict. *See* Richardson v. Richardson-Merrell, Inc., 649 F. Supp. 799 (D.D.C. 1986). Others ruled that the plaintiffs lacked sufficient evidence to meet their burden of proof. *See* Brock v. Merrell Dow Pharms., Inc., 874 F.2d 307, 315 (5th Cir. 1989) (expecting the decision to "encourag[e] district judges faced with medical and epidemiologic proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and conclusiveness of studies presented by both sides").
- 26. Linda Lloyd, \$19 Million Award Against Drug Firm, THE PHILADELPHIA INQUIRER, Feb. 2, 1987, available at http://www.klinespecter.com/news_blum_pi020287.html.
- 27. Howard A. Denemark, Improving Litigation Against Drug Manufacturers for Failure to Warn Against Possible Side Effects: Keeping Dubious Lawsuits from Driving Good Drugs off the Market, 40 CASE W. RES. L. REV. 413, 428 (1990); see also Ealy v. Richardson-Merrell, Inc., No. 83-3504 (D.D. C. Oct. 1, 1987) (LEXIS, Genfed library, Dist. file) (upholding the \$20 million compensatory award, but granting a remittur on the award of \$75 million in punitive damages based on insufficient evidence of malice), rev'd, 897 F.2d 1159 (D.C. Cir. 1990).
- 28. Finley, *supra* note 18, at 339; *see, e.g.*, Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 830 (D.C. Cir. 1988) (holding that plaintiff's chemical, in vitro, and in vivo studies "are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence" presented by defendant); Lynch v. Merrell-Nat'l Labs., 830 F.2d 1190, 1194–95 (1st Cir. 1987); *Ealy*, 897 F.2d at 1160.
 - 29. Finley, supra note 18, at 349-50.
 - 30. Daubert v. Merrell Dow Pharms., Inc., 727 F. Supp. 570, 572, 575 (S.D. Cal. 1989).

criteria, invoking a respected prior case: Frye v. United States.³¹ Frye, a widely accepted³² D.C. Court of Appeals case, held that an admissible scientific opinion must be "generally accepted" within the scientific community.³³ By definition, opinions contrary to the weight of a growing body of studies could not satisfy the Frye standard.³⁴ Frye also maintained that peer review and publication are essential to an opinion's general acceptance.³⁵ Thus, the Ninth Circuit held that the plaintiff's unpublished—and therefore unreviewed—controversial expert testimony on causation was inadmissible since it did not meet the threshold set by the trial court.³⁶ Upon these findings, the court of appeals dismissed the case.³⁷

II. THE SUPREME COURT'S DAUBERT TRILOGY

Evidentially unsupported jury verdicts in the Bendectin litigation led to federal courts' zealous efforts to exclude what was widely regarded as "junk science." Growing concern about overly sympathetic juries prompted the Supreme Court to review the standards for admitting scientific evidence. This Part follows the Supreme Court's evolving articulation of the new federal standard through its decisions in Daubert and General Electric Co. v. Joiner. The lower court judges' differing interpretations of this standard has ultimately lead to discrepancies between federal and state admission standards, which significantly impact diversity suits in the Ninth and Eleventh Circuits.

- 31. Daubert v. Merrell Dow Pharms., Inc., 951 F.2d 1128, 1129 (9th Cir. 1991) ("Expert opinion based on a scientific formula is admissible if it 'is generally accepted as a reliable technique among the scientific community." (citing Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)))
- 32. See generally Paul C. Giannelli, The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later, 80 COLUM. L. REV. 1197, 1200–31 (1980); Stan Kitzinger, Note, The Supreme Court Waves Good-Bye to Frye: Daubert v. Merrell Dow Pharmaceuticals, Inc., 58 ALB. L. REV. 575, 578–90 (1994).
- 33. Frye, 293 F. 1013. In Frye, a criminal defendant appealed from conviction based on a rudimentary lie detector test. The court found that "the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made." *Id.* at 1014.
 - 34. Daubert, 951 F.2d at 1130.
 - 35. Id. at 1130-31.
 - 36. Id. at 1131.
 - 37. Id.
- 38. "Junk science" is a pejorative term used to deride specious scientific claims that are made for monetary or political ends. Thomas O. McGarity, Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability for Risk-Producing Products and Activities, 52 U. KAN. L. REV. 897, 899–901 (2004). Peter Huber was one of the first to use the term. See HUBER, supra note 5. Huber colorfully describes the term as follows: "Courts resound with elaborate systematized, jargon-filled, serious-sounding deceptions that fully deserve the contemptuous label used by trial lawyers themselves: junk science. Junk science is the mirror image of real science, with much of the same form but none of the same substance" Id. at 2.
 - 39. 522 U.S. 136 (1997), rev'g Joiner v. Gen. Elec. Co., 78 F.3d 524 (11th Cir. 1996).

A. Daubert v. Merrell Dow Pharmaceuticals, Inc.

The *Daubert* plaintiffs appealed from the Ninth Circuit's unfavorable verdict, claiming that the venerable *Frye* "general acceptance" rule was now outdated and was superseded by the more inclusive—and potentially plaintiff-friendly—Federal Rule of Evidence 702 ("Rule 702"). 40 Rule 702 states:

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. ⁴¹

The Supreme Court granted certiorari, limiting its determination to whether *Frye* was consistent with Rule 702.⁴²

The Supreme Court reversed the Ninth Circuit, holding that the liberal standards of Rule 702, rather than *Frye*, governed the admission of scientific expert testimony. Noting the Federal Rules' "permissive backdrop" and the fact that Rule 702 did not specifically mention a "general acceptance" test, the Court found that the Rules did not assimilate the *Frye* standard. The Court then examined what limits the Rules placed on the admissibility of scientific evidence. "[U]nder the Rules," the Court held, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." The Court explained the reliability standard first and then discussed the relevance standard.

When determining the reliability of scientific evidence, the Supreme Court held that the trial court should base its determination on scientific validity. ⁴⁶ Scientific expert opinion testimony "requires a valid scientific connection" to the inquiry at bar. ⁴⁷ The Court stressed that the validity assessment was flexible, so judges should focus on the experts' principles and methods, rather than on the experts' conclusions. ⁴⁸ The Court analyzed Rule 702's language of "scientific . . . knowledge" to require that the evidence was "ground[ed] in the methods and procedures of science" and represented more than a "subjective belief or unsupported speculation." ⁴⁹ Though expert testimony

^{40.} Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 587 (1993).

^{41.} FED. R. EVID. 702.

^{42.} Daubert, 509 U.S. at 585.

^{43.} Id. at 587.

^{44.} Id. at 588-89.

^{45.} Id. at 589.

^{46.} Id. at 590. The Court noted that "scientists typically distinguish between 'validity' (does the principle support what it purports to show?) and 'reliability' (does the application of the principle produce consistent results?)." Id. n.9. For the purposes of evidence admissibility, the Court merged the two criteria. Id.

^{47.} Id. at 592.

^{48.} Id. at 594-95.

^{49.} Id. at 590.

did not have to achieve complete certainty, any assertion or inference must be supported by "good grounds." 50

Rule 702 also requires that evidence or testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." This condition guided the Court's standard of relevance; the judge must ascertain whether the fact-finder can apply the testimony to the case's facts. Although the Court did not set out a "definitive checklist," it mentioned four key factors. First, a court must determine whether the theory is testable, and if so, whether it has been tested. Second, a court should also take into account whether the study or theory has been peer-reviewed or published. Third, when an expert testifies about a specific technique, a court should consider the technique's "known or potential rate of error." Fourth, in a nod to the *Frye* standard, the trial court can consider whether the scientific community has generally accepted the theory or technique. In reversing the Ninth Circuit's use of the *Frye* "general acceptance" standard, the *Daubert* Court charged trial judges with a more active role in evidence admission. Federal trial judges must flexibly ascertain whether proffered expert scientific testimony is both valid and relevant to the inquiry at bar.

- 50. Id. at 589-90.
- 51. FED. R. EVID. 702.
- 52. Daubert, 509 U.S. at 591.
- 53. Id. at 593.
- 54. Id. at 593-94. The Court noted:

Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability . . . and in some instances well-grounded but innovative theories will not have been published Some propositions, moreover, are too particular, too new, or of too limited interest to be published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected.

Id. (citations omitted).

- 55. Id. at 594.
- 56. *Id.* "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community,' . . . may properly be viewed with skepticism." *Id.* (quoting United States v. Downing, 753 F.2d 1224 (3d Cir. 1985).
- 57. Daubert was remanded to the Court of Appeals for the Ninth Circuit "for further proceedings consistent" with the Court's opinion. Daubert, 509 U.S. at 598. The Ninth Circuit did not further remand the case to the district court despite the plaintiff's request. Instead, the Ninth Circuit held that "justice and judicial economy" would be better served by deciding the issues at the appellate level. Daubert v. Merrell Dow Pharms. Inc., 43 F.3d 1311, 1315 (9th Cir. 1995), cert. denied, 516 U.S. 869 (1995). The district court had already made an admissibility decision and granted Defendant's motion for summary judgment. Since a summary judgment grant may be sustained on any basis supported by the record, the Ninth Circuit considered whether the district court's grant of summary judgment could be sustained under the new standard. Id. After carefully examining the case in light of the new standard put forth by the Supreme Court, the Ninth Circuit affirmed the district court's grant of summary judgment. Id. at 1322. The Supreme Court denied certiorari. Daubert v. Merrell Dow Pharms. Inc., 516 U.S. 869 (1995).

B. General Electric Co. v. Joiner

The Supreme Court's *Daubert* opinion reads like a pro-plaintiff ruling. In fact, many commentators expected *Daubert* to open the floodgates to new and controversial expert testimony for plaintiffs; however, this prediction did not come true. Subsequent cases following *Daubert* actually excluded more of plaintiffs' proposed experts when plaintiffs argued new or controversial scientific theories. The exclusion occurred not because of *Daubert*'s substantive standard, but instead because of the strong gatekeeping function it established for the district courts. In effect, *Daubert* empowered district judges to make their own judgments about the validity of scientific evidence.

Shortly after *Daubert*, some circuits questioned the Supreme Court's statement that admissibility determinations should be based solely on a court's assessment of an expert's methods and principles, as opposed to the expert's conclusions.⁶⁰ The Third Circuit, for example, held that for courts to function as gatekeepers, judges must not only evaluate methods but also ascertain whether the conclusions drawn by experts from their methodology are scientifically supportable.⁶¹ Other circuits maintained the distinction between the evidence's admissibility and the weight to be assigned to it by the trier of fact.⁶²

The Eleventh Circuit, in contrast, provided an example of the latter: a circuit adhering to *Daubert*'s focus on methods, instead of conclusions. The Supreme Court addressed the method versus conclusion divide among the circuits in *General Electric Co. v. Joiner*. ⁶³ In *Joiner*, a case on appeal from the Eleventh Circuit, the plaintiff, Robert Joiner, alleged that his workplace exposure to PCBs "promoted" his stem cell lung cancer. But for his exposure, Joiner claimed, he would not have developed the cancer for years, if at all. ⁶⁴ The district court excluded the plaintiff's experts because

^{58.} See, e.g., Anthony Z. Roisman, Conflict Resolution in the Courts: The Role of Science, 15 CARDOZO L. REV. 1945 (1994).

^{59.} Finley, *supra* note 18, at 341 (describing the "post-*Daubert* era" as a period of "strict scrutiny' of science by non-scientifically trained judges").

^{60.} Id. at 342.

^{61.} The Third Circuit justified its decision as follows:

[[]A]fter *Daubert*, we no longer think that the distinction between a methodology and its application is viable. To begin with, it is extremely elusive to attempt to ascertain which of an expert's steps constitute parts of a "basic" methodology and which constitute changes from that methodology. If a laboratory consistently fails to use certain quality controls so that its results are rendered unreliable, attempting to ascertain whether the lack of quality controls constitutes a failure of methodology or a failure of application of methodology may be an exercise in metaphysics. Moreover, any misapplication of a methodology that is significant enough to render it unreliable is likely to also be significant enough to skew the methodology.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745–46 (3d Cir. 1994).

^{62.} See, e.g., Ambrosini v. Labarraque, 101 F.3d 129, 141 (D.C. Cir. 1996); In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124 (2d Cir. 1995).

^{63. 522} U.S. 136 (1997).

^{64.} Id. at 139-40.

the court "drew different conclusions from the research than did each of the experts." The court of appeals reversed the district court's decision to exclude the opinions of plaintiff's experts, reasoning that the trial court had improperly conducted an analysis of the experts' conclusions rather than the experts' methods. 66

When General Electric appealed the Eleventh Circuit's decision, the Supreme Court reversed. The Court endorsed the Third Circuit's competing view that "a court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Justice Breyer's concurring opinion stated the two value choices underlying *Joiner*. First, Justice Breyer emphasized the need for judges, not juries, to make their own judgments about an expert's conclusions in uncertain or "tentative" areas of science. Second, Justice Breyer urged caution with respect to the tort system, explaining:

[M]odern life, including good health as well as economic well-being, depends on the use of artificial or manufactured substances, such as chemicals. And it may... prove particularly important to see that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability... points toward the right substances and does not destroy the wrong ones.⁷⁰

Thus, *Daubert* and *Joiner* established a clear set of policy choices. First, judges should be trusted more than juries.⁷¹ Second, in light of the technology's benefits, courts should err on the side of conservative scientific principles when deciding whether to admit or reject expert evidence.⁷² Finally, the decisions of the trial court—at least when plaintiffs' experts are at issue—are to be afforded great deference.

This gatekeeping role is simply to guard the jury from considering as proof pure speculation presented in the guise of legitimate scientifically-based expert opinion. It is not intended to turn judges into jurors or surrogate scientists. Thus, the gatekeeping responsibility of the trial courts is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions from the material in the field. Rather, it is to assure that an expert's opinions are based on relevant scientific methods, processes, and data, and not on mere speculation, and that they apply to the facts in issue.

Id. at 530.

^{65.} Joiner v. Gen. Elec. Co., 78 F.3d 524, 533 (11th Cir. 1996).

^{66.} Id. at 529-30. The Eleventh Circuit wrote:

^{67.} Joiner, 522 U.S. at 144-46.

^{68.} *Id.* at 147-50. Part III will discuss the rigorous standards subsequently applied in the Ninth and Eleventh Circuits. Parts III and IV will establish that policy choices like Justice Breyer's are at work in those circuits' decisions.

^{69.} *Id.* at 147–48 (Breyer, J., concurring). Justice Breyer's concurrence contrasts with Justice Stevens's partial dissent, which argues that *Joiner* usurps the traditional role of the jury to assess the strength of an expert's conclusions. *Id.* at 154–55 (Stevens, J., dissenting).

^{70.} *Id.* at 148-49 (Breyer, J., concurring).

^{71.} Finley, *supra* note 18, at 345.

^{72.} Id.

III. APPLYING DAUBERT

After the Supreme Court's charge in *Daubert* and *Joiner*, the Ninth and Eleventh Circuits developed particularly rigorous rules on evidence admissibility. In several instances, however, state courts falling within these federal districts put forth substantially more lenient admissibility standards. As will be more fully developed later in this Note, the rift between strict federal standards and moderate state standards creates a serious *Erie* problem for federal courts hearing diversity cases.⁷³

A. Diverging Standards for Admitting Epidemiological Studies

The *Daubert* Court held that admitted scientific evidence must be "reliable." Therefore, citing the reliability criterion from *Daubert*, courts often create a "hierarchy" with regard to potentially causation-proving evidence. Epidemiology is the only type of science that studies causal associations in human populations, which means that epidemiological evidence is the most adept at proving causation in humans. Thus, epidemiological evidence achieves the highest rank in the hierarchy.

- 74. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 (1993).
- 75. Berger, supra note 73, at 302.

^{73.} See infra Parts IV, V. Many authors have also expressed concerns that the federal evidence standard goes against contemporary scientific standards, prompting some to worry that many deserving plaintiffs are denied their day in court. See, e.g., Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 401, 414-15 (Fed. Judicial Ctr. ed., 2d ed. 2000), available at http://purl.access.gpo.gov/ GPO/LPS19667 (concluding that the Court's narrow focus on epidemiology goes against contemporary scientific understanding); Margaret A. Berger, Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation, LAW & CONTEMP. PROBS., Spring/Summer 2001, at 289, 303-05 (agreeing with Goldstein's conclusion and further arguing that the focus goes against the Supreme Court's ruling in Joiner); Finley, supra note 18, at 349-50 (noting that the federal standard improperly conflates the admissibility of the evidence with the question of whether the evidence by itself meets plaintiff's burden of proof); Sander Greenland & James M. Robins, Epidemiology, Justice, and the Probability of Causation, 40 JURIMETRICS J. 321, 325 (2000) (explaining that the Court's "doubling of the risk" standard improperly assumes that background risks can be calculated separately from the risk the defendant's product creates); Thomas O. McGarity, On the Prospect of "Daubertizing" Judicial Review of Risk Assessment, LAW & CONTEMP. PROBS., Autumn 2003, at 155, 172-73 (pointing out various flaws in the federal court sanctioned "corpuscular approach" to evaluating expert conclusions); Joseph Sanders, Scientific Validity, Admissibility, and Mass Torts After Daubert, 78 MINN. L. REV. 1387, 1416-17 (1994) (arguing for a weight-of-the-evidence standard, rather than the Court's currently favored approach); Joseph Sanders, The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts, 43 HASTINGS L.J. 301, 321-28 (1992) [hereinafter Sanders, Bendectin Litigation] (worrying that, in the absence of trial publicity, scientists might not get funding to research a drug—thus failing to generate the needed epidemiological studies for plaintiffs to win their case).

^{76.} See Sanders, supra note 1, at 47 ("Epidemiological studies on the teratogenic effects of drugs compare the incidence of birth defects among those exposed and those not exposed to a drug.").

^{77.} Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005). See also In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998) (stating that "epidemiological

Other studies, and particularly studies on animals, are of lower value, especially when contrary epidemiological evidence exists. ⁷⁸ Other courts go further, holding that the only admissible expert opinions are those based on epidemiological evidence. These courts reason that scientifically valid types of evidence, like in vitro studies, ⁷⁹ animal studies, ⁸⁰ chemical structure analyses, ⁸¹ and clinical experience or case studies are not legally relevant unless they are supported by epidemiological studies. ⁸²

Submission of epidemiological evidence alone, however, is not always enough for plaintiffs to prevail on summary judgment. If an epidemiological study shows a doubling of risk when a human is exposed to the defendant's product (i.e., a relative risk of 2.0), then the study concludes that there are twice as many cases of the disease in people exposed to the defendant's product as there are in people who are not exposed to the defendant's product.⁸³ Therefore, the study finds that it is fifty percent likely that any particular case of a disease is attributable to the defendant's product,

studies are necessary to determine the cause and effect between breast implants and allegedly associated diseases"); LINDA A. BAILEY, LEON GORDIS, MICHAEL GREEN & PAUL ROTHSTEIN, Reference Guide on Epidemiology, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 121, 126 (1994) ("In the absence of an understanding of the biological and pathological mechanisms by which disease develops, epidemiological evidence is the most valid type of scientific evidence of toxic causation.").

- 78. See, e.g., In re "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1231, 1237, 1241 (E.D.N.Y. 1985).
- 79. "In vitro studies test teratogenicity by exposing single cells, organs, culture-maintained embryos, or limb buds to a suspect substance and examining the biochemical events [B]y using animal and human cell cultures, in vitro studies allow direct comparisons across species of the effects of cell and organ exposure to drugs." SANDERS, supra note 1, at 46 (citation omitted).
- 80. Animal studies, sometimes called in vivo studies, study a drug's effects on an animal species thought to exhibit a reaction to the drug close to that of a human. No one particular laboratory animal is the best prognosticator of human reaction to teratogenicity. Id. at 47. Courts often reject animal studies without accompanying epidemiological data since animal studies require "extrapolation from animals to humans" and from higher doses to lower doses. Berger, supra note 73, at 302; see, e.g., In re Breast Implant Litig., 11 F. Supp. 2d at 1224 (finding that since breast cancer occurs in nonimplanted women and implanted women, "epidemiological studies are necessary to determine the cause and effect between breast implants and allegedly associated diseases"); Tyler ex rel. Tyler v. Sterling Drug, Inc., 19 F. Supp. 2d 1239, 1244 (N.D. Okla. 1998) (excluding expert's use of animal studies because "test results on animals are not necessarily reliable evidence of the same reaction in humans"); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1410 (D. Or. 1996) (rejecting expert testimony based on extrapolations from animal studies because plaintiff did not show that the results of those studies could be applied to humans); Minnesota Mining & Mfg. Co. v. Atterbury, 978 S.W.2d 183, 199-202 (Tex. App. 1998) (rejecting animal studies, case studies, and clinical experience as unlikely to support a finding of causation).
- 81. In chemical structure-activity analyses, scientists draw inferences about the biological activity of a drug through an examination of the drug's chemical structure, followed by a comparison of that structure to the structure of drugs whose biological activities are well documented. SANDERS, *supra* note 1, at 46.
- 82. Finley, *supra* note 18, at 350; Rider v. Sandoz, 295 F.3d 1194, 1202 (11th Cir. 2002) (preferring "peer-reviewed epidemiological literature, a predictable chemical mechanism, general acceptance in learned treastises, or a very large number of case reports").
 - 83. Finley, supra note 18, at 349 n.49; BAILEY, ET AL., supra note 75, at 168-69.

rather than background risk or "unexplained causes." The Ninth and Eleventh Circuits, for example, have requirements over and above the mere tendering of epidemiological data. The Eleventh Circuit requires presentation of epidemiological evidence that shows at least a doubling of relative risk. The Ninth Circuit similarly requires that admissible epidemiological evidence display a doubling of the plaintiff's risk, unless the substance at issue is generally understood to cause harm or the plaintiff proves that her personal susceptibility is greater than the average.

1. State Standards in the Eleventh Circuit

Some state courts within the Ninth and Eleventh Circuits, however, provide more moderate rules for evidence admission. For example, Florida state courts, which are in the Eleventh Circuit, allow plaintiffs to submit epidemiological evidence that does not meet the 2.0 threshold of relative risk. Plaintiffs must merely show "association" and not "causation." The *Berry* court wrote that it would not "seize on the putative flaws of studies favorable to plaintiff, and then . . . privilege certain studies favorable to the defendant." Doing so would "impermissibly . . . place a thumb on defendant's side of the scale" and encroach on the jury's prerogative to weigh both sides of the case. 90

Florida federal district courts, on the other hand, require a 2.0 showing. In *Barrow* v. *Bristol-Myers Squibb*, a Florida federal district court held that, without "statistically significant" epidemiological data (i.e., data showing a doubling of the relative risk), the plaintiff did not meet her burden of proof. Tellingly, the district court recognized the "unfairness" its decision propagated, even as it explained its duty to follow precedent. Proof the district court worried that the current law placed the burden of proof on the person least likely to have the "financial means or scientific knowledge to conduct epidemiological studies." The district court's concerns are similar to those held by

^{84.} Finley, supra note 18, at 349-50; see also Michael D. Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substance Litigation: The Legacy of Agent Orange and Bendectin Litigation, 86 Nw. U. L. Rev. 643, 647 (1992).

^{85.} Allison v. McGhan Med. Corp., 184 F.3d 1300, 1315 n.16 (11th Cir. 1999) ("The threshold for concluding that an agent more likely than not caused a disease is 2.0."); Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584, 591 (D.N.J. 2002); *In re* Breast Implant Litig., 11 F. Supp. 2d at 1217; Sanderson v. Int'l Flavors and Fragrances, Inc. 950 F. Supp. 981, 1000 (C.D. Cal. 1996) (holding that since plaintiff's probability estimate was "not founded upon epidemiological studies showing a relative risk of greater than two," it did not establish "a valid scientific connection to the pertinent inquiry" (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592 (1993)).

^{86.} In re Berg Litig., 293 F.3d 1127, 1129 (9th Cir. 2002).

^{87.} In re Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1137 (9th Cir. 2002).

^{88.} Berry v. CSX Transp., Inc., 709 So. 2d 552, 567–69 (Fla. Dist. Ct. App. 1998).

^{89.} Id. at 571.

^{90.} *Id.* (quoting *In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1135 (2d Cir. 1995)).*

^{91.} Barrow v. Bristol-Myers Squibb Co., No. 96-689-CIV-ORL-19B, 1998 WL 812318, at *23 (M.D. Fla. Oct. 29, 1998).

^{92.} Id. at *38.

^{93.} Id. at *37. Furthermore, this rule created a transparency paradox. The fewer tests conducted by a defendant, the less likely that plaintiffs could prove adverse effects stemming

Florida's state courts, but the Florida state courts were able to promulgate a more lenient evidentiary standard.⁹⁴

2. State Standards in the Ninth Circuit

Arizona state courts do not require a 2.0 threshold for admissible epidemiological evidence. Sciting the state's goal of balancing fairness with efficiency, one Arizona state court explained that Arizona did not mandate an "arbitrary" 2.0 threshold. But Arizona federal district courts, located in the Ninth Circuit, are considerably stricter. In Grant v. Bristol-Myers Squibb, for example, an Arizona federal district court applying Arizona law to a diversity case held that "studies showing a relative risk less than 2.0 would not be helpful, and indeed would only serve to confuse the jury, if offered to prove rather than refute causation."

The Ninth Circuit has also refused to adopt state standards in cases coming from Washington and Idaho. Washington courts do not require any epidemiological evidence at all because they are concerned that a stricter requirement coupled with a dearth of studies linking the disease to the hazard would force the first victims of any newly recognized occupational disorder to go uncompensated.⁹⁹ Nonetheless, in two

from the defendant's product. "The law thus encourages corporations to act irresponsibly in failing to develop and disclose information relating to potential harms caused by defects in their products." *Id.* at *37–38. For more on transparency paradoxes, see generally Daniel R. Cahoy, *Medical Product Information Incentives and the Transparency Paradox*, 82 IND. L.J. (forthcoming Summer 2007).

- 94. A number of cases establish the difference in evidentiary standards between Florida state courts and Eleventh Circuit federal courts. *Compare* Castillo v. E.I. Du Pont de Nemours & Co., 854 So. 2d 1264, 1270–72 (Fla. 2003) (accepting controversial epidemiological data, differential diagnosis, and "pioneering" in vitro studies; affirming that the evaluation of an expert's conclusions are the proper issue for a trier of fact, not a judge), *and* U.S. Sugar Corp. v. Henson, 787 So. 2d 3, 17–18 (Fla. Dist. Ct. App. 2000) (allowing plaintiff to continue, despite a lack of epidemiological evidence, only because plaintiff's expert's testimony was based on "widely-accepted scientific texts and other accepted . . . literature"), *with* Bushore v. Dow Corning-Wright Corp., No. 92-344-Civ-T-26C, 1999 U.S. Dist. LEXIS 20697, at *9–15 (D. Fla. Nov. 15, 1999) (rejecting the expert's new theory, even though the theory was supported by several peer-reviewed, published studies because the expert "has yet to publish a peer-reviewed epidemiological study," the expert's own studies are subject to error, and several other authors disagree with the expert's conclusions).
- 95. Lofgren v. Motorola, Inc., No. CV 93-05521, 1998 WL 299925, at *14 (Ariz. Super. June 1, 1998) (requiring only a "significant increase in the probability of the relative risk of the disease to an exposed group similar to that experienced by the plaintiffs").
 - 96. Id. at *9.
 - 97. Id. at *14.
 - 98. 97 F. Supp. 2d 986, 992 (D. Ariz. 2000).
- 99. See Bowman v. Dep't of Labor & Indus., No. 30824-0-II, 2004 Wash. App. LEXIS 2843, at *13-14 (Wash. Ct. App. Nov. 23, 2004) ("'[I]f this court were to accept [the employer's] argument, the first victims of any newly recognized occupational disease would always go uncompensated." (quoting Intalco Aluminum Corp. v. Dep't of Labor & Indus., 833 P.2d 390, 399 (Wash. Ct. App. 1992))); Intalco, 833 P.2d at 399 ("The absence of studies linking aluminum plant pot room exposure to neurologic disease does not compel the conclusion that the claimants failed to make a showing of . . . cause. . . . The claimants should not be denied benefits simply because Drs. Longstreth and Rosenstock were the first physicians

cases originating from Washington federal district courts, the Ninth Circuit established that it requires an epidemiological study showing a doubling of the risk, unless the substance at issue is known to cause harm¹⁰⁰ or the plaintiff somehow establishes that her individual susceptibility is greater than average.¹⁰¹

Similarly, Idaho courts allow plaintiffs to prove their cases using "tissue samples, standard tests, and [the results of] patient examination[s], provided the plaintiffs' experts' methods are sound." A state court explained that Idaho law ought not "preclude recovery until a 'statistically significant' number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical." This focus on methods, as opposed to conclusions, goes against the federal standard articulated by judges who scrutinize an expert's methods and conclusions. The Ninth Circuit, in contrast, issues a blanket requirement that epidemiological studies show a doubling of the risk, unless the substance at issue is known to cause harm or the plaintiff establishes that her individual susceptibility is greater than average. Accordingly, the Ninth Circuit's standard clashes with Idaho's refusal to require epidemiological data to bolster nonepidemiological evidence.

B. Diverging Standards for the Admissibility of Other Scientific Evidence

State and federal courts disagree about more than just epidemiological standards. Federal courts in the Eleventh Circuit put forth stronger standards than the circuit's corresponding state courts with respect to both experts' qualifications and the admissibility of non-epidemiological evidence such as animal studies and challenge test results. ¹⁰⁷ The Ninth Circuit diverges from its corresponding state courts in its treatment of evidence that is based primarily on clinical or practical experience.

to systematically study the effects of toxic pot room exposures on the central nervous system of humans.").

^{100.} In re Berg Litig., 293 F.3d 1127, 1129 (9th Cir. 2002).

^{101.} In re Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1137 (9th Cir. 2002).

^{102.} Earl v. Cryovac, 772 P.2d 725, 733 (Idaho Ct. App. 1989) (quoting Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1536 (D.C. Cir. 1984)).

^{103.} Earl, 772 P.2d at 733 (quoting Ferebee, 736 F.2d at 1536).

^{104.} See supra Part II.

^{105.} In re Berg, 293 F.3d at 1129.

^{106.} In re Hanford, 292 F.3d at 1137. See also Longmore v. Merrell Dow Pharms., Inc., 737 F. Supp. 1117, 1118 (D. Idaho 1990) ("These three types of studies then—chemical, in vitro [test tube], and in vivo [animal]—cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind... are not capable of proving causation in human beings" when substantive epidemiological evidence exists to the contrary. (alterations in original) (quoting Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1161 (D.C. Cir. 1990))).

^{107.} Challenge testing exposes the individual to a substance that the doctor suspects is making her sick. The purpose is to gather evidence linking the patient's symptoms to the patient's exposure to the challenged substance. Marc Treadwell, *Annual Survey of Georgia Law*, 55 MERCER L. REV. 249, 260 (2003).

1. State Standards in the Eleventh Circuit

Alabama state courts, located in the Eleventh Circuit, put forth comparatively relaxed evidentiary standards governing the admissibility of nonepidemiological evidence and expert qualifications. In Cooper v. Diversey Corporation, an Alabama appellate court admitted an expert's opinion on the toxicity of silicate compounds found in industrial laundry detergent even though: (1) his opinion relied only upon research and studies conducted on the medical problems resulting from silicone breast implants; and (2) he produced no studies showing that the silicate compounds in the laundry detergent caused similar ailments in persons other than the plaintiff. ¹⁰⁸ In Tidwell v. Upjohn Co., the Alabama Supreme Court allowed a pharmacologist's expert testimony on causation, even though causation was admittedly far outside his area of expertise. 109 But in McClain v. Metabolife International, Inc., a case filed in Alabama's federal district court, the Court of Appeals for the Eleventh Circuit rejected a clinical medical doctor's expert testimony partly because he was not a researcher in the field. 110 The court also rejected differential diagnosis 111 and case studies. 112 Were the McClain court to have applied Alabama's permissive common law standard under Cooper and Tidwell, the above evidence likely would have been admitted as reliable methods of establishing causation.

Likewise, the Georgia Court of Appeals has expressly declined to adopt the *Daubert* standard. 113 Accordingly, it allowed the admission of "challenge testing," despite the fact that the testing was not "formalized" and possessed some methodological flaws. 114 The court explained that problems with the method applied to the evidence's weight, rather than its admissibility. 115 Still, in recent cases originating in Georgia federal districts, the Eleventh Circuit rejects challenge testing evidence. 116

^{108. 742} So. 2d 1244, 1247–48 (Ala. Civ. App. 1998), rev'd on other grounds sub nom. Exparte Diversey Corp., 742 So. 2d 1250, 1254–55 (Ala. 1999).

^{109. 626} So. 2d 1297, 1300 (Ala. 1993) (finding that causation was related to "complex issues of psychopharmacology, pharmokinetics, epidemiology, and psychiatry") (emphasis omitted).

^{110. 401} F.3d 1233, 1252 (11th Cir. 2005) ("Dr. Hakim is a medical doctor specializing in the practice of neurology; he is a clinician and not a medical researcher. . . . [His] opinions lack sufficient reliability to satisfy *Daubert*.").

^{111.} Differential diagnosis is "the distinguishing between two or more diseases with similar symptoms by systematically comparing their signs and symptoms." MOSBY'S MEDICAL & NURSING DICTIONARY 347 (Walter D. Glanze et al. eds., 2d ed. 1986).

^{112.} McClain, 401 F.3d at 1252-54. But see Brasher v. Sandoz Pharms. Corp., 160 F. Supp. 2d 1291, 1297 (N.D. Ala. 2001) (allowing expert opinion based on differential diagnosis when conducting an epidemiological study would be "dangerous and not in the best interests of the people").

^{113.} Bryant v. Hoffmann-LaRoche, Inc., 585 S.E.2d 723, 729 n.4 (Ga. Ct. App. 2003).

^{114.} Orkin Exterminating Co. v. Carder, 575 S.E.2d 664, 667-69 (Ga. Ct. App. 2002).

^{115.} Id. at 669.

^{116.} Rider v. Sandoz Pharms. Corp., 295 F.3d 1199–204 (11th Cir. 2002) (rejecting dechallenge/rechallenge evidence—which is another name for challenge testing).

2. State Standards in the Ninth Circuit

Similar examples of disparate treatment in the state and federal courts exist in the Ninth Circuit as well. In *Logerquist v. McVey*, for instance, the Arizona Supreme Court held that evidentiary standards applicable to novel scientific evidence should not apply to an expert's testimony when that testimony is based on "experience, observation, and study of literature." When an expert bases her opinion on experience, the validity of her argument should be tested by witness interrogation, rather than via an inquiry into general acceptance. However, in *Cloud ex rel. Cloud v. Pfizer, Inc.*, an Arizona federal district court rejected a psychiatrist's testimony that was based on several articles, his thirty-three years of experience as a psychiatrist, and his research in conducting clinical trials of the drug at issue. In explaining its decision, the court implicitly rejected Arizona's common law standard under *Logerquist*, writing that the expert's "conclusions are not supported by the . . . literature or any admissible evidence." 120

Both the Ninth and Eleventh Circuits' rules require that plaintiffs benefit from considerable knowledge about the disorder at issue. The general rule requiring a 2.0 showing in epidemiological studies, for instance, mandates that either current plaintiffs or previous plaintiffs spend a great deal of time and money proving causation. The Ninth Circuit does provide two exceptions to its 2.0 rule: the 2.0 showing is not required (1) when the substance is generally known to be harmful, or (2) when the plaintiff can establish that her individual susceptibility is higher than normal. But even plaintiffs covered under the Ninth Circuit's exceptions must expend resources or benefit from a previous plaintiff's expenditure of considerable resources. For a substance to be generally recognized as harmful, the substance would have needed to cause well-publicized problems for a significant amount of time.

Similarly, if plaintiffs wish to establish a greater-than-average individual susceptibility, they must first show what an average susceptibility to the substance is—which, again, requires expenditures of time and money. By rejecting less expensive evidence, such as animal studies or challenge testing, these federal courts place an extremely difficult burden on poor—and even affluent—plaintiffs who are the first to learn of a causal link between a product and an injury or disease. Public safety concerns for such plaintiffs likely contributed to the more lenient evidentiary criteria

^{117. 1} P.3d 113, 122 (Ariz. 2000).

^{118.} Id. at 133.

^{119. 198} F. Supp. 2d 1118, 1131-34 (D. Ariz. 2001).

^{120.} Id. at 1132.

^{121.} GOLDSTEIN & HENIFIN, supra note 73, at 414. Consequently, scientists are often unwilling or unable to conduct third-party epidemiological studies in the absence of litigation or a public health concern. This creates a no-win situation for plaintiffs. Plaintiffs need epidemiological data in order to litigate, but epidemiological studies are not often performed without there first being litigation. As a result, a requirement of exclusive or extensive reliance on epidemiological data is controversial. Berger, supra note 73, at 303; see also Sanders, Bendectin Litigation, supra note 71, at 321-28. These authors explain that in the absence of some sort of publicity, scientists may be unable to obtain funding. This Note adds that some scientists may not see the need for research in the absence of controversy about the drug in question.

put forth in Florida, Alabama, Georgia, Arizona, Washington, and Idaho. The federal courts, in refusing to apply these state standards, provide diverse defendants with an unfair advantage over forum-state plaintiffs—an advantage that courts in the states intentionally disallowed.

IV. ERIE ANALYSIS

As explained in Part III, at least six state courts in the Ninth and Eleventh Circuits have propounded a more lenient standard of evidence admissibility than their federal counterparts. Their standards are likely driven by worries that the indigent plaintiffs or the first plaintiffs to contract a disease may not have the resources to bridge the causation gap. ¹²² The Florida, Alabama, Georgia, Arizona, Washington, and Idaho state courts place a priority on public safety over technological development. The federal courts in the Ninth and Eleventh Circuits, however, err on the side of scientific caution, possibly guided by concerns that productive defendants like the Bendectin manufacturers might be subject to unwarranted tort liability. Thus, under Justice Breyer's rationale in *Joiner*, the federal circuits reverse the states' priorities and privilege technological development over public safety. ¹²³

The federal circuits' more rigorous admissibility standards often produce outcomes more favorable to defendants. ¹²⁴ By requiring a more difficult evidentiary threshold for plaintiffs, the federal courts are more likely to dismiss plaintiffs' cases on summary judgment. As a result, the federal standard encourages forum shopping by defendants brought to trial in forum states that have a more lenient evidentiary standard. Since out-of-state defendants can remove to federal jurisdiction, ¹²⁵ such defendants are more likely to do so since they know that plaintiffs will face a greater evidentiary burden in

^{122.} As even the Ninth Circuit admits, "[a]n average plaintiff alleging a connection between latent disease and exposure to hazardous substances does not have the means to conduct the type of . . . epidemiological study necessary to bridge the causation gap." O'Connor v. Boeing N. Am., Inc., 311 F.3d 1139, 1156 (9th Cir. 2002). To that end, one state court wrote that products liability law "does not preclude recovery until a 'statistically significant' number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical." Earl v. Cryovac, 772 P.2d 725, 733 (Idaho Ct. App. 1989) (quoting Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1536 (D.C. Cir. 1984)). Another court concluded that plaintiffs should not have to wait for "general acceptance' . . . of . . . systemic harm as a condition to . . . proceeding" with a claim. Dow Chem. Co. v. Mahlum, 970 P.2d 98, 124 n.1 (Nev. 1998) (Springer, J., concurring in part and dissenting in part), overruled in part by GES, Inc. v. Corbitt, 21 P.3d 11, 15 (Nev. 2001). A third state worries that if courts were to accept a more stringent standard, "the first victims of any newly recognized . . . disease would always go uncompensated." Bowman v. Dep't of Labor & Indus., No. 30824-0-II, 2004 Wash. App. LEXIS 2843, at *13-14 (Wash. Ct. App. Nov. 23, 2004) (quoting Intalco Aluminum Corp. v. Dep't of Labor & Indus., 833 P.2d 390, 399 (Wash. Ct. App. 1992)).

^{123.} See supra text accompanying note 70.

^{124.} Berger, *supra* note 73, at 316–17 ("When a court excludes the plaintiff's proffered expert testimony on the basis of a policy-based rule and then grants summary judgment, the result is outcome determinative.").

^{125.} All defendants may remove any civil case to federal court if the case could have been originally brought in federal court. Diversity is one such ground for removal. 28 U.S.C. § 1441 (2000).

federal court than in state court. This forum shopping enables defendants to elude the consequences of state standards. ¹²⁶ The dramatic outcome differences between federal circuit courts and the state courts within those federal circuits provoke *Erie* concerns of federalism and state comity. Though *Erie* doctrine is unsettled at present, ¹²⁷ the Ninth and Eleventh Circuits' applications of the *Daubert* trilogy constitute an *Erie* violation, regardless of whether the situation is considered under the standard set out in any of the Supreme Court's potentially viable *Erie* tests.

A. Erie Railroad v. Tompkins

Erie Railroad Co. v. Tompkins first recognized that federal courts must apply state substantive law in diversity cases. ¹²⁸ A passing freight train injured plaintiff Tompkins while he was walking along the railroad's right-of-way in Hughestown, Pennsylvania. ¹²⁹ The case centered on the standard of duty that the railroad owed Tompkins. The defendant argued that its duty was "no greater than that owed to a trespasser" under Pennsylvania common law. ¹³⁰ The plaintiff, however, contended that since there was no state statute on that subject, the railroad's duty and liability should be determined in the federal courts according to the holding in Swift v. Tyson. ¹³¹

In finding for the defendant and overruling *Swift*, the *Erie* Court established that federal courts do not have a lawmaking function in areas of substantive law reserved to the states. ¹³² In *Erie* cases, the federal court sitting in diversity must determine whether the state practice at issue is sufficiently "substantive" as to raise an *Erie* issue—meaning state law applies—or whether the federal court is instead free to follow its own procedures. ¹³³ Subsequent cases substantially expanded and modified *Erie*'s original holding.

^{126.} State standards tend to be more democratic than federal standards because state judges are more likely to be elected. Pasquale A. Cipollone, Section 2 of the Voting Rights Act and Judicial Elections: Application and Remedy, 58 U. CHI. L. REV. 733, 760 (1991) ("The democratic pedigree of elected judges is purer than that of appointed judges in the sense that the former are selected directly by the people, rather than indirectly by executives or legislators representing the people.").

^{127.} See infra Part IV.D, explaining the confusion engendered by Justice Ginsberg's majority opinion in Gasperini v. Center for Humanities, Inc., 518 U.S. 415 (1996).

^{128. 304} U.S. 64 (1938).

^{129.} Id. at 69.

^{130.} Id. at 70.

^{131.} Id. at 70-71 (citing Swift v. Tyson, 41 U.S. 1, 18 (1842)).

^{132.} Berger, supra note 73, at 310.

^{133.} Id. But there is some disagreement about whether an Erie analysis should be applied to the Federal Rules of Evidence. The Supreme Court has never applied an Erie analysis to the Federal Rules of Evidence. Robin Kundis Craig, When Daubert Gets Erie: Medical Certainty and Medical Expert Testimony in Federal Court, 77 DENV. U. L. REV. 69, 80–81 (1999). Most circuits that have addressed the application of Erie to the Federal Rules of Evidence agree that "there are some State evidentiary rules so bound up with the substantive law of the State that a federal court sitting in that State should accord it the same treatment as the State courts in order to give effect to the State's substantive policy." Stonehocker v. Gen. Motors Corp., 587 F.2d 151, 155 (4th Cir. 1978) (citing Conway v. Chemical-Leaman Tank Lines, Inc., 540 F.2d 837 (5th Cir. 1976)); see also Allstate Ins. Co. v. Sunbeam Corp., 53 F.3d 804, 806 (7th Cir. 1995);

B. Hanna v. Plumer

Hanna v. Plumer was the first case to expand on the Erie doctrine. ¹³⁴ In Hanna, service of a tort complaint was made to a decedent's estate by leaving copies of the complaint with the defendant executor's wife. ¹³⁵ This procedure complied with Federal Rule of Civil Procedure 4(d)(1), but did not comply with the "in hand" method prescribed by Massachusetts law. ¹³⁶ Chief Justice Warren's majority opinion held that service should be made in accordance with the Federal Rules of Civil Procedure, rather than the state rules of civil procedure because holding otherwise would "disembowel either the Constitution's grant of power over federal procedure or Congress'[s] attempt to exercise that power in the Enabling Act." ¹³⁷

The *Hanna* court established that an *Erie* analysis has two parts. First, if the Federal Constitution or an act of Congress applies to the issue at bar, then federal judges must follow the federal practice even if there is a contrary state rule. ¹³⁸ This result derives from the Supremacy Clause of the United States Constitution ¹³⁹ and, in the case of the Federal Rules of Civil Procedure, the Rules Enabling Act. ¹⁴⁰ This part of the *Erie* analysis is sometimes known as the "*Hanna* prong." ¹⁴¹ Second, if neither the Constitution nor Congress has issued an applicable directive, the court makes its choice of law under the Rules of Decision Act (RDA). ¹⁴² The RDA analysis "assesses whether an issue involves a matter of substance (as to which state law must govern) or procedure (as to which federal law may govern)." ¹⁴³ This is the RDA prong of the *Erie* analysis.

Hottle v. Beech Aircraft Corp., 47 F.3d 106, 109 (4th Cir. 1995); Espeaignnette v. Gene Tierney Co., 43 F.3d 1, 9 (1st Cir. 1994); Washington v. Dep't of Transp., 8 F.3d 296, 300 (5th Cir. 1993); Grossheim v. Freightliner Corp., 974 F.2d 745, 754 (6th Cir. 1992); Potts v. Benjamin, 882 F.2d 1320, 1324 (8th Cir. 1989); Romine v. Paman, 831 F.2d 944, 944–45 (10th Cir. 1987). Since most circuits agree that the Federal Rules of Evidence should be treated similarly to the Federal Rules of Civil Procedure for the purposes of *Erie* analysis, this Note will assume that majority opinion. However, for a detailed analysis of both sides of this issue, see Craig, *supra*, at 80–88.

- 134. 380 U.S. 460 (1965).
- 135. Id. at 461.
- 136. Id. at 462.
- 137. Id. at 473-74.
- 138. *Id.* at 471. There are two exceptions: (1) if the federal practice "transgresses... the terms of the Enabling Act," or (2) the federal practice runs afoul of the Constitution. *Id.*
 - 139. U.S. CONST. art. VI, § 2.
- 140. 28 U.S.C. § 2072 (2000) (providing that the Supreme Court has the power to "prescribe general rules of practice[,]... procedure[,]... and evidence" in United States federal district courts and that "all laws in conflict with such rules shall be of no further force or effect").
- 141. Richard D. Freer, Some Thoughts on Erie After Gasperini, 76 Tex. L. Rev. 1637, 1637 (1998).
 - 142. 28 U.S.C. § 1652 (2000).
 - 143. Freer, supra note 141, at 1637.

C. RDA Analysis Tests

The Supreme Court propagated several tests for ascertaining whether an issue is substantive or procedural under the RDA prong. These tests will be discussed in chronological order. In cases decided in the 1940s and 1950s, the courts "ben[t] over backward to find that state law governed." The basis for these outcomes was Guaranty Trust Co. v. York, 145 a 1945 case which established an outcome determination test. 146 In Guaranty Trust, the Court asked whether, when a state statute of limitations barred the action, "a federal court in equity [could] take cognizance of the suit because there is diversity of citizenship between the parties." Disregarding whether the question was one of substance or procedure, the Court held that since a federal court sitting in diversity is "in effect, only another court of the State," the federal court cannot allow recovery if the right to recover is unavailable under the state's statute of limitations. 148 Under the rule established in Guaranty Trust, any state practice was substantive if its application in federal court might produce a different result than the Federal Rules. 149

The Court redesigned its analysis in 1958. In *Byrd v. Blue Ridge Rural Electrical Cooperative, Inc.*, the Court adopted a three-part series of tests requiring courts to consider factors other than strict outcome determination. ¹⁵⁰ The court must first ascertain the interests served by the competing state rule. ¹⁵¹ Only if the state rule is not clearly substantive, but appears to be merely procedural, can the court apply an outcome determination test. ¹⁵² The outcome determination test answers whether the "federal court's refusal to apply the state rule" would decide the outcome of the case. ¹⁵³ Finally, if such a refusal would be outcome determinative, then the court should apply the state's practice—but only if the court finds no "affirmative countervailing considerations" in favor of the federal practice. ¹⁵⁴

^{144.} Id. at 1645.

^{145. 326} U.S. 99 (1945).

^{146.} *Id.* at 107. Justice Frankfurter, writing for the Court, explained that *Erie*'s essence was the "requirement of vertical uniformity" between state court decisions and federal court decisions. Berger, *supra* note 73, at 313 (explaining *Guaranty Trust*).

^{147.} Guaranty Trust, 326 U.S. at 107.

^{148.} Id. at 108-09.

^{149.} Id. at 109.

^{150. 356} U.S. 525 (1958).

^{151.} *Id.* at 535–36. The court determines the weight of the state's interest by ascertaining whether the state practice is "bound up with the definition of the rights and obligations of the parties" and consequently furthers a substantive state policy. Berger, *supra* note 73, at 315.

^{152.} A procedural rule enforces merely "form and mode," rather than substantial state policies. Byrd, 356 U.S. at 536.

^{153.} Freer, supra note 141, at 1648-49; see also Berger, supra note 73, at 314.

^{154.} Byrd, 356 U.S. at 537–38. The "affirmative countervailing considerations" requirement introduced the famous "balancing" aspect of the Byrd test. Freer, supra note 141, at 1649–50. The weight afforded to the federal practice depends on the role that the federal rule plays in the federal system. The Byrd Court evinced concern that "[t]he policy of uniform enforcement of state-created rights and obligations, see, e.g., Guaranty Trust Co. v. York, . . . cannot in every case exact compliance with a state rule—not bound up with rights and obligations—which disrupts the federal system of allocating functions between judge and jury." Byrd, 356 U.S. at

The Court applied this test in *Byrd* to hold that federal interests weighed in favor of the federal practice of a jury trial. In *Byrd*, the Court had to ascertain whether a plaintiff's status as an employee must be decided by a judge, in keeping with South Carolina's common law, ¹⁵⁵ or by a jury, according to federal practice. ¹⁵⁶ After finding the South Carolina common law at issue merely "administrative," ¹⁵⁷ the Court then admitted that the difference between having a factual issue decided by a judge versus a jury might often be an outcome-determinative distinction. ¹⁵⁸ Yet, the Court found that the federal court system's "distribution of functions" between the judge and jury is an "essential characteristic" of that system. ¹⁵⁹ Since there is a strong federal policy in favor of maintaining that distribution of functions, the Court allowed the plaintiff to try his case before a jury, in contravention of the state practice. ¹⁶⁰

In *Hanna v. Plumer*,¹⁶¹ the Court seemed to retreat from both the outcome determination test and the *Byrd* balancing test by endorsing a modified outcome determination test.¹⁶² The *Hanna* test suggested that courts should apply a state procedure if the state procedure promotes *Erie*'s "twin aims": avoidance of both forum shopping and discrimination against citizens of the forum state.¹⁶³

D. Gasperini v. Center for Humanities, Inc.

Gasperini is the most recent Erie case to come before the Supreme Court. ¹⁶⁴
Gasperini held that a state practice contrary to the common law of federal procedure must be applied when the state practice is substantive according to the court's RDA analysis. ¹⁶⁵ In Gasperini, the district court entered judgment on a jury award of \$450,000. In New York, state appellate courts may review the size of a jury verdict and order a new trial when the jury's award "deviates materially from what would be reasonable compensation." ¹⁶⁶ Conversely, the federal standard allowed courts to grant a new trial for excessiveness only when the award "shock[ed] the [court's] conscience." ¹⁶⁷

^{537–38 (}footnote omitted). Thus, as Freer explains, "[t]he federal courts can, in essence, be conscripted to help enforce a state policy, but not if doing so will harm the integrity of the federal judicial system." Freer, *supra* note 141, at 1650.

^{155.} Adams v. Davison-Paxon Co., 96 S.E.2d 566, 571-72 (S.C. 1957).

^{156.} Byrd, 356 U.S. at 533-34.

^{157.} *Id.* at 535–36.

^{158.} Id. at 537.

^{159.} Id.

^{160.} Id. at 538.

^{161. 380} U.S. 460 (1965).

^{162.} Berger, supra note 73, at 315-16.

^{163.} Hanna, 380 U.S. at 468 n.9.

^{164.} Gasperini v. Center for Humanities, Inc., 518 U.S. 415 (1996).

^{165.} Id. at 427-28.

^{166.} Id. at 418 (quoting N.Y. C.P.LR. § 5501(c) (McKinney 1995)). "To determine whether an award 'deviates materially from what would be reasonable compensation,' New York state courts look to awards approved in similar cases." Id. at 425 (quoting N.Y. C.P.L.R. § 5501(c) (McKinney 1995)).

^{167.} Id. at 422–23. The difference in the standard's strictness is no accident. New York "lawmakers found the 'shock the conscience' test an insufficient check on damage awards; the legislature therefore installed a standard 'invit[ing] more careful appellate scrutiny." Id. at 423

In its RDA analysis, the Supreme Court first addressed whether the federal court's application of the state standard was outcome effective; that is, whether such an application provoked forum shopping or unfair discrimination against the citizens of the forum state. ¹⁶⁸ The Court reported that both parties agreed that the issue, a statutory cap on damages, was substantive under *Erie*. ¹⁶⁹ Since the application of federal law would produce "substantial" outcome variation from a court applying the state law, the Court reasoned that the New York statute implicated the twin aims of *Erie*. ¹⁷⁰ Even if the difference between state and federal standards leads to forum shopping and unfair discrimination, courts must also consider the federal court system's "essential" attributes. ¹⁷¹ The Court specified that one example of an important federal interest is the preservation of traditional federal distributions of trial functions between judge and jury "under the influence . . . of the Seventh Amendment."

The Gasperini Court then noted that unlike the Byrd Court, it did not face a "one-or-the-other choice." Instead, the Court found that both federal and state interests could be accommodated via a compromise. Justice Ginsberg, writing for the Court, held that the federal trial court must apply New York's "deviates materially" standard. Both practical considerations and the Seventh Amendment weighed in favor of allocating this responsibility to the trial judge. Still, in a nod to federal concerns, the district court's application of the standard would be subject to review under the usual federal abuse of discretion standard—the same standard currently used for traditional federal appeals on the grounds of an excessive verdict.

In Gasperini, the Hanna twin aims test was not used to determine whether the state practice was substantive; that determination appeared to have already been made using common sense and the Guaranty Trust outcome determination test. ¹⁷⁷ Instead, Hanna was used as a separate factor in the analysis, perhaps even as an "afterthought." The Byrd balancing test received a mention, but only after the state practice had been declared substantive. Strikingly, the Court in Byrd had declared that a balancing of

⁽alteration in original) (citation omitted).

^{168.} *Id.* at 428.

^{169.} Id. at 428-29.

^{170.} Id. at 430.

^{171.} See id. at 431 (quoting Byrd v. Blue Ridge Rural Elec. Coop. Inc., 356 U.S. 525, 537 (1958)). To that end, the Court mentioned that the "outcome determination" test from Guaranty Trust was "insufficient . . . in cases presenting countervailing federal interests." Id. at 432.

^{172.} Id. at 432 (quoting Byrd, 356 U.S. at 537). Under the Seventh Amendment's influence, the federal courts assign decisions about disputed questions of fact to the jury. Id.

^{173.} *Id.* at 436. In *Byrd*, the defendant either had to be tried by a judge or a jury. Therefore, since the defendant could not be tried by both a judge and the jury or by some compromise of the judge and the jury, the court faced a "one-or-the-other" choice: either the judge or the jury must try the defendant.

^{174.} *Id.* at 437.

^{175.} *Id.* at 438. "Trial judges have the 'unique opportunity to consider the evidence in the living courtroom context,' while appellate judges see only the 'cold paper record." *Id.* (citations omitted).

^{176.} Id.

^{177.} Freer, supra note 141, at 1654-55.

^{178.} *Id.* at 1655.

federal interests with state interests should occur only when the state practice had been declared *procedural*. ¹⁷⁹

Therefore, commentators and lower courts are uncertain about the weight afforded to outcome determination, how the test proposed by *Hanna* fits into the *Erie* analysis, and whether *Byrd* is good law. ¹⁸⁰ As explained in the following Part, however, it does not matter which test (*Byrd*, *Hanna*, or *Gasperini*) is used to determine whether the application of the *Daubert* trilogy violates the *Erie* line of cases. The Ninth and Eleventh Circuits' case law, when applied to diversity actions originating in the more lenient state courts, violates every test the Supreme Court has put forth. ¹⁸¹

V. APPLYING ERIE ANALYSIS TO THE DAUBERT TRILOGY

While there is much confusion about the state of the *Erie* doctrine, none of the current *Erie* tests sanction the difference between federal and state common law as discussed in Part III. A defendant's ability to avoid a state's constitutionally-enacted standards by removing a case to federal court violates every principle implicit in the original *Erie* decision.

A. The Hanna Prong Does Not Apply

The *Hanna* court held that if the Constitution or an act of Congress applies to the issue at bar, then federal judges must follow the federal practice despite a contrary state rule. Thus, the *Hanna* prong might appear to apply to the federal common law of evidence admission since Federal Rule of Evidence 702 governs the admission of evidence. Yet this conclusion misses an important distinction. The federal trial courts move beyond the statutory rules of evidence in excluding epidemiological evidence with a relative risk of less than 2.0 or in refusing to admit certain types of evidence without epidemiological evidence. "Generalizations such as those are judge-made procedural rules rather than rules adopted under the Rules Enabling Act or by statute." Therefore, the *Hanna* prong does not exempt the case law surrounding the *Daubert* trilogy from scrutiny under *Erie*.

^{179.} Byrd v. Blue Ridge Rural Elec. Coop., Inc., 356 U.S. 525, 537-38 (1958).

^{180.} See, e.g., Michael A. Berch & Rebecca White Berch, An Essay Regarding Gasperini v. Center for Humanities, Inc. and the Demise of the Uniform Application of the Federal Rules of Civil Procedure, 69 Miss. L.J. 715, 716 (1999); C. Douglas Floyd, Erie Awry: A Comment on Gasperini v. Center for Humanities, Inc., 1997 BYUL. Rev. 267, 290; Freer, supra note 141, at 1662—63; Eva Madison, The Supreme Court Sets New Standards of Review for Excessive Verdicts in Federal Court in Gasperini v. Center for Humanities, Inc., 50 ARK. L. Rev. 591, 602—03 (1997).

^{181.} See Berger, supra note 73, at 313 (reaching a similar conclusion, but for different reasons).

^{182.} Hanna v. Plumer, 380 U.S. 460, 472-474 (1965).

^{183.} Berger, supra note 73, at 311-12.

B. The Byrd Test

In the first part of the Byrd test, the court determines the interests the competing state rule serves. 184 There is almost certainly a substantive state interest in regulating the plaintiffs' evidence admission criteria because at least two policy judgments influence a state's standards of evidence admission. 185 First, the state procedure helps to decide whether the tort system should place the onus for uncertainty about product risks on the manufacturer or the purchaser. The state makes a choice between the precautionary values protective of public health (pro-plaintiff) and the conservative values of scientific proof (pro-defendant). 186 Second, through evidence admission standards, states decide whether they trust judges more than juries to understand and fairly apply an expert's conclusions. The states' conclusions were presumably based on a reasoned analysis supported by the beliefs of the state's citizens. Both of these state policies are "bound up in the rights and obligations of the parties." Consequently, a court applying Byrd to the federal common law would find a substantial state interest. The court would not need to attempt the other portions of the tripartite Byrd test. 188 So. under the original Byrd test, when the state expert evidence admission procedure conflicts with federal practice, the state evidence procedure should govern in a federal diversity case.

C. Hanna's Twin Aims Test

A Hanna analysis also concludes that certain federal circuits violate Erie by applying the federal common law of evidence admission to diversity cases. Hanna's dicta on the RDA suggested that a court should apply the state procedure over a competing federal rule if the state procedure discourages forum shopping and avoids discrimination against the forum state's citizens. The Ninth and Eleventh Circuits' interpretations of Daubert and Joiner actually encourage defendant forum shopping because federal evidentiary standards disadvantage many forum-state plaintiffs. Upon the defendants' motions for summary judgment, federal courts in those circuits dismiss diversity cases that would have gone to trial at the state level. This harm to the plaintiffs prompts the defendants to remove when the forum state employs a more lenient standard than the federal common law. Additionally, plaintiffs in the Ninth and Eleventh Circuits who sue out-of-state defendants experience discrimination relative to similarly located plaintiffs who sue forum-state defendants. When out-of-state defendants remove, the stricter federal courts deny the plaintiffs recourse to the more lenient state laws that plaintiffs suing forum-state defendants enjoy. Consequently,

^{184.} Byrd, 356 U.S. at 535-36 (1958); Berger, supra note 73, at 315.

^{185.} See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 147-48 (1997) (Breyer, J., concurring).

^{186.} Finley, supra note 18, at 336.

^{187.} Byrd, 356 U.S. at 535-36.

^{188.} Id. at 536.

^{189.} Or, equivalently, the federal procedure encourages forum shopping.

^{190.} Hanna v. Plumer, 380 U.S. 460, 468 n.9 (1965).

^{191.} Even though a grant of summary judgment is "outcome determinative" via the grant of summary judgment to defendants, federal courts are privileged to use federal standards. Gen. Elec. Co. v. Joiner, 522 U.S. 136, 143 (1997).

under the original *Hanna* analysis, the federal standard for evidence admissibility violates both of *Erie*'s twin aims. 192

D. The Gasperini Test

Applying Gasperini to the evidence admissibility question would lead to the same result, even though the Gasperini Court applies Byrd and Hanna in unexpected ways. In Gasperini, the Court first determined that the state procedure was "substantive" and only then asked whether it "implicate[d]" the twin aims of Erie. 193 The Court based its substance determination on outcome determination or possibly common sense. 194 The Ninth and Eleventh Circuits' rules are outcome determinative because, without the key pieces of evidence excluded under the federal standard, plaintiffs will likely lose on summary judgment; whereas, in some state courts, plaintiffs would have been granted a chance at trial. 195 Common sense also suggests that the federal standard makes substantive policy judgments about the function of tort law and whether juries are capable of deciding cases based on controversial scientific evidence. 196 Under the Gasperini test, the next step is to question whether this substantive federal policy implicates a violation of Erie's twin aims. As demonstrated in Part V.C, the Ninth and Eleventh Circuits' common laws of evidence admission do implicate Erie's twin aims.

After the Gasperini Court ascertained that the state practice was substantive and implicated the twin aims of Erie, the Court evaluated whether conflicting federal interests existed. ¹⁹⁷ In Gasperini, the Court specifically discussed the federal interest in preserving the traditional federal distribution of trial functions between judge and jury "under the influence . . . of the Seventh Amendment." ¹⁹⁸ In fact, courts that have had

^{192.} Perhaps the best counterargument comes from Edward K. Cheng and Albert H. Yoon, who argue that the circuits' interpretation of *Daubert* does not lead to forum shopping. Edward K. Cheng & Albert H. Yoon, *Does* Frye or Daubert Matter? A Study of Scientific Admissibility Standards, 91 VA. L. REV. 471 (2005). Their study purports to measure the effect of the federal Daubert standard on forum shopping by determining whether the federal courts' switch from the old Frye standard to the Daubert standard increased the rate at which defendants remove cases from Frye-standard state forums to the federal court. Id. at 482. Cheng and Yoon found "no evidence that . . . [the federal courts' adoption of] Daubert ma[de] a difference" to defendants' removal rates from Frye standard state forums to federal courts. Id. at 511. But defendants may try to remove to federal court whenever possible because of factors unrelated to Daubert. Therefore, although Daubert's related common law might encourage forum shopping, its effect might be negligible.

^{193.} Gasperini v. Center for Humanities, Inc., 518 U.S. 415, 427–30 (1996).

^{194.} Freer, *supra* note 141, at 1660.

^{195.} Joiner, 522 U.S. at 143; see also Arthur R. Miller, The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis," and Efficiency Clichés Eroding Our Day in Court and Jury Trial Commitments?, 78 N.Y.U. L. REV. 982, 1104 n.623 (2003).

^{196.} See supra Part V.B.

^{197.} Gasperini, 518 U.S. at 431.

^{198.} *Id.* at 431–32 (quoting Byrd v. Blue Ridge Rural Elec. Coop. Inc., 356 U.S. 525, 537 (1958)). Under the Seventh Amendment's influence, the federal courts assign decisions about disputed questions of fact to the jury. *See id*.

occasion to consider *Byrd* have applied it to the distribution of functions between judge and jury. ¹⁹⁹

Since the Ninth and Eleventh Circuits' rules assign more power to the judge during summary judgment and, consequently, less power to the jury, one might assume that the circuits' holdings preserve the important distribution of trial functions between the judge and jury. But in fact, as the *Gasperini* Court implied, the usual application of *Byrd* preserves the federal court's Seventh Amendment-inspired practice of jury supremacy. Historical applications of *Byrd* do not preserve a federal common law that takes the power out of the hands of the jury. The Court is unlikely to break with this tradition to encourage a federal practice that is not "under the influence" of the Seventh Amendment.²⁰⁰

The federal government also retains an interest in maintaining consistency and administrative ease via a uniform federal standard. Richard D. Freer, a leading *Erie* scholar, convincingly argues, however, that asserting a uniformity interest begs the question. "Federal uniformity is proper only if the matter is not one entrusted by *Erie* to state law. The very point of *Erie* is that uniformity among federal courts must give way to promote vertical uniformity for citizens of the various states, at least with regard to substantive matters." Moreover, the Supreme Court has referred to uniformity as "that most generic (and lightly invoked)" federal interest. Therefore, the Supreme Court is unlikely to view the federal interest in uniformity, without more, as dispositive.

At this point in its analysis, the Gasperini Court rendered a compromise between state and federal rights. In contrast, the current Erie dilemma forces a "one-or-the-other" choice. Either the federal court sitting in diversity adopts its own evidentiary standard or it adopts the standard of the forum state. Since there is no possible compromise, the Gasperini test dictates that the Ninth and Eleventh Circuits' evidence admissions standards, when applied to diversity cases, violate Erie. Therefore, under all three Supreme Court tests—Hanna, Byrd, and Gasperini—the Ninth and Eleventh Circuits violate Erie in their applications of the Daubert trilogy. 203

^{199.} See, e.g., Dill v. Scuka, 279 F.2d 145, 147 (3d Cir. 1960) (citing Byrd in a discussion about the roles of judge and jury in federal and state cases, but not applying Byrd); Walker v. United States Gypsum Co., 270 F.2d 857, 862 n.12 (4th Cir. 1959).

^{200.} Byrd, 356 U.S. at 535.

^{201.} Richard D. Freer, Erie's Midlife Crisis, 63 Tul. L. Rev. 1087, 1140 n.241 (1989). But federal courts sometimes see the issue differently. See, e.g., Boyle v. United Techs. Corp., 487 U.S. 500, 508 (1988) ("In some cases, for example where the federal interest requires a uniform rule, the entire body of state law applicable to the area conflicts and is replaced by federal rules."); Wilson v. Garcia, 471 U.S. 261, 275 (1985) (stating that the Court's interpretation of a statute is supported by federal interests in uniformity, certainty, and the minimization of unnecessary litigation); Taylor v. Titan Midwest Constr. Corp., 474 F. Supp. 145, 147 (N.D. Tex. 1979).

^{202.} O'Melveny & Myers v. FDIC, 512 U.S. 79, 88 (1994).

^{203.} Christopher Mueller poses an interesting objection to this conclusion. He writes that although some federal circuits implement different evidence standards from those in the forum state, the circuits do not violate *Erie*. The federal circuits' dissimilar standards are not "policy-driven," but are instead "epistemological." Christopher B. Mueller, Daubert Asks the Right Questions: Now Appellate Courts Should Help Find the Right Answers, 33 SETON HALL L. REV. 987, 1003 (2003). "If the results were policy-driven, one would expect to see opinions linking

VI. SOLUTION

The Ninth and Eleventh Circuits have put forth, to varying degrees, a rigorous common law standard requiring plaintiffs to prove causation by submitting epidemiological evidence with a relative rate of 2.0 or more. This Note has shown that this rule, applied in diversity cases arising from states with more lenient evidentiary requirements, violates *Erie* under all three *Erie* tests. To avoid the *Erie* problem, all federal courts should consider their evidence admission determinations to be governed by the forum state's substantive common law.

State courts reach results that are unrelated to whether they apply the federally-favored *Daubert* standard or continue to rely on the *Frye* rule to determine evidence admissibility. Therefore, the federal courts should neither automatically apply the federal courts' *Daubert* precedent when the forum state follows *Daubert*, nor should they presumptively invoke a more permissive federal standard when the forum state follows *Frye* or a mix of *Daubert* and *Frye*. Instead, federal courts need to make a unique investigation into the common law of the forum state before ruling on any set of evidentiary standards. ²⁰⁶

In deferring to state common law, the federal circuits will respect state policy determinations about whether the state's tort law should further product safety (proplaintiffs) or encourage increased manufacturer innovation (pro-defendants). The circuits will also respect the forum state's policy decision to place more trust in judges or juries. This new federal standard would discourage forum shopping by defendants and reduce discrimination against forum-state plaintiffs. Such deference would not infringe upon any substantive countervailing federal interests. Furthermore, the federal courts would not be overly taxed by the application of a nonuniform standard. Developing a reference manual for each state's substantive common law of evidence admissibility would be a relatively quick process. The manual could be updated yearly

the discussion of 'how much is enough' to particular substantive standards, or to the purposes of tort law as compensatory and loss-spreading, or as shifting to manufacturers only actual costs of injury while keeping innovation alive" *Id.* Mueller's understanding of *Erie* is incorrect. First, there *are* opinions linking the evidentiary discussion to policy concerns. *See*, *e.g.*, Joiner v. Gen. Elec. Co., 522 U.S. 136 (1997). More importantly, though, even if the federal government does not strive to implement its own policy, the *Erie* analysis does not consider the federal government's intentions, but only its effects.

204. See supra Part III.

205. Berger, supra note 73, at 322; see, e.g., Linnen v. A.H. Robins Co., Inc., 11 Mass. L. Rptr. 205 (Mass. Super. Ct. 2000) (following Daubert but allowing epidemiological evidence with a relative risk of less than 2.0); Hand v. Norfolk S. Ry. Co., No. 03A01-9704-CV-00123, 1998 WL 281946, at *3 (Tenn. Ct. App. June 2, 1998) (following a mixed Frye and Daubert analysis and holding that an epidemiological study did not have to show a relative risk greater than 2.0).

206. For example, New Jersey courts follow *Daubert*, but reject a 2.0 relative risk as a threshold to admitting epidemiological evidence. *See, e.g.*, Landrigan v. Celotex Corp., 605 A.2d 1079, 1087 (N.J. 1992) (following *Daubert* but rejecting a 2.0 relative risk as a threshold to admitting epidemiological evidence). Conversely, Michigan follows the ostensibly more lenient *Frye* standard, but Michigan's state courts *do* require a relative risk of greater than 2.0. *See, e.g.*, DePyper v. Navarro, No. 83-303467-NM, 1995 WL 788828, at *33 (Mich. Cir. Ct. Nov. 27, 1995) (following *Frye* but requiring a relative risk over 2.0 to show "statistical significance" and a relative risk of 2.5 or greater to demonstrate "strong association").

by district court clerks in each jurisdiction or perhaps by a private enterprise, such as Westlaw or LexisNexis. Between revised manuals, each court's judicial clerks could run a brief search at the beginning of each case to determine whether that forum state's evidentiary standard had recently changed. Even in the absence of a reference manual, though, the parties to litigation would almost certainly notify the court of any evidentiary changes, since at least one side would cite the change in order to reap its benefits.

CONCLUSION

Reacting to pervasive criticism about "junk science" in the courtroom, the Supreme Court crafted the *Daubert* test. That opinion was intended to strengthen the trial judge's role as a gatekeeper in admitting expert scientific evidence, and it did. *Daubert* and *Joiner* established a clear set of federal policy choices. ²⁰⁷ First, the federal courts should trust judicial determinations more than juries' conclusions with respect to scientific evidence. Second, courts should err on the side of conservative scientific principles when deciding whether to admit or reject expert evidence. Finally, the federal trial courts' decisions on plaintiffs' expert evidence should be afforded great deference.

The Ninth and Eleventh Circuits have promulgated a particularly stringent set of evidentiary standards based on these policy choices. The Eleventh Circuit requires presentation of epidemiological evidence that shows at least a doubling of relative risk. The Ninth Circuit similarly requires that admissible epidemiological evidence display a doubling of the plaintiff's risk, unless the substance at issue is generally understood to cause harm²⁰⁹ or the plaintiff proves that her personal susceptibility is greater than the average. Yet six state courts located in the Ninth and Eleventh Circuits set out a more lenient standard of evidence admissibility than their federal counterparts. The departure from the federal standard is likely driven by the desire to privilege juries over judges or the fear that the first plaintiffs to contract a disease may not have the resources to bridge the causation gap.

The Ninth and Eleventh Circuits' rigorous admissibility standards tend to produce defendant-friendly outcomes. In requiring a more difficult evidentiary threshold for plaintiffs, the federal courts in those circuits are more likely to dismiss plaintiffs' cases on summary judgment. Accordingly, diverse defendants are more likely to remove to federal court when they face civil charges in a more lenient state in the Ninth or

^{207.} See supra Part II.

^{208.} Allison v. McGhan Med. Corp., 184 F.3d 1300, 1315 n.16 (11th Cir. 1999) ("The threshold for concluding that an agent more likely than not caused a disease is 2.0."); Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584, 591 (D.N.J. 2002); *In re* Breast Implant Litig., 11 F. Supp. 2d 1217, 1274 (D. Colo. 1998); Sanderson v. Int'l Flavors and Fragrances, Inc., 950 F. Supp. 981, 1000 (C.D. Cal. 1996) ("Since [plaintiff's] probability estimate [was] not founded upon epidemiological studies showing a relative risk of greater than two, [it did not establish] 'a valid scientific connection to the pertinent inquiry...") (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592 (1993)).

^{209.} In re Berg Litig., 293 F.3d 1127, 1129 (9th Cir. 2002).

^{210.} In re Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1137 (9th Cir. 2002).

^{211.} See supra Part III.

Eleventh Circuit. Such forum shopping enables defendants to elude the consequences of more lenient state standards. The distinction in evidence admissibility between federal and state courts consequently provokes the *Erie* concerns of federalism and state comity.

In fact, the Ninth and Eleventh Circuits' strict evidentiary requirements do not survive the application of a single *Erie* test. ²¹² These circuits fail the *Byrd* test because there is a substantive state interest in enforcing lighter evidentiary standards to preserve public safety. A *Hanna* analysis concludes that the circuits violate *Erie*'s twin aims of discouraging forum shopping and avoiding discrimination against the forum state's citizens. Finally, a court applying *Gasperini* would almost certainly find that the federal interests in uniformity do not outweigh the states' substantive interests in protecting their citizens. To avoid this *Erie* problem, federal courts sitting in diversity should defer to the forum state's substantive common law. In deferring, the federal courts would neither undergo undue administrative burden, nor would they subvert their own substantive interests to those of the state. More importantly, though, the federal courts would recognize and respect state policies that respect juries and favor consumer safety over manufacturer innovation.

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