UPSETTING THE BALANCE BETWEEN ADVERSE INTERESTS: THE IMPACT OF THE SUPREME COURT'S TRILOGY ON EXPERT TESTIMONY IN TOXIC TORT LITIGATION

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I

INTRODUCTION

In 1948, in *Michelson v. United States*,[1] Justice Jackson declined to modify the common law rules on character evidence. He warned that "[t]o pull one misshapen stone out of the grotesque structure is more likely simply to upset its present balance between adverse interests than to establish a rational edifice."[2] Justice Jackson's comment is worth pondering in a very different context. Beginning in 1993, the Supreme Court, in a trilogy of opinions, has explicitly sought to rationalize the law on expert testimony.[3] This article examines Justice Jackson's prediction that a change in an evidentiary rule may realign the balance that previously existed between adverse interests.

My inquiry is limited to toxic tort cases for a number of reasons. First, these are the cases that drove the demand for expert testimony reform.[4] These are

This article is also available at http://www.law.duke.edu/journals/64LCPBerger.

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I wish to thank Brooklyn Law School for support I received from a summer research stipend and my research assistant, Robert F. LeMoine, Brooklyn Law School, class of 2002.

1. 335 U.S. 469 (1948).

2. *Id.* at 486.

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

4. *See* Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 644 (1992) (explaining that the Agent Orange and Bendectin toxic tort cases have "fueled a reform movement in the treatment of expert witness testimony regarding causation in the toxic arena that extends beyond Agent Orange and Bendectin"). The Carnegie Commission's Task Force on Judicial and Regulatory Decision Making, which had begun in 1989 to examine ways to assist the judiciary in the management of science and technology issues, prepared a report detailing their findings. *See generally* CARNEGIE COMMISSION ON SCIENCE, TECHNOLOGY, AND GOVERNMENT, SCIENCE AND TECHNOLOGY DECISION MAKING: CREATING OPPORTUNITIES AND MEETING CHALLENGES (1993). The Task Force recognized the recurring problem of how to handle different types of proof in toxic tort litigation and initiated the preparation of a scientific reference manual, a project ultimately completed by the Federal Judicial Center. *See also* JUDICIAL CONFERENCE OF THE U.S., REPORT OF THE FEDERAL COURTS STUDY COMMISSION (1990).

the cases that produced allegations about venal experts who bring "junk science" into the courtroom[5] and that seem to have piqued the Supreme Court's interest in expert proof perhaps because of the huge amounts of damages and transaction costs at stake.[6] The first two opinions in the trilogy deal with the admissibility of expert proof on causation in toxic tort cases. Second, Justice Jackson's thesis seems applicable to toxic tort litigation because the trilogy may be leading some district court judges to exclude experts proffered by plaintiffs on the issue of causation who previously would have been permitted to testify.[7] The Federal Judicial Center conducted surveys in 1991 and 1998 asking federal judges and attorneys about expert testimony. In the 1991 survey, seventy-five percent of the judges reported admitting all proffered expert testimony. By 1998, only fifty-nine percent indicated that they admitted all proffered expert testimony without limitation. Furthermore, sixty-five percent of plaintiff and defendant counsel stated that judges are less likely to admit some types of expert testimony since *Daubert*.[8] Without the means to prove causation, which is always a crucial element of the plaintiff's case, the plaintiff must lose, and the litigation ends with summary judgment for the defendant. The consequence, according to some observers,[9] is that toxic tort law is being reformulated in the federal courts to the advantage of defendants, a result that accords with Justice Jackson's predictions about the impact an evidentiary change may have.

This article seeks to uncover the various ingredients that have contributed to this result. Part II contains an overview of the trilogy on expert proof and examines its message for the federal district judge. Part III examines the unstated assumptions some federal courts are making about science that affect a judge's rulings on the admissibility of plaintiffs' expert testimony. Part IV deals

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5. *See generally* PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991) (arguing that too much "junk science" was entering the courtroom via expert witnesses). For a critique of Huber's work, see Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637 (1993).

6. Certainly, the movement to reform expert testimony has been intertwined with demands for tort reform.

7. Statistics are not available on the outcome of motions to exclude plaintiffs' experts. Cases in which a judge grants summary judgment after a successful motion to exclude plaintiff's experts often result in reported opinions, while many cases in which a judge denies such a motion undoubtedly settle and disappear from view. In its Note to the Amendment to Rule 702, which took effect on December 1, 2000, the Advisory Committee on the Federal Rules of Evidence states without reference to any authority that "a review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule." FED. R. EVID. 702 advisory committee's note. This statement apparently refers to all kinds of expert testimony. For a narrower view, see Daniel J. Capra, *The* Daubert *Puzzle*, 32 GA. L. REV. 699, 732 (1998) ("Many of the reported cases on *scientific* experts after *Daubert* have resulted in exclusion of the proffered testimony." emphasis added). Professor Capra is the Reporter to the Committee.

8. *See* MOLLY TREADWAY JOHNSON ET AL., EXPERT TESTIMONY IN FEDERAL CIVIL TRIALS: A PRELIMINARY ANALYSIS (Federal Judicial Center ed., 2000) (outlining the FJC survey); *see also* Michael D. Green, *The Road Less Well Traveled (And Seen): Contemporary Lawmaking in Products Liability*, 49 DEPAUL L. REV. 377, 400 n.119 (1999) (noting that in 10 to 12 reported cases a week invoking *Daubert*, the "vast majority" hold the "challenged expert's testimony inadmissible").

9. *See* 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, 335 (1999); Green, *supra* note 8, at 399-403.

with a striking paradox. As every first-year law student knows, the *Erie* doctrine[10] requires a federal judge who sits in diversity jurisdiction to apply state substantive law. Toxic tort cases almost invariably come into federal court on the basis of diversity jurisdiction. Nevertheless, federal courts have ignored *Erie* in ruling on the admissibility of plaintiffs' experts, even in situations in which sensitivity to state law would seem appropriate under current Supreme Court jurisprudence, but have relied on *Erie* to convert rulings on the admissibility of evidence into determinations about the sufficiency of the evidence. This conflating of sufficiency and admissibility began before the recent amendment to Rule 702, which added a sufficiency requirement to the rule.[11] Finally, Part V considers how the trilogy on the admissibility of expert proof has intersected with the Supreme Court's previous trilogy on summary judgment to move final adjudication in the toxic tort case from the trial to the pretrial stage, and from jury consideration to a decision by the judge.

As a consequence of these developments, federal district courts have acquired enormous power to shape toxic tort litigation. They have been freed from constraints that previously tempered their authority: the command of state law, the authority of the jury, and strict scrutiny by the appellate courts. Not all district judges are taking advantage of this new autonomy, and not all appellate courts are acceding to this change. But generally trial courts that wish to control the outcome of toxic tort litigation now have ample tools to do so.[12] This recasting of toxic tort law, which is being fueled by the trilogy on expert proof, is consistent with other developments in the federal courts that demonstrate an increased emphasis on efficiency and economy, procedural goals so powerful that they have reshaped both the evidentiary and the substantive law pertaining to toxic torts.

II

THE SUPREME COURT'S TRILOGY ON EXPERT PROOF

A. *Daubert*

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[13] the first and seminal case in the expert proof trilogy, the Supreme Court construed Rule 702 of the Federal Rules of Evidence to determine under what circumstances expert testimony

10. *See* Erie R.R. v. Tompkins, 304 U.S. 64 (1938) (overruling Swift v. Tyson, 41 U.S. 1 (1842)).

11. *See infra* Part V.

12. *See* Eleanor Swift, *One Hundred Years of Evidence Law Reform: Thayer's Triumph*, 88 CAL. L. REV. 2437, 2466-68, 2472-74 (2000) (discussing enlargement of trial court discretion with regard to admissibility of expert testimony).

13. 509 U.S. 579 (1993) (considering plaintiffs' claims that their birth defects were caused by Bendectin, an anti-morning-sickness pill that had been taken by their mothers and more than 20 million other women). For a detailed discussion of the Bendectin litigation, see Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts,* 43 HASTINGS L.J. 301 (1992). *See generally* Green, *supra* note 4 (discussing the Bendectin litigation at length).

relating to "scientific knowledge" is admissible.[14] The lower courts in *Daubert* had relied on the so-called "general acceptance" test first enunciated by a federal appeals court in *Frye v. United States*[15] as a basis for finding inadmissible the epidemiological and toxicological evidence offered by plaintiffs' experts to prove causation. The Supreme Court unanimously held that *Frye* had been superseded by Rule 702[16] and then, over the objections of the Chief Justice and Justice Stevens,[17] sketched out a new, two-pronged test. The objective, said the Court, is to ensure that testimony about scientific evidence "is not only relevant, but reliable."[18]

In order to satisfy the reliability prong, the expert's proffered opinion must be the product of scientific reasoning and methodology. That is, the expert had to have reached his conclusions through a valid scientific method. The Court suggested a number of non-exclusive factors that a court might consider in determining whether the expert's opinion met the reliability criterion. First and foremost, the *Daubert* Court viewed science as an empirical endeavor: "Whether a theory or technique can be (and has been) tested" is the "methodology" that "distinguishes science from other fields of human inquiry."[19] The Court also mentioned peer review or publication,[20] the existence of known or potential error rates, and standards controlling the technique's operation as indicators of reliability.[21] General acceptance of the methodology within the scientific community, while no longer dispositive, still remained a factor to be considered.[22] As to the second prong, the Court explained that the relevancy requirement meant that the expert's theory must "fit" the facts of the case; oth-

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14. From the time of its enactment in 1975 until its amendment in 2000, Rule 702 read as follows:

> 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.

FED. R. EVID. 702.

15. 293 F. 1013 (D.C. Cir. 1923). *Frye* had not been followed by all federal circuits and had been used primarily in criminal cases. It is still the test for the admissibility of scientific evidence in some state courts. In 1999, the Conference of Commissioners on Uniform State Laws approved an amendment to Rule 702 of the Uniform Rules of Evidence that would "convert the Frye standard of admissibility into a presumption of reliability or unreliability depending upon whether the science, technology, or specialized knowledge has substantial acceptance within the concerned scientific community and to provide for the rebuttal of the presumption through resort to reliability criteria, including the criteria established" in *Daubert* and *Kumho*. Leo Whinery, *The American Version of the Rules of Evidence–Can They be Improved?*, 195 F.R.D. 57, 94 n.55 (1999).

16. *See Daubert*, 509 U.S. at 587.

17. Chief Justice Rehnquist's partial dissent, in which Justice Stevens joined, stated: "I do not doubt that Rule 702 confides to the judge some gatekeeping responsibility in deciding questions of the admissibility of proffered expert testimony." *Id.* at 600 (Rehnquist, C.J., dissenting in part). They would have decided only the *Frye* issue and left "the further development of this important area of the law to future cases." *Id.* at 601 (Rehnquist, C.J., dissenting in part).

18. *Id.* at 589.

19. *Id.* at 593 (internal quotations omitted) (quoting Green, *supra* note 4, at 645).

20. *See id.*

21. *See id.* at 594.

22. *See id.*

erwise, the expert's hypothesis would not assist the trier of fact as required by Rule 702.[23]

In *Daubert,* the Supreme Court did not apply its new test. Instead, the Court remanded, and the Ninth Circuit again excluded the proffered testimony under the new test, granting summary judgment for the defendant.[24]

Two strong messages emanated from *Daubert.* The first, and perhaps the most consequential, was the new role it thrust upon the district judge.[25] The opinion explicitly anointed the trial judge as the "gatekeeper" who must screen proffered expertise to determine whether it satisfied the relevancy and reliability prongs.[26] Although there was nothing particularly novel about a trial judge having the *power* to exclude inappropriate expert testimony,[27] *Daubert* stressed the trial court's *obligation* to exercise this power.[28] Defendants were quick to see the implications. The emphasis on admissibility and the judge's responsibility to screen this type of evidence encouraged defendants to seek pretrial rulings on the admissibility of expert testimony[29] and to follow a favorable result with a motion for summary judgment if the experts excluded were essential to the plaintiff's *prima facie* case. The result was an enormous increase in *in limine* motions asking for a *Daubert* hearing.[30]

Second, judges were put on notice that—like it or not—they were going to have to deal with science. No longer could they allow an expert witness with excellent credentials to validate his or her own expertise. The Court assumed that the plaintiffs' experts in *Daubert* were qualified; whether their testimony was based on "scientific knowledge" was a separate question that the trial court had to confront.[31]

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23. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591-92.

24. *See* Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311 (9th Cir. 1995).

25. *See* Margaret A. Berger, *Procedural Paradigms for Applying the Daubert Test,* 78 MINN. L. REV. 1345 (1994).

26. *See Daubert*, 509 U.S. at 589.

27. This consequence, as the Court recognized in *Daubert,* followed from a straightforward application of FED. R. EVID. 104(a). *See id.* at 592-93.

28. *See id.* at 589.

29. Although some expert proof was excluded before trial on admissibility grounds prior to *Daubert*, the Bendectin litigation demonstrates that this was not the customary procedure in the federal courts. Plaintiffs were uniformly unsuccessful in these cases in federal court, not because judges refused to admit their proffered expert proof, but because trial and appellate courts found it insufficient even when plaintiffs received a jury verdict at trial. *See* Sanders, *supra* note 13, at 374-79. Four years before *Daubert*, Judge Higginbotham suggested in a Bendectin case that the real issue was the *admissibility* of expert evidence, rather than the sufficiency grounds upon which the case was decided, and urged a rehearing *en banc* at which this issue could be addressed. *See* Brock v. Merrell Dow Pharms., Inc., 884 F.2d 167, 169 (5th Cir. 1989) (majority denied a rehearing *en banc*; Judge Higginbotham joined the dissent).

30. The most frequent response chosen by attorneys surveyed about how their practice changed following *Daubert* was that 32% of them acknowledged making more motions *in limine* to exclude opposing experts. *See* JOHNSON ET AL., *supra* note 8, at 4 .

31. *See Daubert*, 509 U.S. at 592-93.

B. *Joiner*

General Electric Co. v. Joiner,[32] the second case in the trilogy, was significant on two counts. First, the Supreme Court unanimously found that an appellate court must use an abuse-of-discretion standard in reviewing a district judge's *Daubert* ruling, even when that ruling was "outcome-determinative" because the exclusion of plaintiff's expert proof on causation led to a grant of summary judgment.[33] Second, the *Joiner* opinion provides insights into applying the *Daubert* test in a toxic tort context. With the exception of Justice Stevens, who dissented from this part of the opinion,[34] the majority did not remand, as it had in *Daubert*. Instead, the Court reviewed the trial court's ruling and found that it had not abused its discretion in holding that the studies on which the plaintiff's experts relied were "not sufficient, whether individually or in combination, to support their conclusions."[35] The Court stated that the plaintiff never explained "how and why the experts could have extrapolated their opinions" from animal studies far removed from the circumstances of the plaintiff's exposure.[36] The studies had been conducted with infant mice, who not only were injected with much higher doses of PCBs than were present in the transmission fluids with which the plaintiff came into contact at work, but also developed a different type of cancer than the plaintiff had.[37] The Supreme Court noted that the plaintiff chose "'to proceed as if the only issue [was] whether animal studies can ever be a proper foundation for an expert's opinion.'"[38] That, said the Court, was "of course . . . not the issue. The issue was whether *these* experts' opinions were sufficiently supported by the animal studies on which they purported to rely."[39]

Furthermore, the Court found that the trial court had not erred in rejecting the proffered epidemiological evidence. The authors of one study had refused to conclude that PCBs had caused a somewhat higher rate of lung cancer at an Italian plant than might have been expected; the results of another study were not statistically significant; a third study did not mention PCBs; and the workers in the fourth study cited by the trial judge had been exposed to numerous other potential carcinogens.[40] Consequently, the Court found that the trial judge

32. 522 U.S. 136 (1997) (considering the claim of a 37-year-old plaintiff, a long-time smoker with a family history of lung cancer, that exposure to polychlorinated biphenyls ("PCBs") and their derivatives had promoted the development of his small-cell lung cancer).

33. *Id.* at 141-43.

34. Justice Stevens expressed doubt as to whether the admissibility question had been adequately briefed and in any event thought that the record could be studied more efficiently by the Court of Appeals than by the Supreme Court. *See Joiner*, 522 U.S. at 150 (Stevens, J., dissenting in part). In addition, he expressed concern as to how the Court applied the *Daubert* test to the reliability ruling by the trial judge. *See id.* at 151.

35. *Id*. at 146-47.

36. *Id.* at 144.

37. *See id.*

38. *Id.* (quoting Joiner v. General Elec. Co., 864 F. Supp. 1310, 1324 (N.D. Ga. 1994), *rev'd,* 78 F.3d 524 (11th Cir. 1996), *rev'd*, 522 U.S. 136 (1997)).

39. *Id.*

40. *See id*. at 143-45.

could conclude that statements of plaintiffs' experts with regard to causation were nothing more than "speculation."[41]

C. *Kumho*

Kumho Tire Co. v. Carmichael,[42] the final case in the trilogy, although not a toxic tort case, does deal with expert proof of causation. The Court had to decide whether the *Daubert* test applies to non-scientific evidence, in this case engineering testimony offered to prove that the blow-out of plaintiff's tire—which resulted in a death and serious injuries—was due to a manufacturing or design defect.[43] The Supreme Court unanimously held that the trial court's gatekeeping function extends to all expert testimony and that *Daubert's* two-pronged relevancy-reliability test applies to all forms of expertise. It also extended the *Joiner* abuse-of-discretion standard to all decisions a district judge makes in ruling on the admissibility of expert testimony, including the procedures it uses in making *Daubert* determinations.[44]

Nothing in Justice Breyer's opinion in *Kumho* is inconsistent with Justice Blackmun's reasoning in *Daubert*. Nevertheless, the two opinions differ somewhat in tone. Although *Daubert* had described "the Rule 702 inquiry as 'a flexible one,'"[45] and made "clear that the factors it mentions do not constitute a 'definitive checklist or test,'"[46] some commentators and courts had interpreted *Daubert* as laying down a four-factor test for the admissibility of scientific evidence and predicted that the Court would develop a taxonomy of expertise.[47] *Kumho* rejects this notion. The Court shows no interest in articulating guidelines for particular categories of expert testimony or in singling out testability as the preeminent factor of concern as it did in *Daubert*. The *Kumho* opinion makes clear that the four *Daubert* factors "may" bear on a judge's gatekeeping determination.[48] The factors "may or may not be pertinent"[49] and "do not all necessarily apply even in every instance in which the reliability of scientific tes-

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41. *Id.*

42. 526 U.S. 137 (1999).

43. The court below, as well as some other circuits, had held that a less stringent test applies in the case of non-scientific expert testimony. *See generally* Carmichael v. Samyang Tire, 131 F.3d 1433 (11th Cir. 1998) (holding that non-scientific testimony was not held to the Daubert test), *rev'd, Kumho*, 526 U.S. 137 (1999).

44. *See Kumho*, 526 U.S. at 152.

45. *Id.* at 150 (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993)).

46. *Id.* (quoting *Daubert*, 509 U.S. at 593).

47. *See* Edward J. Imwinkelried, *The Taxonomy of Testimony Post-*Kumho*: Refocusing on the Bottomlines of Reliability and Necessity,* 30 CUMB. L. REV. 185 (2000) (arguing that *Kumho* questions some of the classification system that had been previously thought to apply); s*ee also* Margaret A. Berger, *The Supreme Court's Trilogy on the Admissibility of Expert Testimony, in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 9, 73 & n.73 (Federal Judicial Ctr. ed., 2d ed. 2000) [hereinafter FJC REFERENCE MANUAL] (noting how some viewed *Daubert* as setting forth a four-factor test).

48. *See Kumho*, 526 U.S. at 150.

49. *Id.* (interior quotations and citation omitted).

timony is challenged."[50] In some cases, "the relevant reliability concerns may focus upon personal knowledge or experience."[51]

The Court emphasized that, in all cases, admissibility will depend "on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[52] The trial court is instructed "to determine reliability in light of the particular facts and circumstances of the particular case,"[53] taking care, however, to ensure that the expert, whether relying on "professional studies or personal experience," must employ "the same level of intellectual rigor" that the expert would use outside the courtroom when working in the relevant discipline.[54] A large portion of the opinion is devoted to a remarkably detailed examination of the testimony that the plaintiff's expert gave at his deposition.[55] The Court concluded that the trial court did not abuse its discretion in excluding the expert's testimony and granting summary judgment for the defendant.[56]

Kumho differs from *Daubert* in another respect as well. While *Daubert* emphasized the trial judge's power and obligation to screen expert testimony, it also assumed that there would be instances of "shaky but admissible [expert] evidence" that a jury would hear, although the evidence ultimately might not be sufficient.[57] The final section of the *Daubert* opinion contains a short paean to the adversary system and cross-examination as the means for dealing with unfounded opinions.[58] *Kumho* and *Joiner* concentrate almost exclusively on issues of admissibility. Although there is a passing reference in *Kumho* to the expert's testimony falling "outside the range where experts might reasonably differ, and where the jury must decide among the conflicting views of different experts, even though the evidence is 'shaky,'"[59] no further attention is paid to the possibility that questions about expert proof may have to be resolved at trial. The Court takes no note of the enormous shift to pretrial resolution that developed in response to *Daubert*, as defendants began making *in limine* motions to exclude plaintiffs' experts. It may be that the Court is satisfied with this trend, which furthers both case-processing efficiency and economy. If the defendant wins the *Daubert* motion, the case terminates with a motion for summary judgment. If the plaintiff wins, many defendants undoubtedly will prefer to settle rather than to pay for an expensive trial and risk a high verdict.

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50. *Id.* at 151.

51. *Id*. at 150.

52. *Id.* (quoting Brief for United States as *Amicus Curiae* Supporting Petitioners at 19, Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999) (No. 97-1709)).

53. *Id.* at 158.

54. *Id*. at 152. The "intellectual rigor" test originated in two opinions by Chief Judge Posner in 1996. *See* Braun v. Lorillard, Inc., 84 F.3d 230, 234 (7th Cir. 1996); Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318 (7th Cir. 1996).

55. *See Kumho*, 526 U.S. at 153-58.

56. *See id.* at 158.

57. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596 (1993).

58. *See id.*

59. *Kumho*, 526 U.S. at 153 (quoting *Daubert*, 509 U.S. at 596).

Read together, the three opinions in the trilogy may convey another unstated message as well. In all three cases decided by the Court, the plaintiff's expert testimony was excluded. Although the abuse of discretion standard adopted in *Joiner* and confirmed in *Kumho* requires equal deference to a trial court's ruling admitting or excluding evidence, we have no example of the Supreme Court reviewing an appellate court's disagreement with a trial court ruling that allowed the plaintiff's experts to testify.[60] It remains to be seen whether the deference accorded trial judge rulings will be symmetrical in cases admitting or excluding expert proof. Three justices of the Court have indicated concern about trial judges allowing too much expert testimony. Justices O'Connor and Thomas joined Justice Scalia in a brief concurring opinion in *Kumho,* which warned that the trial court's discretion is "not discretion to perform the [gatekeeping] function inadequately. Rather, it is discretion to choose among reasonable means of excluding expertise that is *fausse* and science that is junky."[61] It may well be that the trial judge who excludes expert proof is more likely to be affirmed than colleagues who deny a *Daubert* motion. Certainly trial judges who exclude the testimony of plaintiffs' experts are reshaping the law of toxic torts. Part III considers how the courts' view of science enters into these determinations.

III

THE SCIENCE OF PROVING CAUSATION

The decisive issue in a toxic tort case is causation.[62] Plaintiffs have the burden of proving that the defendant's product was capable of causing the health effects in question (general causation) and then establishing, in addition, that the exposure to the defendant's product was the specific cause of their injury (specific causation).[63]

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60. The unlikelihood that the Supreme Court will review such an issue is perhaps underlined by its recent unanimous decision in *Weisgram v. Marley Co.,* 528 U.S. 440 (2000). In *Weisgram*, the district court had admitted the plaintiff's expert testimony on causation in a products liability action involving a baseboard heater. The jury found for the plaintiff. The Court granted certiorari to consider whether the appellate court could reverse and enter judgment for the defendant as a matter of law without granting a new trial and held that the appellate court could do so. The Court refused to review whether the appellate court had acted appropriately when it found the plaintiff's experts unreliable, reversed the district court's ruling admitting the expert proof, and consequently found the plaintiff's proof insufficient. *See Weisgram*, 528 U.S. at 446, n.3.

61. *Kumho*, 526 U.S. at 158-59 (Scalia, J., concurring).

62. *See* JACK B. WEINSTEIN, INDIVIDUAL JUSTICE IN MASS TORT LITIGATIONS: THE EFFECT OF CLASS ACTIONS, CONSOLIDATIONS, AND OTHER MULTIPARTY DEVICES 148 (1995) ("The only real liability issue becomes causation: was this manufacturer's product a substantial cause of this plaintiff's medical problems—however we define them?").

63. *See In re* Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1131 (2d Cir. 1995) ("Causation in toxic torts normally comprises two separate inquiries: Whether the epidemiological or other scientific evidence establishes a causal link between c (asbestos exposure) and d (colon cancer), and whether plaintiff is within the class of persons to which inferences from the general causation evidence should be applied.") (quoting *In re* Agent Orange Prod. Liab. Litig., 611 F. Supp. 1223, 1261-62 (E.D.N.Y. 1985) ("Agent Orange II"), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988)). Plain-

In most toxic tort cases—unlike the usual products liability case—proving causation does not mean that the plaintiff can explain the causal process by which the defendant's product supposedly brought about the adverse health effects for which the plaintiff is suing.[64] We do not yet fully comprehend the mechanisms that produce birth defects and illnesses, such as the cancers and auto-immune diseases for which plaintiffs seek compensation, or their interrelationship.[65] Only rarely—in the case of so-called "signature" diseases—is the sufficiency of the statistical association between a product and a particular disease so compelling that courts and scientists are willing to assume a causal connection.[66] In most instances, however, the adverse health effects for which plaintiffs seek damages are also found in others who have not been exposed to the substance or product in question.

Because direct proof of causation is usually unavailable, and experimentation on humans is ethically proscribed, plaintiffs must rely on the kind of evidence that scientists gather when they investigate a causal link between a substance and disease. Scientists use a number of methods based on reasoning by analogy and statistics. Two of these approaches, although useful as screening devices that may point to the need for more research, are of such limited probative value that expert testimony based solely on such studies is not admitted to prove general causation. Structure-activity analysis[67] examines other substances

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tiffs typically prove specific causation by calling a physician to testify that a differential diagnosis of plaintiff revealed no other explanation for the plaintiff's disease.

64. *See* Mario J. Rizzo, *Foreword: Fundamentals of Causation*, 63 CHI.-KENT L. REV. 397, 403 (1987) ("A rise in the probability (frequency) of an outcome may be evidence of causation. It is not the causal phenomenon itself.") (footnote omitted). Sometimes, as in the Dalkon Shield litigation, plaintiffs are able to offer an explanation about how the product caused their injury. *See* MORTON MINTZ, AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALKON SHIELD 131-48 (1985) (explaining how the string attached to the Shield and the failure to seal its opening introduced "wicked" bacteria into the wearer's uterus).

65. Even if causal mechanisms were better understood, it appears that disease may result from the interaction of multiple factors, including genetic susceptibility, environmental insults, and exposure to pathogens. If this theory of disease is validated, under current tort law plaintiffs would still have the burden of establishing that the product in question was a legally sufficient cause of plaintiff's disease. *Cf.* David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849, 851 (1984) (suggesting that liability should be imposed in proportion to the probability of causation attributable to the substance in issue, regardless of whether the probability is above or below 50%); Jerome Groopman, *Genes That Let Illness In*, N.Y. TIMES, July 19, 2000, at A25 (noting that a recent study estimating the contribution of inherited genes to the development of cancer did not consider the "dynamic interaction" between genes and the environment and further suggesting that this interaction should be the researchers' focus).

66. A "signature" disease is one that nearly always occurs as a result of exposure to a certain substance. For example, "mesothelioma is [nearly] always associated with exposure to asbestos, and vaginal adenocarcinoma is [nearly] always associated with exposure to DES." Betsy Grey, *Bendectin on Trial: A Study of Mass Tort Litigation*, 40 JURIMETRICS J. 257, 260 n.8 (2000) (book review).

67. This type of analysis looks to see whether any other substances with a similar chemical structure have been implicated in causing adverse health effects. If, however, the precipitating mechanism that caused these ill-effects is unknown, it will be impossible to tell whether they are due to the attributes the substances have in common or those that set them apart. *See* 2 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 27-1.3.1, at 263 n.27 (1997) ("[W]e are not aware of any case where expert opinion based solely on a structure-activity relationship has been admitted."); *see also* Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH L.J. 189, 225 ("No two chemicals have the

with a similar chemical structure to see whether they have been implicated in health problems, and in vitro analysis[68] examines the effect of the substance on living cells. The scientist's main tools in investigating a substance's toxicological properties are in vivo studies—which measure a substance's effect on laboratory animals under strictly controlled experimental conditions—and epidemiological studies—which observe human populations to determine whether the incidence of a defined health effect exceeds the background rate in persons exposed to the substance in question.[69]

Difficulties arise, however, when the results of these studies are transferred to a judicial setting. On the surface, the issue seems straightforward, especially after the Supreme Court trilogy on expert proof, which directs the trial court to look at science when dealing with scientific knowledge. Consequently, because the scientific community and the legal system are both concerned with the same question—whether there is a causal connection between product A and health effect B—some courts conclude that evidence that is inconclusive from a scientific perspective automatically fails to satisfy the trilogy's standards and must be excluded. This formulation is overly simplistic because it neglects to take into account some of the attributes of science and how science differs from the law. In this section, I will only consider how a court's view of science affects its decision-making. Part IV of this article considers the appropriateness of having a federal court in a diversity case make choices dictated by policy considerations without first looking at how the state court would proceed.

Before looking at courts' assumptions about science, I want to stress that I am not arguing that plaintiffs' experts should never be excluded. There are cases in which plaintiffs rely on a chronological association between the exposure and the injury and the hope that their experts' sterling qualifications will overcome the admissibility hurdle, even though no studies or observations support their witnesses' hunches about causation.[70] In such instances of sheer speculation by the expert, the trilogy's insistence on screening and excluding ir-

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same structure, so the question is always whether the similarities are more important than the differences in predicting toxicological properties.").

68. In vitro analysis examines how a substance reacts with living cells, bacteria, body organs, or animal embryos. Even when adverse consequences result, the implications for humans are uncertain, because the tests are performed in isolation from the rest of the organism, which may have other resistive mechanisms that would block the harmful reaction. *See* Poulter, *supra* note 67, at 224 (In vitro "tests are fraught with uncertainties, however, related to whether and to what degree the chemical in question would reach or react with the sensitive cells or organs in a whole organism.").

69. *See* Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology, in* FJC REFERENCE MANUAL, *supra* note 47, at 401, 405.

70. *See, e.g.,* Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) (holding that a physician's deposition testimony that plaintiff's heart attack, suffered while wearing a nicotine patch for three days as he continued smoking, was caused by the patch was unreliable under *Daubert*, because the physician presented no evidence whatsoever—experimental, statistical, or other scientific data—to substantiate his findings); Estate of Mitchell v. Gencorp, Inc., 968 F. Supp. 592, 596-97 (D. Kan. 1997), *aff'd*, 165 F.3d 778 (10th Cir. 1999) (holding that a scientist's testimony that benzene exposure caused plaintiff's chronic leukemia was unreliable under *Daubert*, because only a few studies found links between benzene and acute leukemia, but none showed any relationship between benzene and chronic leukemia, and, additionally, all considered a much higher exposure level than that suffered by plaintiff).

relevant, unreliable evidence works very well. Indeed, I do not wish the discussion that follows to be misunderstood as a criticism of the trilogy. Its emphasis on the expert's reasoning process has undoubtedly improved the quality of expert proof in the federal courts; the cases clearly show that federal judges and the bar have become far more sophisticated about scientific concepts.[71]

The cases also indicate, however, that courts do not always understand the boundaries of science when they are forced to evaluate expert testimony that is not completely speculative but is supported by some toxicological or epidemiological studies. Two major misunderstandings about the nature of science contribute to this difficulty. The first is the assumption that science and the law are answering the same question when asked to determine causation; and the second is the view that scientific studies invariably rest on objective, verifiable truth.[72]

The first misunderstanding arises because of a failure to understand that science and the law do not necessarily have the same objectives. The scientific process operates by testing hypotheses. Because the aim is to obtain the most knowledge possible, the system deliberately chooses to err on the side of wrongly rejecting the hypothesis being tested rather than erroneously finding that it was proven.[73] A not-proven verdict in the context of scientific research on causation may signify only that more research should be done. In order to encourage further study, scientists have developed a number of conventions, such as requiring a .05 level of statistical significance.[74] Conventions such as these, which are not universally accepted even within the scientific community,[75] seek to ensure that results will be termed inconclusive until an extremely stringent standard of proof is met.

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71. The recent focus on expert testimony has had an enormous educational impact. The Federal Judicial Center has been active in conducting educational programs for judges and has now published two editions of a Reference Manual on Scientific Evidence that have been made widely available. The Center estimates that 100,000 copies of the first edition have been distributed. *See* Fern M. Smith, *in* FJC REFERENCE MANUAL, *supra* note 47, at v. It also has been accessible on-line at <http://www.fjc.gov/public/fjcweb.nsf/pages/173>. Scientific expert testimony has become a staple of law review commentary, the topic of numerous continuing legal education symposiums, and the subject of numerous new books as well as a comprehensive treatise by Faigman et al. *See* FAIGMAN ET AL., *supra* note 67. *Daubert* has a database of its own and has now been cited over 4000 times in a little over seven years. Search of Westlaw, MDAUBREP (Mealey's Daubert Reports), and DAUBERT (the Daubert Citator).

72. *See* Alvin M. Weinberg, 10 MINERVA (London) 209, 209 (1972) (pointing out "questions which can be asked of science and yet which cannot be answered by science" because scientists cannot perform the experiments to test these hypotheses that have been termed trans-scientific). It is, for instance, impossible to correlate results in animals with results in humans because it is unethical to subject humans to the kind of experimentation that would be required. *See* Goldstein & Henifin, *supra* note 69, at 405; Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1619-22 (1995).

73. False positives are called Type I errors and false negatives are Type II errors. *See* Michael D. Green et al., *Reference Guide on Epidemiology, in* FJC REFERENCE MANUAL, *supra* note 47, at 333, 356-62.

74. *See id.* at 357-58.

75. *See id.* at 359; *see also* KENNETH J. ROTHMAN, MODERN EPIDEMIOLOGY 116-19 (1986) (advocating the use of confidence intervals in place of strict significance testing).

The consequence of a "not-proven" verdict is very different in the legal setting. The plaintiff with the burden of proof on causation will lose permanently if he or she cannot produce adequate proof of causation by the time the court is ready to rule on a *Daubert* motion. Plaintiffs are forced to sue regardless of the information then available because the statute of limitations is running. Given the very different consequences, it is certainly debatable whether the legal system—whose aim is to do justice—should use a scientific standard designed to defer resolution until an optimal amount of information is available. This is especially the case because plaintiffs are rarely in a position to initiate scientific research, have access to far less information than defendants have about its product, and often have fewer resources than defendants do. Nevertheless, many courts reject opinions based on epidemiological studies that fail to satisfy a .05 level of statistical significance as though these studies had no probative value.[76]

The standard courts should use in evaluating scientific proof requires a consideration of the rationale underlying toxic tort litigation. Some endorse science's strict standard because they doubt that such litigation serves a useful social purpose.[77] Others point to the need to deter future risks and to compensate those exposed to excessive risk through no fault of their own.[78] These issues are beyond the scope of this article. The point is that whatever standard of proof is chosen—whether by the scientific or legal community—reflects and furthers the policy objectives that the particular discipline is seeking to achieve. When judges exclude scientific evidence in some of the particular circumstances discussed below, their decisions reflect a policy choice; they are not making value-

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76. *See, e.g.*, DeLuca *ex rel.* DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 955 (3d Cir. 1990) (discussing whether to require a 0.05 level of statistical significance and concluding that the court might resolve the issue in a future case); Brock v. Merrell Dow Pharms., Inc., 874 F.2d 307, 312 (5th Cir. 1989) (overturning a jury verdict for plaintiff because no "statistically significant" study showed an increased risk of birth defects to children born of mothers who had taken Bendectin); Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 4 F. Supp. 2d 435, 461 (M.D.N.C. 1998) (criticizing the EPA for changing the confidence interval from 95% to 90%, because that "looks like a[n] attempt to achieve statistical significance for a result which otherwise would not achieve significance") (quoting Geoffery Kabat, *Comments on EPA's Draft Report: "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*," II.SAB.9.15 at 6 (July 28, 1992) (JA 12,185)); Raynor v. Merrell Dow Pharms., Inc., 104 F.3d 1371, 1374 (D.C. Cir. 1997) (holding plaintiff's epidemiological studies inadmissible in part because the studies' statistical significance fell below 95%). *But see In re* Hanford Nuclear Reservation Litig., 1998 WL 775340, at *23 (E.D. Wash. 1998) ("Ninety-five percent statistical significance is not a sine qua non for association . . . ."). Arguments to the contrary are discussed by Erica Beecher-Monas, *A Ray of Light for Judges Blinded by Science: Triers of Science and Intellectual Due Process*, 33 GA. L. REV. 1047, 1099-1102 & n.322 (1999).

77. *See*, *e.g.*, PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 440 (Kenneth R. Foster et al. eds., 1993) (noting that toxic tort litigation imposes huge costs without demonstrably reducing risk or compensating victims fairly and consistently); *see also id.* at 442 (explaining that the time, money and effort spent on risk research could be much "more productively directed toward other health issues"; toxic tort litigation often seeks to impose liability for exposures that are not very risky, or not risky at all compared to the much larger "everyday risks that are under a person's voluntary control," such as driving without seat belts, eating a rotten diet, or smoking or drinking too much).

78. *See* Finley, *supra* note 9, at 335, 364-71; *see also* Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence,* 96 YALE L.J. 376, 396 (1986) (advocating a flexible case-by-case approach to determining the correct evidentiary rules to apply in toxic torts).

free determinations that are the inevitable consequence of a system of rational proof.

A second misunderstanding arises from the assumption that all the components of a scientist's opinion on causation are the product of empirically validated hypotheses. In actuality, as discussed below, many conclusions rest on conventions or models about which there may be considerable disagreement within the scientific community.[79] Although we may be standing on the threshold of understanding the etiology of some diseases, we have yet to unravel the complexities.

This over-simplified view of science has increased the ability of federal trial judges to exclude plaintiffs' experts by ignoring the differing objectives of science and the law and by failing to examine the premises on which some scientific conclusions rest. In addition, some courts have moved beyond science by creating new rules in the name of science that do not exist in the scientific community.

A. Epidemiological Studies versus Animal Studies

Some courts have created a hierarchy with regard to evidence used to prove causation by insisting on epidemiological proof. It is one thing to say that animal studies will not suffice to prove general causation when substantial epidemiological evidence to the contrary exists in a mature case involving a substance that has been the subject of extensive scientific research.[80] It is quite another to say that only expert opinions based on epidemiological evidence are admissible, and that animal studies have no probative value because they require extrapolation from animals to humans and from higher doses to lower doses.[81]

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79. *See, e.g.*, NATIONAL RESEARCH COUNCIL, HORMONALLY ACTIVE AGENTS IN THE ENVIRONMENT 18 (1999). The Council presented a study of effects of substances, such as PCBs, dioxin, DDT, and DES done at the request of Congress, EPA, DOI, and the U.S. Centers for Disease Control. After noting that members of the committee were unable to agree on a number of issues, the report stated:

> Some of the differences reflect areas where additional research would help; others reflect differing judgments about the significance of the existing information. The differences are not confined to this committee but are reflected in the scientific community at large. Some differences appear to stem from different views of the value of different kinds of evidence obtained by experiments, observations, weight-of-evidence approaches, and extrapolation of results from one compound or organism to others, as well as allowable sources of information and criteria for arriving at meaningful conclusions and recommendations.

Id.

80. *See, e.g., In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1231, 1237, 1241 (E.D.N.Y. 1985).

81. *See, e.g.,* 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 "[t]est results on animals are not necessarily reliable evidence of the same reaction in humans"), s*ee also* Wade-Greaux v. Whitehall Labs., Inc., 874 F. Supp. 1441, 1480 (D.V.I. 1994):

> The notion that one can accurately extrapolate from animal data to humans to prove causation without supportive positive epidemiologic studies is scientifically invalid because it is inconsistent with several universally accepted and tested scientific principles. The principle of species specificity has been tested and demonstrates that different species can react differently to the same agent.

Animal studies, by definition, do not deal with humans, and the animals will always be exposed to much higher doses than the plaintiff. Despite this, a blanket rejection of animal studies runs counter to scientific thinking[82] and to the Supreme Court's discussion in *Joiner* and *Kumho.* In *Joiner*, the Court rejected the notion that all animal studies are categorically inadmissible,[83] instead finding that the trial court had not abused its discretion when it excluded studies that failed to match plaintiff's circumstances in a number of significant respects beyond those that always exist.[84] This emphasis on the particular circumstances of the case presages the Court's language in *Kumho* declining to rule "for all cases and for all time" which factors must be applied to subsets of cases categorized by category of expert or by kind of evidence.[85] "Too much depends upon the particular circumstances of the particular case at issue."[86] In other words, a particular animal study may not satisfy the relevancy or "fit" prong, but it should not be rejected as per se unreliable.

The insistence on epidemiological proof also has policy implications. Epidemiological studies take considerable time and money to design and to implement. Animal studies are less costly, less time-consuming, and much easier to administer.[87] We know that scientists may not be interested in researching the health effects of a product and may not be provided funding to do so until a critical mass of litigation is instituted[88] or a public health outcry is raised.[89] Until then, no one may have the incentive to investigate the product in question.[90] Furthermore, even when government regulations require initial testing, which is not the case with many chemical substances on the market,[91] the product may not have been studied in interaction with other substances, tested on a repre-

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Id.; *see also* Bell v. Swift Adhesives, Inc., 804 F. Supp. 1577, 1579-80 (S.D. Ga. 1992) (surveying cases that have held that animal studies alone cannot prove causation and rejecting opinion based on studies that found that methylene chloride produced cancer in laboratory animals).

82. *See* Goldstein & Henifin, *supra* note 69, at 414-15.

83. *See* Joiner v. General Elec. Co., 522 U.S. 136, 144 (1997) ("[W]hether animal studies can ever be a proper foundation for an expert's opinion was not the issue. The issue was whether these experts' opinions were sufficiently supported by the animal studies on which they purported to rely.").

84. *See id.* at 144-45.

85. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999).

86. *Id.*

87. *See* Goldstein & Henifin, *supra* note 69, at 414.

88. *See* Sanders, *supra* note 13, at 321-28.

89. The moratorium on breast silicon implants imposed by the FDA prompted many such studies. *See* FDA's announcment of moratorium (Jan. 6, 1992) (visited Dec. 30, 2000) <http://www.fda.gov/bbs/topics/NEWS/NEW00263.html>.

90. *See* Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2135-40 (1997); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products,* 82 CORNELL L. REV. 773, 775-76 (1997).

91. *See* Wagner, *supra* note 90, at 782.

> In its comprehensive 1984 study, which still remains largely up-to-date, the NRC found that for approximately eighty percent of the estimated 48,523 unregulated chemicals in commerce, no toxicity information existed. For the remaining chemicals in commerce, scientific uncertainty was also prevalent—a full health assessment could not be completed for any of these chemicals.

Id. (footnotes omitted).

sentative sample of the population,[92] or had its effects tracked over time.[93] Moreover, some epidemiological research has been faulted as unlikely to "be gender, race, or class neutral."[94] Ultimately, if scientific research is undertaken, particularly for a product to which very large numbers of people have been exposed, sufficient data may be assembled to enable the courts and the scientific community to reach agreement that causation exists—as in the case of asbestos and tobacco[95]—or that it does not, as occurred with Bendectin[96] and seems to be happening with silicon breast implants.[97]

But until this happens, the more stringently trial courts insist on epidemiological studies and studies that meet a ninety-five percent confidence level, the more likely the first plaintiff will be to lose. If every action is nipped in the bud, the relevant research may never be done, and we may never find out how much risk a defendant's product poses, unless the effect is enormous, as with tobacco, or highly unusual, as with a new signature disease. Critics of toxic tort litigation would applaud such a result; those who believe that the law must provide incentives to guard society against unknown risks would disagree. These differences reflect policy choices about the objectives of tort law that are furthered by evidentiary rulings about the admissibility of proof of causation.

B. Relative Risk

Even when epidemiological evidence exists, some courts have adopted a rule of law that a plaintiff's epidemiological evidence must be rejected if the plaintiff's expert relies on a study that has a relative risk of less than 2.0.[98] Rela-

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92. *See* Melody Petersen, *Unforseen Side Effects Ruined One Blockbuster,* N.Y. TIMES, Aug. 27, 2000, § 3, at 11 (relating that an antibiotic being prescribed at the rate of three million patients per month was taken off the market after fatal liver toxicity complications became apparent, even though no problems had surfaced during clinical trials; chairman of drug company explained that all patients in drug trials are carefully screened and are not representative of general population).

93. For a discussion of the paucity of data, see Carl F. Cranor & David A. Eastmond, *Scientific Ignorance and Reliable Patterns of Evidence in Toxic Tort Causation: Is There a Need for Liability Reform?*, 64 LAW & CONTEMP. PROBS. (forthcoming 2001).

94. Finley, *supra* note 9, at 374.

95. Many years elapsed with regard to both products before this risk was acknowledged by makers of these products. *See, e.g.*, MARY SUE HENIFIN ET AL., *Reference Guide on Medical Testimony in* FJC REFERENCE MANUAL, *supra* note 47, at 439, 474 ("[T]he association between asbestos and lung cancer was first reported in a 1933 case report, although the first controlled epidemiological study on the association was not published until the 1950s." (footnotes omitted)). As recently as 1994, the top executives of America's seven largest tobacco companies testified before a House subcommittee that they did not know that tobacco was addictive. *See* Philip J. Hilts, *Tobacco Chiefs Say Cigarettes Aren't Addictive,* N.Y. TIMES, Apr. 15, 1994, at A1.

96. *See* JOSEPH SANDERS, BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION 19-20 (1998).

97. *See* 3 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 41-2.0 (1997) (containing extensive excerpts from the Report of the Scientific Evidence Panel appointed by Chief Judge Samuel Pointer in the multi-districted proceedings in the Northern District of Alabama; the Panel, consisting of a toxicologist, an epidemiologist, a rheumatologist, and an immunologist found virtually no support for the hypothesis that silicone gel breast implants cause auto-immune diseases).

98. *See, e.g.,* Allison v. McGhan Med. Corp., 184 F.3d 1300, 1313-15 n.16 (11th Cir. 1999) (ruling four epidemiological studies inadmissible under *Daubert* because all had a relative risk of less than 2.0);

tive risk measures the increased risk caused by exposure to a substance by comparing the incidence of disease in the population exposed to the risk with a control group of the unexposed.[99] That means that if 100 persons in a given population are expected to develop a particular disease, but instead 160 persons exposed to the product become ill, only sixty illnesses, or forty percent of the whole, would seem to be attributable to the product because 100 would have suffered adverse health effects in any event. Because this probability is less than fifty percent, courts that insist on a minimum relative risk of 2.0 reason that no plaintiff will be able to satisfy the preponderance of the evidence standard; the evidence must therefore be excluded as failing to prove general causation.[100]

Courts that make this argument fail to understand that reaching this conclusion about attributable risk depends on a number of assumptions that do not necessarily hold true in all cases and that cannot be verified given our present state of knowledge. Underlying a requirement that relative risk must exceed 2.0 is the unprovable assumption that background risks are independent of the risks posed by the substance in question and can therefore be calculated separately.[101] Many scientists reject such a model as inconsistent with a multi-factor theory of disease. "It is possible for exposure to have causally contributed to every case of disease, even if the exposure elevates the rate only slightly."[102] Moreover, the insistence on a relative risk of at least 2.0 is insensitive to the relationship between exposure and the incidence time of developing a particular disease. It is possible that the background cases (who would, in any event, have gotten the disease) developed the disease years earlier because of their exposure. This acceleration is itself an injury. Whether or not such an injury should be compensated is a matter of policy that courts ignore when they equate attributable risk with the probability of causation.[103] The doubling of the risk rule is a legal invention that creates a hard and fast rule that disposes of cases efficiently but rests on assumptions that cannot be scientifically validated at this time.

In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1226 (D. Colo. 1998) (interpreting Colorado's more likely than not standard as meaning that epidemiological studies must have a relative risk greater than 2.0); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1403-05 (D. Or. 1996) (ruling that sixteen epidemiological studies were unreliable under *Daubert* because the relative risk associating silicone breast implants to atypical connective tissue disease was less than 2.0 in each study). *But see In re* Joint E. and S. Dist. Asbestos Litig., 52 F.3d 1124, 1139 (2d Cir. 1995) (holding that the District Court erred by rejecting epidemiological studies with relative risk values below 1.5 and stating that the jury should be allowed to evaluate the studies' significance).

99. *See* Green, *supra* note 73, at 348-49.

100. *See id.* at 382-86; cases cited, *supra* note 98.

101. *See* Jan Beyea & Daniel Berger, *Scientific Misconceptions Among* Daubert *Gatekeepers: The Need for Reform of Expert Review Procedures*, 64 LAW & CONTEMP. PROBS. 327 (Spring/Summer 2001); Sander Greenland & James M. Robins, *Epidemiology, Justice, and the Probability of Causation*, 40 JURIMETRICS J. 321, 326-27 (2000).

102. Greenland & Robins, *supra* note 101, at 325.

103. *See id.* at 327 (providing the example of a mother of two small children who develops cancer and suggesting that a just compensation scheme should take into account that the earlier the cancer occurs, the greater the emotional and financial loss).

Furthermore, even putting aside the failure of some courts to understand the scientific uncertainties that underlie estimates of causation, the refusal to allow experts to testify about epidemiological studies with a relative risk of less than 2.0 is questionable from an evidentiary standpoint. An epidemiological study reaches conclusions about a population and expresses an average. The particular plaintiff's risk may be higher or lower than this average because of personal factors, such as family history or exposures to other toxic substances. In a mass tort action, in which cases have been aggregated, it is perhaps appropriate as a matter of policy to insist on strong epidemiological evidence, because inducements for further research do exist in that type of case, and defendants need protection against the dire financial consequences that might otherwise ensue, regardless of whether a causal link is ultimately shown.[104] But the balance is different in the non-mass tort. In such cases, when the relative risk is greater than 1.0 but less than 2.0—suggesting that some relationship exists between exposure and disease—the plaintiff should have an opportunity to show that his or her particular risk is higher than the relative risk.[105] Applying a per se rule of exclusion to studies that do not show a doubling of the risk is at odds with the Supreme Court's command in *Kumho* to consider the "particular circumstances of the particular case."[106]

C. Exposure and Dose-Response

Plaintiffs often have to face yet another hurdle. Federal courts have at times dismissed a plaintiff's action on the ground that the plaintiff failed to prove exposure to the defendant's product at a level that could cause the injuries the plaintiff claims to have suffered.[107] Clearly, the plaintiff must lose if she cannot show any exposure to the defendant's product.[108] But when there is evidence of some exposure, requiring the plaintiff to prove the exact level of her exposure to the defendant's substance, and that this level of exposure is hazardous, may

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104. *See* Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181 (1993) (suggesting that requirement of epidemiological evidence is appropriate in mass exposure cases but not in cases of isolated exposure).

105. In addition, it must be remembered that epidemiological studies are not controlled studies in the scientific sense. *See* Green, *supra* note 73, at 338-39. The results of epidemiological studies may be skewed because of bias and confounding. *See id.* at 369-73; s*ee also* Lynch v. Merrell-National Labs., Div. of Richardson-Merrell, Inc., 830 F.2d 1190, 1195 (1st Cir. 1987) (explaining the possibility of "maternal recall bias" in studies involving Bendectin and birth defects); Valentine v. Pioneer Chlor Alkali Co., 921 F. Supp. 666, 678 (D. Nev. 1996) (excluding physician's testimony and epidemiological report because, among other things, he did not control for recall bias); *In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 783 (E.D.N.Y 1984) (discussing that confounding factors, such as the stress of combat and local carcinogens, might skew the results of a study of the effects of Agent Orange on Vietnam Veterans).

106. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999).

107. *See infra* note 112; *see also* Mascarenas v. Miles, Inc., 986 F. Supp. 582, 587-88 (W.D. Mo. 1997) (reviewing the cases in which courts have dismissed a plaintiff's claim).

108. *See Mascarenas*, 986 F. Supp. at 588.

place an insurmountable burden on the plaintiff.[109] Courts that exclude a plaintiff's proof on causation if the plaintiff's experts fail to meet both requirements ignore the scientific uncertainty that surrounds questions of exposure and the policy implications that flow from such determinations.

Even in the case of substances that are known to be hazardous, establishing the level of exposure necessary to cause injuries can be a contentious issue within the scientific community.[110] Often the data are taken from animal studies; that means that a dose-response ratio has to be extrapolated from the higher doses administered to animals and then further extrapolated to humans.[111] The various formulas for making these calculations cannot, of course, be validated through human testing. Furthermore, dose-response rates to a particular substance may vary from person to person.[112]

In a number of situations, plaintiffs will lose if they have to bear the stringent burden of proving the actual level of exposure to the defendants' products. In the case of injuries that do not become manifest for many years after exposure, a plaintiff may not be able to find evidence of the exposure level so many years after the event. And in the case of a sudden exposure, such as a spill or a contamination that was subsequently reduced, no precise measurement of exposure is possible unless monitoring equipment was in place at the critical moments. Imposing a burden on a plaintiff to prove the actual level of exposure in these kinds of cases is tantamount to holding that the plaintiff has no claim for relief.[113] And yet it may be desirable for reasons of substantive tort policy either to shift the burden to the defendant to prove the actual exposure level or to make exposure a question for the jury.

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109. *See generally* Wade Kimmel, Note, *Requiring Level of Exposure Showings in Toxic Tort Litigation After* Wright v. Willamette*: Is the Plaintiff's Burden Insurmountable?* 52 ARK. L. REV. 263 (1999).

110. *See In re* Agent Orange Prod. Liab. Litig., 597 F. Supp. 740, 783 (E.D.N.Y. 1984) ("'The dose-response relationship at low levels of exposure for admittedly toxic chemicals is one of the most sharply contested questions currently being debated in the medical community.'") (quoting Ferebee, Jr. v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir. 1984), *aff'd*, 818 F.2d 145 (2d Cir. 1987)).

111. For a discussion of different models and policy factors that are used to convert high-dose effects to low-dose effects in animals and then to extrapolate to humans, see Wagner, *supra* note 90, at 1623-27; *see also* Ralph D'Agostino, Jr. & Richard Wilson, *Asbestos: The Hazard, the Risk, and Public Policy, in* PHANTOM RISK: SCIENTIFIC INFERENCE AND THE LAW 192 (Kenneth R. Foster et al. eds., 1993) (discussing various models used with asbestos disease and concluding that "no one can prove that a linear dose-response relationship is correct," but that it is used by most regulatory agencies because it is most protective of public health).

112. *See* Bernard D. Goldstein, *Toxicology: Dose Response Considerations*, *in* MODERN SCIENTIFIC EVIDENCE, *supra* note 67, § 27-2.1.4 (noting that some may be more susceptible to toxic agents than others; possible reasons include different rates of absorption, distribution, metabolism and excretion, environmental factors, and genetic differences).

113. *See, e.g.*, Moore v. Ashland Chem. Corp., 151 F.3d 269, 278 n.10 (5th Cir. 1998) (en banc) (in finding that district court properly excluded testimony of plaintiff's expert that chemical spill caused his respiratory illness, the court stated: "Given the paucity of facts Dr. Jenkins had available about the level of Moore's exposure to the Toluene solution, his causation opinion would have been suspect even if he had scientific support for the position that the Toluene solution could cause RADS in a worker exposed to some minor level of the solution."); s*ee also* Wright v. Williamette Inds., Inc., 91 F.3d 1105, 107-08 (8th Cir. 1996) (reversing judgment for plaintiffs after jury verdict; although plaintiff proved that levels of formaldehyde emitted by defendant's plant exceed industry and state standards, plaintiff failed to prove actual level of exposure).

I have discussed these three kinds of issues regarding proof of causation as though they are separate and distinct, but they often are seen in combination. The plaintiff may be relying on data from animal studies or weak epidemiological data or may have little proof available about exposure. When a federal court excludes all of the plaintiff's expert proof in such a case on the ground that it is unreliable and therefore must be excluded under the teachings of the Supreme Court's expert trilogy, it is treating these issues as though they only raise evidentiary concerns. This approach fails to consider the nature of science—either its objectives or the policy choices science makes in order to deal with uncertainty. In making such determinations in diversity cases, the federal court is also assuming that it is free to ignore a state court's treatment of these issues, even if the state court views them as intertwined with its substantive policy of risk allocation in toxic tort litigation.

IV

THE *ERIE* DOCTRINE

This section asks whether a federal court sitting in diversity in a toxic tort action is free to treat all issues about the admissibility of scientific expert proof as raising purely procedural concerns, such as improving the accuracy of determinations or making dispositions more efficient and economical. Or are there certain kinds of issues, such as those discussed in the previous section, that are so intertwined with a state's substantive policy of risk allocation that the question of what a federal judge may do cannot be answered without reference to the *Erie*[114] doctrine? When exercising their gatekeeping function by ruling on the admissibility of expert testimony in toxic tort cases, federal courts have almost completely ignored *Erie* and its progeny, except that some courts have cited the case to justify excluding a particular expert's testimony as insufficient to establish a plaintiff's prima facie case. Both the failure to mention *Erie* and the limited references to *Erie* deserve more detailed attention. The courts' assumption that they are not constrained by state law has greatly increased the power of federal judges to reshape toxic tort law.

Before turning to this discussion, a few introductory comments are in order. First, although I conclude that a federal court should consider state law before it makes the kind of rulings discussed in the previous section, I am certainly not claiming that a federal district court may not decide any *Daubert* motion without first determining how the state court would have ruled in a similar case. Obviously, it is impossible to match cases, and in any event, I am only concerned with judge-made rules, such as those discussed above, that reflect policy choices about how to handle uncertainty in science and the law. I use the shorthand phrase "policy-based rules" in the discussion that follows. Second, the application of state law by federal courts may lead to either the admission or the exclusion of expert testimony. It may be that some states have adopted

114. Erie R.R. v. Tompkins, 304 U.S. 64 (1938).

policy-based evidentiary rules to favor defendants in toxic tort litigation. Third, although some state cases are mentioned in the discussion that follows, I have not systematically surveyed state law to determine how particular states deal with these issues.

In *Daubert,* the Supreme Court stated in a footnote that because Rule 702 of the Federal Rules of Evidence superseded the *Frye* test, "we do not address petitioner's argument that application of the *Frye* rule in this diversity case, as the application of a judge-made rule affecting substantive rights, would violate the doctrine of *Erie v. Tompkins*."[115] But the fact that a federal court in a diversity case need not apply *Frye*'s general acceptance test does not mean that it is free to ignore all state precedent on proving causation in a toxic tort case. Any doubts about a federal court's obligation have been dispelled by the most recent Supreme Court interpretation of the *Erie* doctrine in *Gasperini v. Center for Humanities, Inc*.,[116] decided three years after *Daubert*.

A. The Emergence of the *Erie* Doctrine

To understand why federal courts should consider the implications of *Erie* in rulings on expert proof of causation requires an understanding of the evolution of the doctrine that bears the case's name. First, of course, there was *Erie Railroad v. Tompkins*[117] itself, which recognized that federal courts do not have a lawmaking function with regard to areas of the substantive law relegated to the states. Whether *Erie* rests on constitutional grounds, as the Court suggests,[118] and what its ramifications are have been the subject of an enormous debate.[119] But the setting in which the issue in *Erie* itself arose did not cause problems. The command of *Erie*—to apply state substantive law in diversity cases—obviously applied to the lawsuit brought by Tompkins. Congress had not passed any legislation that governed liability with regard to the occurrence in question, and it was clearly state tort law that established the elements that gave rise to

115. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 n.6 (1993). For an argument to the contrary, see Michael H. Gottesman, *Should Federal Rules Trump State Tort Policy? The Federalism Values Daubert Ignored*, 15 CARDOZO L. REV. 1837 (1994).

116. 518 U.S. 415 (1996) (holding that a New York state law controlling compensation awards for excessiveness or inadequacy could be given effect, without detriment to the Seventh Amendment, so long as the review standard set out in that law is applied by the federal trial court judge, with appellate control of the trial court's ruling is confined to "abuse of discretion").

117. 304 U.S. 64 (1938) (overruling *Swift v. Tyson*, 41 U.S. 1 (1842), and holding that, in a tort action brought by Tompkins against the Erie Railroad Company for negligently causing his injuries, the federal court could not apply federal judge-made law on the issue of what type of duty was owed to Tompkins, but instead had to apply state law).

118. *See id.* at 80 ("We . . . declare that in applying the doctrine [of *Swift v. Tyson*] this Court and the lower courts have invaded rights which in our opinion are reserved by the Constitution to the several States.").

119. *See, e.g.,* Charles E. Clark, *State Law in the Federal Courts: The Brooding Omnipresence of* Erie v. Tompkins, 55 YALE L.J. 267 (1946); John Hart Ely, *The Irrepressible Myth of* Erie, 87 HARV. L. REV. 693 (1974) (explaining the three distinct *Erie* problems controlled by three bodies of law: the Constitution, common law, and the Federal Rules); Henry J. Friendly, *In Praise of* Erie—*and of the New Federal Common Law*, 39 N.Y.U. L. REV. 383 (1964); Lehan Kent Tunks, *Categorization and Federalism: "Substance" and "Procedure" after* Erie Railroad v. Tompkins, 34 ILL. L. REV. 271 (1939).

the plaintiff's claim. That aspect of *Erie* has never been questioned. In the absence of congressional action, a federal court must apply the state law that gives rise to the plaintiff's claim for relief.[120]

In the two decades following *Erie*, the troublesome cases were those in which the state whose substantive law governed had adopted a particular practice, through statute[121] or case law,[122] in connection with the type of claim being asserted. The federal court sitting in diversity then had to decide whether the state's practice was so "substantive" that it had to be applied, or whether the federal court was free to adopt its own procedures. The Supreme Court analyzed these cases under the Rules of Decision Act[123] and proposed a number of different tests and rationales to use in making this determination. I return to these decisions below.[124]

B. The Rules Enabling Act and the Federal Rules of Evidence

In 1965, just as the Advisory Committee on the Federal Rules of Evidence began its task, the Court advanced a new mode of analysis in *Hanna v. Plumer*.[125] The Court explained that *Hanna* differed from the earlier cases because it involved a conflict between state law and a Federal Rule of Civil Procedure; no federal rule or statute had been on point in prior cases. When no conflicting federal law exists, *Hanna* affirmed that the case must be decided under the Rules of Decision Act, and the opinion contains extensive dicta on how a federal court should then proceed.[126] If, however, as in *Hanna*, the situation is governed by a federal rule adopted under the Rules Enabling Act or a statute enacted by Congress, then the Court directed federal judges to follow federal practice even in the face of a contrary state rule, unless the federal practice "transgresses . . . the terms of the Enabling Act [or a] constitutional restriction."[127] The provisions of the Rules Enabling Act to which the Court referred

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120. *See* Gasperini v. Center for Humanities, Inc., 518 U.S. 415, 426 (1996) ("Federal diversity jurisdiction provides an alternative forum for the adjudication of state-created rights, but it does not carry with it generation of rules of substantive law.").

121. *See, e.g.*, Woods v. Interstate Realty Co., 337 U.S. 535, 538 (1949) (considering whether federal courts must apply state statute not to enforce a contract for a broker's commission if the broker was not qualified under the statute to do business in the state).

122. *See, e.g.*, Byrd v. Blue Ridge Rural Elec. Coop., 356 U.S. 525, 537 (1958) (considering whether federal courts must apply state common law rule that required judge to determine whether an employee falls within the state's workers' compensation statute).

123. *See* The Rules of Decision Act, 28 U.S.C. § 1652 (1994) ("The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the courts of the United States, in cases where they apply.").

124. *See infra* Part IV-D.

125. 380 U.S. 460 (1965) (holding that service of process in a diversity case could be made in the manner prescribed by the Federal Rules of Civil Procedure rather than by method prescribed by the state's rules, because federal courts sitting in diversity apply federal procedural law and state substantive law, and service of process relates to "practice and procedure" as described in the Rules Enabling Act).

126. *Id.* at 465-69; s*ee infra* Part IV-D-3.

127. *See Hanna*, 380 U.S. at 471.

stated that rules promulgated under the Act "shall not abridge, enlarge or modify the substantive rights of the litigant."[128]

The Court justified its conclusion that federal judges must apply federal rules adopted through the rule-making process in diversity cases by explaining that

> the constitutional provision for a federal court system (augmented by the Necessary and Proper Clause) carries with it congressional power to make rules governing the practice and pleading in those courts, which in turn includes a power to regulate matters which, though falling within the uncertain area between substance and procedure, are rationally capable of classification as either.[129]

Hanna's formula for applying the *Erie* doctrine when a state practice conflicted with a federal rule seemed to simplify the task of drafting the Federal Rules of Evidence.[130] *Hanna*'s description of matters falling "within the uncertain area between substance and procedure" seemed tailor-made for evidentiary issues and convinced the drafters of the Federal Rules of Evidence that the proposed rules would trump state rules to the contrary.[131] Although some suggested that the "substantive rights" provision of the Enabling Act ought to invalidate rules such as those concerning privilege,[132] any lingering doubts about the impact of *Erie* became moot when Congress, by enacting the evidence rules, rather than letting them take effect through the rule-making process, eliminated any need to construe the Enabling Act.[133] Furthermore, Congress amended the rules on presumptions, privilege, and competency—the rules most likely to be viewed as having an impact on substantive rights—to provide that the application of these evidentiary devices would be determined "in accordance with State law" in all diversity cases.[134]

This history seems to have lulled federal judges into thinking that all decisions about expert proof couched in evidentiary terms can be classified as procedural and thus governed by federal practice. This conclusion is not warranted by the Supreme Court's *Erie* jurisprudence. Lower federal courts may assume that no *Erie* analysis is needed when ruling on the admissibility of expert testi-

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128. 28 U.S.C. § 2072(b) (1994). What this restriction was intended to achieve has been the subject of debate. *See, e.g.,* Stephen B. Burbank, *The Rules Enabling Act of 1934,* 130 U. PA. L. REV. 1015 (1982) (providing a history of the Act, and a discussion of its legal role).

129. *Hanna*, 380 U.S. at 472.

130. *See* Ely, *supra* note 119, at 697.

131. The final draft of the rules as promulgated by the Supreme Court contained no references to state law. *See Rules of Evidence for United States Courts and Magistrates*, 56 F.R.D. 183, 194-353 (1972).

132. *See* Ely, *supra* note 119, at 738-40.

133. *See id.* at 738. Of course, it may be somewhat unlikely that the Court, after promulgating the rules, including the rules on privileges, would then have found them to violate the Rules Enabling Act. *Cf.* Sibbach v. Wilson, 312 U.S. 1, 15-16 (1941) (finding that two Rules of Civil Procedure forcing a party to submit to a physical examination were "procedural" in nature and valid within the meaning of the Rules Enabling Act). An amendment to Rule 702, promulgated through the rule-making process, took effect on December 1, 2000. Some issues regarding Rule 702 may therefore arise under the Rules Enabling Act in the future. *See infra* note 188.

134. *See* FED. R. EVID. 302, 501, 601. State law also applies to "an element of a claim or defense as to which State law supplies the rule of decision." *Id.* (all three rules contain this language).

mony because Rule 702 of the Federal Rules of Evidence regulates the mode of proof, and therefore, under *Hanna*, no further questions remain. But this supposition overlooks an important distinction. When a trial court fashions black-letter policy-based rules, such as those discussed in the previous section, it has moved considerably beyond the scope of Rule 702. It is no longer applying the text of a rule as in *Hanna*. Even after the 2000 amendment to Rule 702, no federal rule demands the exclusion of animal studies or of epidemiological studies that have a relative risk of less than 2.0, or prescribes a particular dose-response curve, or any of the other principles discussed above upon which some courts rely when excluding expert testimony on causation.[135] Generalizations such as these are judge-made procedural rules rather than rules adopted under the Rules Enabling Act or by statute.

C. *Gasperini v. Center for Humanities, Inc.*

Gasperini v. Center for Humanities, Inc. has clarified that federal judge-made procedural rules cannot be applied in a diversity case without first considering whether and why a state has adopted or refused to adopt such a measure.[136] In *Gasperini*, the claim for relief was governed by New York law. The question before the Court was whether the federal district judge, when ruling on a new trial motion, had to assess the potential for an exorbitant verdict in light of the standard in a New York statute.[137] Crucial to the result in *Gasperini* was the majority's characterization of the issue in dispute as one not covered by Rule 59 of the Federal Rules of Civil Procedure, which, although it deals with grants of new trials, does not contain a standard for determining the excessiveness of verdicts.[138] This pivotal conclusion opened the door to analysis under the Rules of Decision Act. The majority justified its narrow reading of Rule 59—which ultimately led to finding the New York statute "substantive" for *Erie* purposes—by stating: "Federal courts have interpreted the Federal Rules . . . with sensitivity to important state interests and regulatory policies."[139] This means that even though there is a federal rule on a particular subject—such as Federal Rule of Civil Procedure 59 dealing with new trials or Federal Rule of Evidence 702 dealing with the admissibility of expert proof—federal judicial interpretations of such a rule may not be given effect automatically when there is a dis-

135. *See supra* Part III.

136. 518 U.S. 415, 418-19 (1996) (holding that "New York's law controlling compensation awards for excessiveness or inadequacy can be given effect, without detriment to the Seventh Amendment, if the [New York] review standard . . . is applied by the federal trial court judge, with appellate control of the trial court's ruling limited to review for 'abuse of discretion'").

137. *See id.*

138. *See id.* at 438 n.22. Justices Scalia, Rehnquist, and Thomas dissented, finding a "direct collision" between Rule 59 and the New York state law. Thus, they would have required the federal court to apply Rule 59. *See id.* at 468.

139. *See id.* at 428 n.7 ("It is settled that if the Rule in point is consonant with the Rules Enabling Act . . . and the Constitution, the Federal Rule applies regardless of contrary state law . . . . Federal courts have interpreted the Federal Rules, however, with sensitivity to important state interests and regulatory policies.").

similar state practice that does not directly collide with the text of the federal rule. That is, a court cannot determine whether it is free to apply a federal judge-made rule—such as the federal practice with regard to excessive verdicts, or insistence on a relative risk of 2.0—without first looking at what the state would do in a comparable situation. But even if the federal court finds a contrary state practice, it must apply the state version only if it is "substantive" pursuant to Rules of Decision Act analysis.[140]

It is at this point that *Gasperini* becomes somewhat confusing; some commentators fault the opinion for leaving *Erie* analysis in a muddle.[141] The problem is that the Supreme Court has used a number of different tests in its Rules of Decision Act line of cases to determine when a practice is "substantive" rather than "procedural," and *Gasperini* does little to clarify the current status of these various tests.[142] But although it is somewhat difficult to understand which test the *Gasperini* Court used in finding that state law governed, choosing between federal and state law should be considerably easier in the context of rules relating to expert proof of causation in a toxic tort case. It does not matter which test is used in a particular case involving the rules described *supra* in Part III. As discussed below, the result will be identical regardless of the test used because each of the tests the Court has embraced to distinguish between "substance" and "procedure" under the Rules of Decision Act points in the direction of applying state law when the issue concerns a policy-based rule on proving causation.

D. Tests Under the Rules of Decision Act Line of Cases

1. The Guaranty Trust *Outcome Determinative Test.* In cases decided in the 1940s and 1950s under the Rules of Decision Act, the Supreme Court regularly upheld state practices and justified its results by reliance on the outcome-determinative test first enunciated in *Guaranty Trust Co. v. York* by Justice Frankfurter.[143] He explained that the essence of *Erie* was the requirement of vertical uniformity between decisions in state courts and decisions in federal courts applying the law of that state: "The nub of the policy

140. *See id.* at 427-28.

141. *See, e.g.,* LARRY L. TEPLY & RALPH U. WHITTEN, CIVIL PROCEDURE 433-37 (2d ed. 2000) (arguing that *Gasperini* "create[s] more confusion than it dispels"); 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 BYU L. REV. 267, 290; Richard D. Freer, *Some Thoughts on the State of* Erie *After* Gasperini*,* 76 TEX. L. REV. 1637, 1663 (1998) (stating that "the Court had another opportunity—perhaps its best in a generation—to make a meaningful contribution to [Erie] analysis . . . . Instead, the Court has left the field about as murky as it was before."). *But see* Thomas D. Rowe, *Not Bad for Government Work: Does Anyone Else Think the Supreme Court Is Doing a Halfway Decent Job in Its* Erie-Hanna *Jurisprudence?*, 73 NOTRE DAME L. REV. 963, 966 (1998) (reviewing critiques of *Gasperini* and stating that "[t]he *Gasperini* majority opinion is not a shining model, but neither does it strike me as a severe muddle").

142. *See supra* text accompanying notes 155-160.

143. 326 U.S. 99 (1945).

that underlies *Erie v. Tompkins* is that for the same transaction the accident of a suit by a non-resident litigant in a federal court instead of in a State court a block away should not lead to a substantially different result."[144] Consequently, *Guaranty Trust* labeled as "substantive" any state practice that might produce a different result in a federal court if the state practice were applied.[145] Justice Frankfurter noted that a desirable by-product of this approach would be a disincentive for litigants to forum shop.[146]

2. The Byrd *Test.* The Supreme Court continued to use the outcome-determinative test until 1958,[147] when the Court reformulated its approach by stating that outcome-determination is not the only concern.[148] Instead, in *Byrd v. Blue Ridge Rural Electrical Co-op., Inc.*, the Court set out a balancing test that requires courts to consider a number of additional factors.[149] Although courts and commentators disagree on how these factors should be weighed,[150]

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144. *Id.* at 109.

145. *See id.*:

> The question is whether [the state] statute concerns merely the manner and the means by which a right to recover, as recognized by the State, is enforced, or whether such statutory limitation is a matter of substance . . . namely, does it significantly affect the result of a litigation for a federal court to disregard a law of a State that would be controlling in an action upon the same claim by the same parties in a State court?

146. *See id.* at 111:

> [I]t would be a mischievous practice to disregard state statutes of limitation whenever federal courts think that the result of adopting them may be inequitable. Such procedure would promote the choice of United States rather than of state courts in order to gain the advantage of different laws. The main foundation for the criticism of *Swift v. Tyson* was that a litigant in cases where federal jurisdiction is based only on diverse citizenship may obtain a more favorable decision by suing in the United States courts.

(quoting Augustus N. Hand) (citation omitted).

147. *See* Cohen v. Beneficial Indus. Loan Corp., 337 U.S. 541, 555-56 (1949) (finding that a New Jersey statute holding the plaintiff in a stockholders' derivative suit liable for the expenses of the defendant if the plaintiff's claims are not proven does not conflict with Federal Rule 23 because all provisions of both rules may be applied, and thus the state statute is applicable in federal court, notwithstanding that some of its provisions are "procedural" in nature); Woods v. Interstate Realty Co., 337 U.S. 535, 538 (1949) (holding that where the state courts were bound by statute not to enforce a contract for a broker's commission because the broker was not qualified under the statute to do business in the state, a federal court sitting in diversity likewise is bound to dismiss the complaint because a "contrary result would create discriminations against citizens of the State in favor of those authorized to invoke the diversity jurisdiction of the federal courts"); Ragan v. Merchants Transfer & Warehouse Co., 337 U.S. 530 (1949) (holding that a state statute that requires service of process officially to commence a case in state court and to satisfy the statute of limitations for a state-created cause of action applies in federal diversity cases, notwithstanding that according to the Federal Rules of Civil Procedure cases commence with the filing of the complaint in federal court).

148. *See* Byrd v. Blue Ridge Rural Elec. Coop., Inc., 356 U.S. 525 (1958).

149. *See id.* at 536-38 (explaining that "there are affirmative countervailing considerations at work here"; thus, the court must consider factors, such as the nature of the federal judiciary and the constitutional allocation of authority between judge and jury in federal courts, and balance these factors against the "policy of uniform enforcement of state-created rights and obligations" and the "interest of furthering the objective that the litigation should not come out one way in the federal court and another way in the state court") (citations and footnotes omitted).

150. *See* Martin H. Redish & Carter G. Phillips, Erie *and the Rules of Decision Act: In Search of the Appropriate Dilemma*, 91 HARV. L. REV. 356, 364-66 (1977) (explaining different approaches to the *Byrd* balancing test). C*ompare* Szantay v. Beech Aircraft Corp., 349 F.2d 60, 63 (4th Cir. 1965) (advocating a two-step approach: "If the state provision is a procedure intimately bound up with the state

Byrd clearly spells out the considerations that enter the equation: the interests served by the competing state and federal practices and the outcome-determinative effect of the state practice.

The weight of the state's interest depends on whether the state practice in question is "bound up with the definition of the rights and obligations of the parties"[151] and furthers a specific substantive policy, or is simply one of "form and mode" that facilitates procedural goals.[152] The strength of the federal interest depends on the role the federal rule plays in the federal system. When the *Byrd* Court evaluated the state and federal interests, it found that the state rule—which required a judge to decide a worker's status as an employee for purposes of the state's workers' compensation statute—was a rule grounded in efficiency concerns, rather than a rule designed to affect who would receive compensation.[153] On the other hand, the federal rule—which allocated the question of the employee's status to a jury—was consonant with "an essential characteristic of the federal procedural system," because it was "under the influence—if not the command—of the Seventh Amendment."[154] Because the state substantive interest was low, and the federal procedural interest was high, the state rule did not apply. The third factor, outcome-determination, also pointed toward the federal rule. The Court redefined this variable to mean that conforming to state practice was likely to produce a different result. Under the facts of *Byrd*, judges and jurors might well reach the same decision about the employment status of someone seeking workers' compensation; requiring application of a state's statute of limitations, as in *Guaranty Trust*,[155] is truly outcome-determinative because it terminates litigation that would otherwise continue in federal court.

3. The Rules of Decision Act Analysis in Hanna. In *Hanna*, the Court appeared to retreat from both its emphasis on outcome-determination and the *Byrd* balancing approach. Although its analysis of how to proceed in a case governed by the Rules of Decision Act is dictum, the new test which the Court endorsed was cited with approval in its subsequent opinions preceding *Gasperini*.[156] *Hanna* suggested that a state rule should be applied if lack of enforcement by a federal court would lead litigants to choose the federal system, and the result in federal court would discriminate unfairly against

right or obligation, it is . . . controlling."), *with* Allen E. Smith, Blue Ridge *and Beyond: A Byrd's Eye View of Federalism in Diversity Litigation*, 36 TUL. L. REV. 443, 464-65 (1962) (arguing that a three-factor balancing test is appropriate), *and* Ely, *supra* note 119, at 709 (describing the *Byrd* test as simply "balancing the relevant state and federal interests" and thus ignoring outcome determination).

151. *Byrd*, 356 U.S. at 536.

152. *Id.*

153. *See id.* at 535-36. This was probably based on procedural efficiency because state judges had a great deal of experience in reviewing administrative decisions.

154. *Id.* at 537.

155. *See supra* Part IVD1.

156. *See, e.g.*, Chambers v. NASCO, Inc., 501 U.S. 32, 52 (1991); Stewart Org., Inc. v. Ricoh Corp., 487 U.S. 22, 27 n.6 (1988); Walker v. Amco Steel Corp., 446 U.S. 740, 752-53 (1980); Alyeska Pipeline Serv. Co. v. Wilderness Soc'y, 421 U.S. 240, 260 n.31 (1975).

citizens of the forum state.[157] These "twin aims"—to discourage forum-shopping and to avoid depriving persons of valuable rights they would have in state court—mesh with the Court's further refinement of the outcome-determination factor to mean that a different outcome would result by playing in federal court by federal rules than would occur by playing in state court by state rules.[158]

E. Applying the Supreme Court's Tests to Expert Proof of Causation in Toxic Tort Actions

I will not enter the fray about which of these approaches the Court would now apply in analyzing cases governed by the Rules of Decision Act. It does not matter whether *Byrd* is dead or alive—dead, because it was supplanted by the dictum in *Hanna* and ignored in all subsequent Supreme Court opinions until *Gasperini*, or alive, because it was resurrected in *Gasperini*[159]—or whether *Gasperini* signals a return to *Guaranty Trust's* emphasis on outcome-determination.[160] The principles that the Court has at various times identified as underlying *Erie* and its progeny all point to a need to consider state law to determine whether a federal court may apply its own judge-made rule on the admissibility of expert proof about causation in a toxic tort action.

This is certainly so to the extent that outcome-determination is significant. 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-

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157. Hanna v. Plumer, 380 U.S. 460, 468 n.9 (1965):

> Erie and its progeny make clear that when a federal court sitting in a diversity case is faced with a question of whether or not to apply state law, the importance of a state rule is indeed relevant, but only in the context of asking whether application of the rule would make so important a difference to the character or result of the litigation that failure to enforce it would unfairly discriminate against citizens of the forum State, or whether application of the rule would have so important an effect upon the fortunes of one or both of the litigants that failure to enforce it would be likely to cause a plaintiff to choose the federal court.

(quoted with approval in Gasperini v. Center for Humanities, Inc., 518 U.S. 415, 428 n.8 (1996)).

158. *See Hanna*, 380 U.S. at 468-69.

159. *See, e.g.,* 19 CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 4504, at 48-49 (2d ed. 1996) ("'Outcome determination analysis is not repudiated by the Hanna case; rather, it is refined by tying it to the policies of the Erie case . . . . The status of the *Byrd* case, however, is less certain."), Ely, *supra* note 119, at 717 n.130 (stating that "there is no place in the analysis for the sort of balancing of federal and state interests contemplated by the Byrd opinion"). *Compare* 19 WRIGHT ET AL., *supra*, § 4511, at 312-14 (describing Byrd as "a good starting place for analyzing the Erie problem" in cases not involving a federal statute or Federal Rule), *with* Allan Ides, *The Supreme Court and the Law to Be Applied in Diversity Cases: A Critical Guide to the Development and Application of the* Erie *Doctrine and Related Problems*, 163 F.R.D. 19, 86-87 (1995):

> My view would be that *Byrd* is no longer useful law. It is quite difficult to imagine a judge-made rule that is outcome-determinative in the sense defined by *Hanna* and yet still applicable under *Byrd* without there being a federal interest strong enough to trigger the district court's authority to make federal common law.

Id. at 86.

160. Apparently that was the district court's conclusion on remand. *See* Gasperini v. Center for Humanities, Inc., 972 F. Supp. 765, 767 (S.D.N.Y. 1997) ("The Supreme Court decision in this case represents an extension of *Erie* . . . or more likely a reversion by the Supreme Court to prior *Erie* doctrine since abandoned, of which *Guaranty Trust* . . . is the outstanding example."), *judgment vacated by* Gasperini v. Center for Humanities, Inc., 149 F.3d 137 (2d Cir. 1998).

determinative. The Supreme Court agreed with this characterization in *Joiner* when it refused to adopt a stricter standard for reviewing district court opinions excluding expert testimony even though it acknowledged that such rulings are "outcome-determinative."[161] Judge-made per se rules of exclusion are outcome-determinative even under the redefinition in *Hanna* if the state court would allow the case to go to the jury, while the federal court would grant a motion for summary judgment after the plaintiff's expert is excluded.[162]

A *Byrd*-based analysis of state and federal interests also points to applying state law in toxic tort cases. Federal judge-made rules on causation should not escape *Erie* scrutiny simply because they are couched in evidentiary terms and are in part responsive to the relevancy and reliability concerns voiced in the trilogy. When a federal court insists on a doubling of relative risk in order to admit epidemiological proof, or requires a particular dose-response, it creates a rule functionally equivalent to a rule on the burden of proof. The Supreme Court has never overruled its 1939 decision in *Cities Service Oil Co. v. Dunlap*,[163] which required a federal court to apply the state's rule on burden of proof, and which *Byrd* cited as an example of a rule bound up with state-created rights and obligations.[164] The lower court in *Cities Service* had claimed that shifting the burden from the person challenging title to the recorded title holder led to a better rule.[165] But a claim that special rules on causation lead to better law governing toxic tort litigation runs smack into the prohibition of the *Erie* case itself—it is not the business of the federal courts to come up with a better law of toxic torts. If, as in *Cities Service,* the rule was intended to make it easier for a party with a particular kind of claim to win, the federal court must abide by the state rule.[166]

From the viewpoint of federal interest, it is difficult to see how the "essential characteristics of the federal system" would be altered if a federal court follows a state's choice on how to resolve a trans-science issue. *Kumho*—with its emphasis on the specific facts of the case, and its acknowledgment that the four *Daubert* factors do not invariably apply even with regard to scientific expert testimony—demonstrates that the federal system does not demand that particular categories of expertise must meet a preordained checklist.[167] Although rules

161. General Elec. Co. v. Joiner, 522 U.S. 136, 142-43 (1997).

162. Of course, if the action continues, the plaintiff need not necessarily win, but this was so even in *Guaranty Trust*, which remains the authority for what outcome-determination means even after the *Hanna* reformulation. If the state statute of limitations in that case were not applied, the action would continue, but there would be no guarantee that the plaintiff would succeed.

163. 308 U.S. 208 (1939).

164. *See* Byrd v. Blue Ridge Rural Elec. Coop., Inc., 356 U.S. 525, 535 (1958).

165. *See Cities Service*, 308 U.S. at 211-12. The Court disagreed with the lower court's conclusion that the federal court sitting in equity could adopt a different rule from the state rule where the state rule placed the burden of proof on the issue of bona fide purchaser for value without notice on the party attacking the legal title. Instead, the Supreme Court held that the state rule related to a substantive right of the legal record holder and could not be subverted by a federal court in a diversity case. *See id.*

166. *See id.*

167. *See supra* Part IIC.

that dispose of difficult cases are valuable in promoting efficiency and economy, these concerns are hardly of the same significance as the constitutionally based right to trial by jury that was the basis of the federal interest in *Byrd*. This is particularly the case when weighed against a state's interest in allocating risk fairly, especially if the outcome-determinative character of the rule is added to the balance.[168]

As to the "twin aims" approach of *Hanna*—the "discouragement of forum-shopping and avoidance of inequitable administration of the laws"[169]—toxic tort litigation often ends up in a federal court because defendants exercise their removal option.[170] A defendant has an overwhelming incentive to remove if it believes that the result will be summary judgment in its favor, rather than a trial in a state court accompanied by expense and uncertainty.[171] This disparity in outcome is inequitable within the meaning of the *Erie* doctrine. If a state court has refused to adopt a rule, such as requiring epidemiological studies to show a doubling of the risk,[172] and therefore would not exclude a particular expert, plaintiffs stand to lose valuable rights in federal court if their cases are dismissed for lack of expert proof, even though they might win a favorable verdict in state court on the basis of the identical expert testimony.

In *S.A. Healy Co. v. Milwaukee Metropolitan Sewerage District*, the Seventh Circuit spelled out yet another possible approach to determine when a state practice is "substantive" so that it must be applied in diversity litigation.[173] *Healy* was cited twice by the majority in *Gasperini*[174] as an opinion illustrating sensitivity to state concerns. In *Healy,* the court had to decide whether a Wisconsin statute awarding a plaintiff double costs if it obtains a favorable judgment after the defendant refuses to accept the plaintiff's settlement offer was "substantive" for *Erie* purposes. Chief Judge Posner, after first noting that no "clear criterion" exists for making this determination, observed that there "are,

168. *See, e.g.*, Ides, *supra* note 159, at 86-87 (advocating a refined outcome-determinative test that includes a balancing of federal and state interests).

169. Stewart Org., Inc. v. Ricoh Corp., 487 U.S. 22, 27 n.6 (1988) (quoting Hanna v. Plumer, 380 U.S. 460, 468 (1965)).

170. Indeed, both *Daubert* and *Joiner* were commenced in state court. *See* General Elec. Co. v. Joiner, 522 U.S. 136, 140 (1997); Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 582 (1993).

171. The defendant may be far better informed about any research that has been done or is being done regarding its product than the plaintiff at the outset of the litigation, so the defendant may be in a good position to estimate its likelihood of success in a federal court by looking at the district judges' previous *Daubert* rulings.

172. *See, e.g.,* Landrigan v. Celotex Corp., 605 A.2d 1079, 1086-88 (N.J. 1992). The court found that an epidemiological study with relative risk of less than 2.0 was admissible, especially when other causation evidence, such as animal studies and in vivo analyses, exists. The court understood the importance of its ruling: "In recent years, we have sought to accommodate the requirements for admission of expert testimony with the need for that testimony. Nowhere is that accommodation more compelling than on the issue of causation in toxic tort litigation concerning diseases of indeterminate origin." *Id.* at 1083 (citations omitted).

173. 60 F.3d 305 (7th Cir. 1995).

174. Gasperini v. Center for Humanities, Inc., 518 U.S. 415, 428 n.7, 429 (1996). *Healy* was the only lower court case cited by the Court after its explanation for interpreting Federal Rules of Civil Procedure narrowly. *See supra* text accompanying note 139. The other cases cited were prior opinions of the Supreme Court.

however, two classes of pretty clear cases."[175] The first category is the Rules Enabling Act line of cases in which the federal rule applies because it is in direct conflict with the state rule.[176] Judge Posner then identified a

> second class of pretty easy cases . . . where the state procedural rule, though undeniably "procedural" in the ordinary sense of the term, is limited to a particular substantive area, such as contract law. For then the state's intention to influence substantive outcomes is manifest and would be defeated by allowing parties to shift their litigation into federal court unless the state's rule was applied there as well.[177]

Judge-made rules about proving causation seem to fall squarely into Judge Posner's second category; they are rules specifically designed to cover one particular substantive area—toxic tort litigation. Judge Posner continued by stating that "[t]he state's goals are substantive—designed to shape conduct outside the courtroom and not just improve the accuracy or lower the cost of the judicial process—though the means are procedural."[178] This definition of "substantive" is derived from Justice Harlan's concurring opinion in *Hanna.*[179] It would certainly seem applicable when a state has interpreted its evidentiary requirements so as to better a plaintiff's odds of prevailing in toxic tort litigation; an increased threat of liability provides an inducement for manufacturers of substances of unknown toxicity to take more care in testing their products.[180] But Judge Posner would apparently apply a state's procedural rule that applies to a particular type of claim even if the rule has no impact on behavior outside the courtroom.[181]

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175. *Healy,* 60 F.3d at 310.

176. *See supra* Part IVB.

177. *Healy*, 60 F.3d at 310 (citations omitted).

178. *Id.* Even if state causation rules do not fall into *Healy*'s second category, the *Healy* court would still characterize them as "substantive." *Id.* Because the Wisconsin statute in question was not limited to a particular area of the law, the court asked two questions: (1) Will the rule lead to forum-shopping? and (2) Is the rule so entwined with procedures dictated by federal rules that it may likely "impair the integrity of federal procedure if it is applied in diversity cases?" *Id.* The court answered the first question "yes" and the second "no." It explained that "[i]f a rule so favorable to plaintiffs is inapplicable in diversity cases, defendants in such cases will have an added incentive to remove a diversity case to federal district court." *Id.* at 311. "States are allowed to favor plaintiffs—or defendants . . . . Under *Erie,* this 'favoritism' is to operate even when the persons who have a dispute over state law find themselves in a federal court." *Id*. at 312.

179. Justice Harlan wrote:

> To my mind the proper line of approach in determining whether to apply a state or a federal rule, whether "substantive" or "procedural," is to stay close to basic principles by inquiring if the choice of rule would substantially affect those primary decisions respecting human conduct which our constitutional system leaves to state regulation. If so, Erie and the Constitution require that the state rule prevail, even in the face of a conflicting federal rule.

Hanna v. Plumer, 380 U.S. 460, 475 (1965). This test has never been adopted by a majority of the Court.

180. *See* Berger, *supra* note 90, at 2131.

181. *See* Herremans v. Carrera Designs, Inc., 157 F.3d 1118, 1122 (7th Cir. 1998) (generally federal procedural rules govern, but there is "an exception for cases in which the application of the federal rule would interfere with substantial state interests, and the exception is more likely to be applicable when the state [rule in question] is limited to some particular body of substantive law and is therefore more likely to reflect state substantive policies than is a procedural rule of general applicability."(citations omitted)).

F. State Evidentiary Rules in Federal Diversity Tort Actions

Federal courts in diversity tort actions have enforced state statutes and common law rules even though they are couched in evidentiary terms. These decisions demonstrate that the admission and exclusion of evidence are not always viewed as purely procedural matters. A fairly large congregation of cases deals with state statutes that prohibit the introduction of evidence that the plaintiff was not wearing a seat belt in a personal injury action.[182] The specific state command—not to admit the failure to wear a seat belt when offered to prove certain propositions, such as contributory negligence—is treated as substantive and given effect by the federal court. The reasoning in these cases is not identical. Some opinions rely on the "twin aims" test of *Hanna*;[183] others view the state rule as being "intimately bound up with the rights and obligations being asserted,"[184] or as affecting behavior outside the courtroom.[185] Some courts assume without any discussion that the issue is governed by state law.[186]

These federal courts have considered themselves bound to apply the state's policy, even though the definition of relevancy set out in Rule 401[187] would seem to make evidence such as the failure to wear a seat belt admissible. The case for giving effect to a state's requirements for proving causation seems considerably stronger because the text of Rule 702, even as amended,[188] does not resolve is-

182. *See, e.g.*, Gardner *ex rel* Gardner v. Chrysler Corp., 89 F.3d 729 (10th Cir. 1996); Dillinger v. Caterpillar, Inc., 959 F.2d 430 (3d Cir. 1992); Barron v. Ford Motor Co. of Canada Ltd., 965 F.2d 195 (7th Cir. 1992); Potts v. Benjamin, 882 F.2d 1320, 1324 (8th Cir. 1989); Sours v. General Motors Corp., 717 F.2d 1511, 1519 (6th Cir. 1983); Milbrand v. Daimler Chrysler Corp., 105 F. Supp. 2d 601(E.D. Tex. 2000); Morton v. Brockman, 184 F.R.D. 211 (D. Me. 1999); MacDonald v. General Motors Corp., 784 F. Supp. 486 (M.D. Tenn. 1992); Pasternak v. Achorn, 680 F. Supp. 447 (D. Me. 1988).

183. *See, e.g., Milbrand,* 105 F. Supp. 2d at 604 ("Courts must also be guided by the purposes served by the *Erie* doctrine: to discourage forum shopping and to avoid an inequitable administration of the laws . . . . [E]mploying federal law in this case would violate the underlying policies of *Erie*."); *Morton*, 184 F.R.D. at 215 ("[T]he 'substantive' nature of [Maine's seat-belt statute] is reflected by the fact that failure to apply [it] in diversity cases would frustrate *Erie's* goals of avoiding inequitable administration of the laws and discouraging forum-shopping.").

184. *See Pasternak,* 680 F. Supp. at 449 ("A federal court should be reluctant to disregard a state statute so closely related to a substantive state legislative policy.").

185. *See, e.g., Barron,* 965 F.2d at 199 ("[A] substantive rule is concerned with the channeling of behavior outside the courtroom, and where as in this case the behavior in question is regulated by state law rather than by federal law, state law should govern even if the case happens to be in federal court."); *Milbrand,* 105 F. Supp. 2d at 604 ("The Texas statute is clearly designed to regulate the behavior of individuals outside of the courtroom and consequently falls on the substantive side of the *Erie* line.").

186. *See, e.g., Gardner*, 89 F.3d 729 (assuming without discussion that Kansas law applies); *Dillinger,* 959 F.2d at 434-35 n.11 ("The propriety of the district court's admission of evidence concerning Dillinger's non-use of the available seat belt to mitigate his damages is a question of Pennsylvania law."); *Potts,* 882 F.2d at 1324 ("[W]e think it rather plain that [the Arkansas seat-belt statute] establishes a rule of substantive law."); *Sours*, 717 F.2d at 1513-14 ("We take it to be common ground that, in this diversity action arising from an accident that occurred in Ohio, the law of that state as enunciated by the Ohio Supreme Court governs."); *MacDonald,* 784 F. Supp. at 495 (citing precedent).

187. FED. R. EVID. 401 provides: "'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."

188. As of December 1, 2000, the following is appended at the end of Rule 702: "[A qualified expert witness may testify] if (1) the testimony is based upon sufficient facts or data, (2) the testimony is

sues about judge-made conventions on proof of causation as specifically as the definition in Rule 401 resolves the issue of relevancy. Yet federal courts have applied state rules that conflict with the test set out in Rule 401 when they conclude that the countervailing state approach is part of the state's substantive policy in the field of torts. Federal courts have also enforced a great variety of other state statutes and common-law rules pertaining to evidence in tort cases. In these cases, the federal courts follow the state practice regardless of whether this leads to the admission[189] or exclusion[190] of evidence. It is difficult to understand why, in light of the policies underlying *Erie,* expert testimony should be treated any differently. If a state has explicitly adopted or refused to adopt a particular convention relating to expert proof, the results in analogous cases all point toward having the federal court enforce the state rule.

It should make no difference in looking at state law whether the state purports to follow *Daubert* or *Frye*. What matters is not the general rule on expert proof but how it has been interpreted. State courts reach divergent results that are unrelated to whether they have adopted *Daubert* or *Frye* with regard to policy-based rules.[191]

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the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." For the text of Rule 702 as originally enacted, see *supra* note 14.

189. *See, e.g.,* Wray v. Gregory, 61 F.3d 1414 (9th Cir. 1995) (holding that state law regarding admissibility of findings of medical malpractice screening panel must be applied; state rule is part of an integrated process for handling malpractice cases, and failure to apply it would result in forum shopping); s*ee also* Daigle v. Maine Medical Ctr., Inc., 14 F.3d 684 (1st Cir. 1994) (surveying cases on admissibility of findings of malpractice panels); Carota v. Johns Manville Corp., 893 F.2d 448, 451 (1st Cir. 1990) ("If a state has a substantive policy to have a jury hear out of court settlement evidence when determining damage awards, we will not contravene that state law in a diversity case."); Stroud v. Cook, 931 F. Supp. 733, 738 (D. Nev. 1996) (making admissible evidence of defendant's misdemeanor conviction, in action arising out of automobile collision for failure to use due care in operation of motor vehicle and finding evidence to be substantive because it was "intimately bound up with the rights and obligations being asserted" and had to be applied even if evidence would have to be excluded as hearsay under Federal Rules of Evidence).

190. *See, e.g.,* Hottle v. Beech Aircraft Corp., 47 F.3d 106 (4th Cir. 1995) (excluding defendant's engineering manual, which constituted relevant evidence under Federal Rules of Evidence, in products liability action, because of Virginia policy that a party's internal rules and regulations may not be admitted to prove negligence; court surveyed Virginia case law and found no countervailing federal policy); Caldarera v. Eastern Airlines, Inc. 705 F.2d 778, 782 (5th Cir. 1983) ("Louisiana forbids evidence of remarriage in a suit seeking damages for the loss of a spouse . . . . That rule binds us."); D'Orio v. West Jersey Health Systems, 797 F. Supp. 371 (D.N.J. 1992) (applying state rule that precluded admission of plaintiff's medical expenses).

191. *See, e.g.,* Landrigan v. Celotex Corp., 605 A.2d 1079 (N.J. 1992) (rejecting 2.0 relative risk as a threshold to the admission of epidemiological evidence); DePyper v. Navarro, 1995 WL 788828, at *33 (Mich. Ct. App. Nov. 27, 1995) (following *Frye*; "To demonstrate statistical significance a relative risk/odds ration of over two is necessary, and for a strong association a relative risk/odds ratio of at least 2.5 or higher in a study whose [95%] confidence interval did not include 1 is necessary."); Linnen v. A.H. Robins Co., Inc., 11 Mass. L. Rptr. 205 (Mass. Super. 2000) (following *Daubert*; admitting epidemiological evidence with an odds ratio of less than 2.0); Hand v. Norfolk S. Ry. Co., 1998 WL 281946, at *3 (Tenn. Ct. App. June 2, 1998) (*Frye/Daubert* analysis; holding that epidemiological study need not show relative risk greater than 2.0).

V

THE TRANSFORMATION OF ADMISSIBILITY INTO SUFFICIENCY

A. *Erie* and the Sufficiency of Evidence

References to state law (with, at times, a mention of *Erie*) have crept into a number of decisions written in response to *Daubert* challenges to plaintiffs' experts. These decisions incorporate a state's sufficiency standard into the federal court's admissibility determination.[192] They exclude an expert's testimony that will not satisfy the plaintiff's substantive burden of proof on the ground that such testimony is not helpful as required by Rule 702, or does not satisfy the "fit" prong of the *Daubert* test.[193] In *Daubert*, the Supreme Court stated that a court could direct summary judgment if the scintilla of admissible expert proof "supporting a position" was "insufficient to allow a reasonable juror to conclude the position more likely than not is true."[194] But the Court did not suggest that the "helpfulness" or "fit" of each expert's testimony should be decided by asking whether it would satisfy the proponent's burden of persuasion on the issue to which the testimony relates.

Nothing in the original text of Rule 702 indicates that the general rule of admissibility expressed in Rule 401 of the Federal Rules of Evidence does not apply. That is, evidence that satisfies Rule 702 is admissible "if it has any tendency" to make a material fact more or less probable. Although Rule 702, as interpreted by the trilogy, heightens the reliability standard that must be met before the evidence will be viewed as having that tendency, the original Rule 702 makes no mention of sufficiency.

B. The Amendment to Rule 702

Rule 702 has been amended, as of December 1, 2000, to require that "the [expert's] testimony is based upon sufficient facts or data."[195] What this is in-

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192. *See, e.g.*, Allison v. McGhan Med. Corp., 184 F.3d 1300, 1320 (11th Cir. 1999) ("Because this action is based on diversity, Georgia substantive standards of law must apply. Proffered expert testimony must meet the legal as well as the substantive issues of the case.") (citing Erie R.R. v. Tompkins, 304 U.S. 64 (1938)); Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1320 (9th Cir. 1995), *cert. denied,* 516 U.S. 869 (1995) (*Daubert II*) (*Daubert* on remand) ("In assessing whether the proffered expert testimony 'will assist the trier of fact' in resolving this issue, we must look to the governing substantive standard, which in this case is supplied by California tort law."); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1398 (D. Or. 1996) ("Under Oregon law, the plaintiffs in this litigation must prove not merely the possibility of a causal connection between breast implants and the alleged systemic disease but the medical probability of a causal connection.").

193. *See, e.g.*, *Allison*, 184 F.3d at 1320; *Baxter Healthcare Corp.,* 947 F. Supp. at 1403; s*ee also Daubert II*, 43 F.3d at 1320.

194. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596 (1993):

> [I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment, FED. R. CIV. PROC. 50(a), and likewise to grant summary judgment, FED. R. CIV. PROC. 56.

Id.

195. *Supra* note 188.

tended to require is unclear,[196] but this addition may perhaps be read to insert a sufficiency requirement into rulings on admissibility that would require the trial court to weigh all of a plaintiff's expert proof on causation when ruling on a *Daubert* motion to exclude a particular expert. This amendment, unlike the original Rule 702 enacted by Congress,[197] was adopted by rule-making, and must therefore satisfy the Rules Enabling Act, which, as discussed above,[198] states that rules adopted pursuant to the rule-making process "shall not abridge, enlarge or modify any substantive rights and shall preserve the right of trial by jury."[199]

No rule has ever been found to violate this directive, and of course the Supreme Court, which must approve proposed amendments during the course of the rule-making procedure,[200] is hardly likely to strike down an amendment that it promulgated. It is, however, theoretically arguable that the incorporation of a sufficiency standard into rulings on the admissibility of expert testimony runs afoul of the Rules Enabling Act because it does not "preserve the right of trial by jury." The plaintiff loses the opportunity to reach a jury if the trial court excludes the evidence on sufficiency grounds, even though the evidence is admissible. Although, as *Daubert* acknowledges, a court may ultimately conclude that admissible evidence is insufficient and set aside a verdict for the plaintiff, this scenario differs from one in which the trial court finds the evidence inadmissible after a *Daubert* hearing and grants summary judgment for plaintiff's failure to make out a prima facie case. Not having a case heard by a jury has consequences, even if the ultimate finding with regard to liability is unaffected. If the case ends at the pretrial stage, the plaintiff will never have the opportunity to tell his or her story in a courtroom. Furthermore, to the extent that toxic tort litigation raises important policy concerns about risk and regulation that ought to be the subject of public debate, shutting cases out of a courtroom may lead to a less well-informed electorate.

In practice, however, imposing a sufficiency requirement is unlikely to produce outcomes different from those that now occur when a district court which has not explicitly adopted a sufficiency standard excludes plaintiff's experts on a *Daubert* motion. Courts are reaching this result by looking at each expert and each study upon which the expert relies separately in determining relevancy and reliability, an approach a majority of the Supreme Court approved without discussion in *Joiner*.[201] If the trial court in this manner, in the exercise of its discre-

196. The Advisory Committee's Note to the amendment states that "Subpart (1) of Rule 702 calls for a quantitative rather than qualitative analysis." *See supra* note 7.

197. *See* FED. RULE EVID. 702.

198. *See* discussion *supra* Part IVB.

199. FED. RULE EVID. 702

200. *See* 28 U.S.C. § 2072(a).

201. *See* General Elec. Co. v. Joiner, 522 U.S. 136, 153 (1997). Only Justice Stevens objected to this process of looking at the parts, rather than the whole, in his opinion concurring in part and dissenting in part:

> The District Court . . . examined the studies one by one and concluded that none was sufficient to show a link between PCB's and lung cancer . . . . [I]t would seem that an expert could reasonably have concluded that the study of workers at an Italian capacitor plant, coupled

tion, eliminates each of the plaintiff's experts on causation, and then grants summary judgment because the plaintiff cannot make out a prima facie case, the consequences are the same as if the court had excluded each of the plaintiff's experts on the ground that the testimony was not helpful because it would not ultimately suffice to prove causation.[202] In either case, the court has terminated the litigation without giving the plaintiff the opportunity for a trial before a jury.

C. The Trilogy on Summary Judgment

Either route to disposing of the case at the pretrial stage furthers case-processing efficiency and economy. The trilogy on expert testimony, therefore, operates in tandem with another trilogy that facilitates similar aims—the three opinions on summary judgment handed down by the Supreme Court in 1986[203] that have made it far easier to obtain summary judgment than before.[204] Indeed, even before *Daubert* was decided, observers writing about the shift of power between plaintiffs and defendants effected by the summary judgment trilogy noted that "[t]he use of summary judgment to deny access to the jury seems particularly prevalent in toxic tort cases where judges do not find the evidence probative."[205] This reallocation of power has been accelerated by the trilogy on expert proof. Not only are district judges granting an increasing number of *Daubert* motions,[206] but in doing so they escape the more stringent de novo standard of review that applies to grants of summary judgment, in favor of the more lenient abuse of discretion standard that governs evidentiary rulings on the admissibility of expert proof.[207] If they have not abused their discretion in excluding all the plaintiffs' experts on causation, they cannot have erred in granting summary judgment, as no material facts remain in issue.[208]

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with data from Monsanto's study and other studies, raises an inference that PCBs promote lung cancer.

Id.

202. When the Supreme Court approved this practice *sub silentio* in *Joiner*, it was interpreting the congressional enactment of Rule 702, so that no issues of the reach of the Rules Enabling Act needed to be considered. Now, however, Rule 702 has been readopted through rulemaking. Does this mean that Rules Enabling Act issues can now be raised even with regard to language that has not been amended?

203. *See* Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986); Celotex Corp. v. Catrett, 477 U.S. 317 (1986).

204. *See* Patricia M. Wald, *Federal Practice and Procedure Symposium Honoring Charles Alan Wright: Summary Judgment at Sixty*, 76 TEX. L. REV. 1897, 1914-15 (1998) ("What almost everyone in the academic and legal communities agreed on was that the Supreme Court had moved summary judgment out of left field and onto first base, where it began shortening the innings by taking out runners before they could even begin to make the rounds.").

205. Samuel Issacharoff & George Loewenstein, *Second Thoughts About Summary Judgment*, 100 YALE L.J. 73, 90 n. 96 (1990). The article concluded that "summary judgment fundamentally alters the balance of power between plaintiffs and defendants by raising both the costs and risks to plaintiffs in the pretrial phases of litigation while diminishing both for defendants." *Id*. at 75.

206. *See supra* note 7.

207. *See supra* text accompanying note 136.

208. FED. R. CIV. P. 56(c) provides for the granting of summary judgment when "there is no genuine issue as to [a] material fact."

The extent to which the landscape has shifted is apparent if we look at *Anderson v. Cryovac*,[209] the Woburn leukemia cluster litigation that is the subject of Jonathan Harr's book, *A Civil Action*.[210] In that case, one of the defendants moved for summary judgment in 1984—before the Supreme Court decided either trilogy—on the ground that "plaintiffs cannot make out a *prima facie* case that a causal nexus exists between exposure to the subject chemicals and leukemia."[211] Less than two weeks after plaintiffs filed their papers in opposition,[212] the federal district judge, without ordering oral argument, denied defendant's motion in a two-page memorandum and order in which he wrote:

> The plaintiffs' expert witness disagrees with the opinions of the defendant's expert witness[es]. Dr. Levin stated that he believes "to a reasonable degree of certainty . . . that the exposure of the plaintiffs to the subject chemicals caused or substantially contributed to the plaintiffs suffering serious illnesses including immune dysfunction and leukemia." Levin Affidavit, ¶ 16. Since the complex factual issue of causation is a subject of heated dispute in this case, summary judgment is clearly inappropriate.[213]

It is inconceivable that a causation issue such as this would not now be the subject of a *Daubert* hearing and that the outcome of that hearing would not determine the future of the case.

VI

CONCLUSION

This article began with Justice Jackson's observation that an evidentiary change may alter the existing balance of power.[214] This has certainly been true in the field of toxic torts: The Supreme Court's trilogy on expert proof has empowered federal judges to adjust the balance in toxic tort cases to favor defendants. This article has examined the means by which judges have been able to achieve these results: by (1) simplifying complex questions about the boundaries of science and about the assumptions on which scientific judgments often rest; (2) ignoring whether the consequent reshaping of toxic tort law is appropriate in light of the *Erie* doctrine; and (3) converting rulings on the admissibility of evidence into rulings on the sufficiency of evidence. The result is that the critical issue of causation in toxic tort cases is being decided by federal judges, not state judges or jurors, and in pretrial proceedings, rather than at trial.

This approach has undoubtedly fostered efficiency and economy, as has the Supreme Court's trilogy on summary judgment with which the trilogy on expert proof operates in tandem. Whether these are the appropriate criteria for determining who should bear the risk of scientific uncertainty deserves more attention. A danger of the post-trilogy approach is that, given the courts' over-

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209. Anderson v. Cryovac, Inc., 862 F.2d 910 (1st Cir. 1988).

210. JONATHAN HARR, A CIVIL ACTION (1995).

211. LEWIS A. GROSSMAN & ROBERT G. VAUGHN, A DOCUMENTARY COMPANION TO A CIVIL ACTION 558 (1999).

212. *See id*. at 577.

213. *Id*. at 578. The case settled before the issue of causation was reached.

214. *See supra* text accompanying note 2.

loaded dockets, their understandable desire to dispose of complex and time-consuming cases may interfere with the evolution of better approaches for dealing with toxic torts.