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THE ROAD LESS WELL TRAVELED (AND SEEN): CONTEMPORARY LAWMAKING IN PRODUCTS LIABILITY

*Michael D. Green**

My assignment, as I understood it when Professor Landsman invited me to speak at this Symposium, was to address the question of whether judges continue to make law in the products liability field. This seemed a sufficiently broad topic, and I assumed, like Mark Twain in his recounting of the early days of his education to become a riverboat pilot in *Life on the Mississippi*,¹ that this would all be pleasant enough work.

To begin my efforts, inquiring into the meaning of “law” seemed an appropriate start. That was the point at which I began to identify with Twain a bit later in his student pilot training. This occurred when, one night at midnight, a watchman awoke him and told him he was expected to be in the pilot-house ready to work in something less than sixty seconds. Twain wrote that getting up in the middle of the night to go to work “was a detail in piloting that never occurred to me at all. I knew that boats ran all night, but somehow I had never happened to reflect that somebody had to get up out of a warm bed to run them.”²

Defining “law” turns out to be only slightly less daunting than being awakened from a sound sleep in the middle of the night to learn to pilot a riverboat down the Mississippi. What I discovered is that this question is one that philosophers and lawyers have been debating for centuries, with no movement toward consensus. A 1974 text on legal process identifies eighteen different answers to the question, “What is Law?”³ Had I found A.E. Hoebel’s remarks about this business of defining law before I began, I suspect that I, like Twain, might have had second thoughts about whether to embark on this journey: “To seek a definition of law is to set forth upon a quest for the Holy Grail.

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1. MARK TWAIN, *LIFE ON THE MISSISSIPPI* 28-29 (Bantam 1985) (1896).

2. *Id.* at 29-30.

3. See STEPHEN D. FORD, *THE AMERICAN LEGAL SYSTEM* 2-4 (2d ed. 1974); see also STEVEN J. BURTON, *AN INTRODUCTION TO LAW AND LEGAL REASONING* 1 (2d ed. 1995) (“Philosophers have debated the question [of what is law] for centuries.”).

Anyone who has made this search will readily sympathize with the lament of Max Radin, 'Those of us who have learned humility have given over the attempt to define law.'"⁴

Deciding that if I had to be up in the middle of the night attempting figuratively to steer a riverboat down the Mississippi, I might as well engage the endeavor a bit, I explored these different meanings and came to the conclusion—prompted by H.L.A. Hart⁵—that the different definitions are meant to do different duties for different people with different purposes in mind. Some are concerned with the authority for law—distinguishing law from fiat backed by force—others are concerned with constitutional law and the political theory justifying courts having the last say. Others recognize that we need the law not only to address primary behavior but also to provide the means by which disputes are resolved, and still others are concerned with the prohibitory nature of criminal law and its impact on freedom.⁶

So, understanding the inquiry about judges making law to be about the resolution of cases in which one party claims that she should obtain compensation for an injury from another, I will, somewhat arbitrarily, utilize an understanding of law as the collection of precedents, rules, principles, and policies that are employed in products liability cases to determine whether the defendant will compensate the plaintiff.⁷

But do judges “make” law? Once again, that requires an interpretive turn: what do we mean by “make?” I sense that often when the accusation “judicial activist making law” is hurled about, there is a normative assumption that “making” law is not an appropriate judicial function. Let me dip my toe briefly in the normative question of whether judges should “make law” (I will return to that question later) by paraphrasing my colleague Arthur Bonfield, who, when I explained to him my task at this conference, observed that “[j]udicial activism occurs when a judge employs a new legal principle I don't like.” A corollary to Professor Bonfield's dictum is what judicial activism is not: “When a judge employs a new legal principle I like.”

4. See EDWARD ADAMSON HOEBEL, *MAN IN THE PRIMITIVE WORLD* 359 (1949).

5. See H.L.A. HART, *THE CONCEPT OF LAW* 1-3 (1961).

6. I think a fair reading of H.L.A. Hart is that a serious answer to the question of what is law requires further specification: for what reason do we want to know what the law is? See *id.*; see also Roscoe Pound, *Hierarchy of Sources and Forms in Different Systems of Law*, 7 *TUL. L. REV.* 475, 475-76 (1933).

7. This definition is an amalgamation drawn from my colleague, Steve Burton, and an observation by Karl Llewellyn. See BURTON, *supra* note 3, at 7; KARL N. LLEWELLYN, *THE BRAMBLE BUSH* 3 (1985) (“What these officials do about disputes is, to my mind, the law itself.”).

Aside from revealing hypocrisy in those criticizing judicial activism, Bonfield's observations also provide the beginning of understanding what we mean when we inquire about judges' "making law." Making law, I take it, is when a judge employs a new principle to decide a case.⁸ The perjorative "making law" is more often employed with regard to a new rule that sweeps broadly and therefore affects many future cases than when the court adopts a new rule that is more narrowly confined to the facts in the case. The latter is, after all, the traditional conception of the common law process, and Karl Llewellyn long ago cautioned that, as a prudential matter, judges should be attuned to confining their declarations of new principles.⁹

What about judges making products liability law? Of course they "make law." They always have, and will continue to do so as long as we ask courts to resolve disputes over accidents that reflect contemporary social and economic activity and the continuing march of technological change. Tort law has been, until recent decades, exclusively judge-made law.¹⁰ Justice Shaw, who in the infancy of tort law in the United States, announced that negligence was to be the basis of liability,¹¹ "made" law every bit as much as Justice Traynor, who in 1963, announced the new law of strict products liability.¹² All of the law contained in the first American treatise on tort law and all of the law contained in the first torts casebook was judge-made law.¹³

8. See LLEWELLYN, *supra* note 7, at 40-41 ("When [the court] speaks to the question before it, it announces law, and if what it announces is new, it legislates, it makes the law.").

9. See *id.* at 41.

10. See Robert L. Rabin, *Federalism and the Tort System*, 50 RUTGERS L. REV. 1, 2 (1997) ("Tort law in America is built on the bedrock of state common law.").

11. See *Brown v. Kendall*, 60 Mass. (6 Cush.) 292 (Mass. 1850). Tort emerged as a separate category of law in the latter half of the nineteenth century. See G. Edward White, *The Intellectual Origins of Torts in America*, 86 YALE L.J. 671, 678-83 (1977).

12. See *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900-02 (Cal. 1963). The approval the following year of a strict products liability standard by the American Law Institute in § 402A of the *Restatement (Second) of Torts* contributed to the widespread adoption of strict products liability by state courts. This was accompanied by a substantial liberalization of other aspects of liability rules that enhanced the ability of injured plaintiffs to recover from those in the chain of distribution. See, e.g., Michael D. Green, *Successor Liability: The Superiority of Statutory Reform to Protect Products Liability Claimants*, 72 CORNELL L. REV. 17, 24-26 (1986) (describing the early expansion of traditional bases of successor liability for long-tail product liability claimants); James A. Henderson, Jr. & Theodore Eisenberg, *The Quiet Revolution in Products Liability: An Empirical Study of Legal Change*, 37 UCLA L. REV. 479, 483 & nn.12-13 (1990) (abrogation of the patent-danger rule and permitting bystanders to employ strict products liability); Barry A. Levansan & Daryl J. Lapp, *Plaintiff's Burden of Proving Enhanced Injury in Crashworthiness Cases: A Clash Worthy of Analysis*, 38 DEPAUL L. REV. 55 (1988) (explaining widespread adoption of a duty upon the manufacturers to make automobiles and other products reasonably safe in the event of an accident).

13. The treatise is FRANCIS HILLIARD, *THE LAW OF TORTS* (1859). The textbook is JAMES BARR AMES, *SELECT CASES ON TORTS* (1874).

But my charge is to address the question of whether judges continue to make products liability law today. This assignment recognizes the role of the common law in developing strict products liability since the early 1960s, a revolution that George Priest claims is "among the most dramatic ever witnessed in the Anglo-American legal system," and which he asserts compares in magnitude to the development of legal realism and the Supreme Court's *Brown v. Board of Education*¹⁴ decision.¹⁵

There are at least three routes that I believe might be taken to address different pieces of the question of whether judges continue to make products liability law. One might be to look to the roll-back in products liability that has occurred over the past fifteen years or so.¹⁶ During this roll-back, courts have moved away from the consumer expectations test for design defects, employed a risk-benefit standard in its place, essentially turning design defect law into a negligence standard, declined to impute knowledge of dangers that reasonably could not have been known by the manufacturer at the time of the manufacture and sale, limited the availability of market share theories of liability to DES cases,¹⁷ reinvigorated the bulk supplier defense, adopted comparative fault as a defense in strict liability, adopted a government contractor defense,¹⁸ insulated prescription drugs from design defect claims, and snuffed out the trend toward recognizing a more liberal rule of successor liability for long-tail plaintiff claims.¹⁹ I chose not to pursue this route for two reasons. First, I want to avoid quibbling about whether rolling back something that is the result of judges' "making law" is itself "making law." One might take the position that the roll-back is merely correcting prior judicial lawmaking activity and returning to the status quo. My second reason is stronger: cataloguing and documenting these changes has already been performed by

14. 347 U.S. 483 (1953).

15. George L. Priest, *The Invention of Enterprise Liability: A Critical History of the Intellectual Foundations of the Modern Tort Law*, 14 J. LEGAL STUD. 461, 461 (1985). Although Priest credits academics for the intellectual roots of this movement, in the end it was judges like Roger Traynor who wrote proselytizing opinions and other judges who adopted this new rule of strict products liability.

16. See Stephen D. Sugarman, *Judges as Tort Law Un-makers: Recent California Experience with "New" Torts*, 49 DEPAUL L. REV. 455 (1999).

17. See *Shackil v. Lederle Labs.*, 561 A.2d 511, 522-28 (N.J. 1989); *Jackson v. Glidden Co.*, 647 N.E.2d 879, 884 (Ohio 1995).

18. See *Boyle v. United Tech., Inc.*, 487 U.S. 500, 512 (1988).

19. See Michael D. Green, *Successors and CERCLA: The Imperfect Analogy to Products Liability and an Alternative Proposal*, 87 NW. U. L. REV. 897, 909 (1993). But see Richard L. Cupp Jr., *Redesigning Successor Liability*, 1999 U. ILL. L. REV. 845 (noting recent decisions favoring successor liability and claiming that courts' interest in "tinkering" with the rule has intensified).

Professors Henderson and Eisenberg.²⁰ The revolution that they explain is no longer a “quiet revolution” to those aware of their work or who follow products liability developments.

A second possibility would be to look at some of the major social engineering tort cases in recent years, including the state attorneys general’s suits in tobacco and the burgeoning claims against gun manufacturers.²¹ These efforts have generated significant controversy and concomitant barbs about the inappropriateness of courts’ making social policy.²² I eschewed this topic, because we are too early in these efforts to make very much of them. The attorneys general’s tobacco suits were, after all, settled. Furthermore, the preliminary judicial decisions in those cases ranged across a substantial spectrum that included decisions quite unsympathetic to the effort and unwilling to break any new ground, to one in Florida, which merely gave effect to applicable legislation, to decisions that, while not pathbreaking, ena-

20. See Henderson & Eisenberg, *supra* note 12, at 488-516.

Although it is difficult to pinpoint precisely, sometime in the early to mid-1980s courts began to publish decisions that, taken in the aggregate, clearly signal a significant change in the direction of judicial lawmaking in products liability. . . . First, several cases are outright retreats from prior pro-plaintiff stances. Courts effectively are taking away what they previously have given or, in matter of first impression within a jurisdiction, are refusing to follow the lead of other courts that had earlier adopted a pro-plaintiff rule. Second, in an area that developed for plaintiffs as rapidly as did products liability, refusals to extend doctrine are almost as significant as withdrawals from earlier holdings. . . .

Id. at 488-89. See also Gary T. Schwartz, *The Beginning and the Possible End of the Rise of Modern American Tort Law*, 26 GA. L. REV. 601, 699-702 (1992) (concluding that the aggressive development of tort law between the 1960s and 1980s ceased in the 1990s).

21. See, e.g., *Hamilton v. Accu-Tek*, 935 F. Supp. 1307 (E.D.N.Y. 1996) (granting partial summary judgment in favor of defendant gun manufacturers in suit by family members of gun-shot victims alleging negligence and design defect); David Kairys, *Legal Claims of Cities Against the Manufacturers of Handguns*, 71 TEMP. L. REV. 1 (1998) (advocating tort suits against handgun manufacturers and cataloguing potential claims that might be asserted); Karen E. Meade, *Breaking Through the Tobacco Industry’s Smoke Screen: State Lawsuits for Reimbursement of Medical Expenses*, 17 J. LEGAL MED. 113 (1996) (describing state attorneys general’s suits against the tobacco industry to recover for medical expenses paid for state residents); see also Raymond E. Gangarosa et al., *Suits by Public Hospitals to Recover Expenditures for the Treatment of Disease, Injury and Disability Caused by Tobacco and Alcohol*, 22 FORDHAM URB. L.J. 81 (1994).

22. See *When Lawsuits Make Policy*, *ECONOMIST*, Nov. 21, 1998, at 17 (“Yet using the courts to bully industries in this way is an abuse of the legal process and an evasion of democratic accountability. . . . If legal extortion comes to replace the democratic process, everyone will suffer. . . . A legal system which, despite its occasional excesses, enjoys the support of most Americans will be brought into disrepute.”); John Herzfeld, *Jury in Brooklyn Finds Gun Makers Negligent, Awards \$520,000 in Damages to One Victim*, 27 BNA PROD. SAFETY & LIAB. REP. 170, 171 (1999) (characterizing verdict against gun manufacturer as “[s]ocial engineering taking place in a courtroom”); *Uncle Sam v Big Tobacco: A Lawsuit that Runs Against Democracy Itself*, *ECONOMIST*, Oct. 2, 1999, at 22 (characterizing United States’ suit against the tobacco industry for recovery of health care costs as “the crowning disgrace of Janet Reno and the Justice Department”).

bled the attorney general's suit to proceed to trial. The gun cases are still at a very preliminary stage—too soon, I think, to evaluate the courts' responses.

The third possibility, and the one that I chose to pursue, is to describe a body of lawmaking that has occurred in the area of mass toxic substances litigation. I chose this topic because the lawmaking has been manifest in several different forms, although all to similar effect. Some of this lawmaking has been quite prominent—the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,²³ was preceded by enormous interest and anticipation. The Court's opinion has created a well-recognized revolution in the treatment of expert witnesses and the admissibility of their testimony. By contrast, few are aware of, or appreciate, the more subtle lawmaking that occurred in this area beginning in the mid-1980s.

We might date the emergence of the mass toxic substances litigation era to Judge Wisdom's seminal opinion in *Borel v. Fibreboard Paper Products Corp.*²⁴ Mass torts since then include the Dalkon Shield, DES, Agent Orange, Bendectin, silicone gel breast implants, and, just when we thought that the mass tort business was about to peter out, fen-Phen arrived to enhance our field of inquiry, if not to provide healthier bodies. Arguably, Judge Wisdom "made" law in *Borel* when he affirmed the first jury verdict on behalf of an asbestos victim.²⁵ On calmer reflection, what one sees in *Borel* is the application of traditional tort principles in a different context, although the adoption of an informed consent standard for determining the adequacy of a warning was seminal.²⁶ In addition, permitting the jury to find that any exposure to a defendant's asbestos over multiple decades of exposure was a cause of the plaintiff's asbestotic disease was essential both to Mr. Borel's ability to succeed in his suit against multiple suppliers of asbestos products to which he had been exposed and to the legions of future asbestos victims who were exposed to multiple asbestos products from various manufacturers over different periods of time.²⁷

What I want to explore though is the converse, not the opening of the courts to mass tort claims, but another of the responses by the

23. See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 586-89 (1993).

24. 493 F.2d 1076 (5th Cir. 1973). Mention should be made of the litigation over the anti-cholesterol drug, MER/29, which caused a variety of adverse effects, the most serious of which were cataracts. MER/29 is responsible for a substantial number of personal injury suits in the early 1960s. See Paul D. Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CAL. L. REV. 116, 120-58 (1968).

25. *Borel*, 493 F.2d at 1109.

26. *Id.* at 1088.

27. *Id.* at 1094.

courts to the demands posed by this new class of products liability cases. One of these responses has been the development of a process of shutting down the courts to mass tort claimants. That has been done in the same insidious, not invidious, way that toxic agents cause their harm, silently and unobserved. Despite the legislative "tort reform" movement of the past several decades, it is judge-made law that has had the deepest impact on this new tort phenomenon. Related, but much more prominent, aspects of law making that emerge are the regulation of expert witness testimony and the dramatic shift in the law regarding the allocation of power between judge and jury.

My focus is the Bendectin litigation and my thesis is that the courts in the Bendectin litigation were "making law" every bit as much as the judges who participated in making strict products liability in its first two decades. A taxonomy of the law making in Bendectin includes law that was applied internally among the cases that made up the Bendectin congregation and law that was made and applied externally to a wide variety of toxic substances (and other) cases. To set forth, at the outset, my conclusions, the developed internal law might be characterized as: "Bendectin does not cause birth defects as a matter of law."²⁸ The external law that emerges consists of a rule that plaintiffs in toxic substances cases cannot satisfy their burden of production on causation without statistically significant epidemiological studies and a paradigm shift from a deference model for courts' treatment of experts to a very different role, one that envisions the expert as a conduit of science.²⁹

A bit of background is necessary to permit an explanation of these claims. First marketed in 1956, Bendectin was a combination drug designed by Merrell Dow Pharmaceuticals to treat the morning sickness of pregnant women.³⁰ With four million pregnancies per year in the United States alone, and millions more worldwide, coupled with estimates that more than half of pregnant women suffer from morning sickness,³¹ the potential market for this drug was quite attractive.

Approved by the FDA before the thalidomide fiasco, Bendectin underwent no reproductive toxicity testing nor any clinical studies to ex-

28. See *infra* note 88 and accompanying text.

29. The work of Ron Allen and Joseph Miller assisted me in appreciating the dramatic change in the courts' approach to expert witnesses, although Allen and Miller's concern was with the role of experts for fact finders, not the way in which courts approach experts. See Ronald J. Allen & Joseph S. Miller, *The Common Law Theory of Experts: Deference or Education?*, 87 *Nw. U. L. Rev.* 1131, 1131 (1993).

30. See Judy Folkenberg, *Mal de Mere: Simple Remedies Best for Morning Sickness*, 22 *FDA CONSUMER* 26 (1988).

31. *Id.* at 28.

amine any teratological (birth defects) or other adverse reproductive effects. At the height of its popularity, Bendectin was consumed by almost one-third of all pregnant women,³² and, by the mid-1980s, over thirty million women had taken the drug worldwide.³³ Yet in the late 1970s when the first lawsuit was brought, there had been one company-run epidemiological study that was quite poor, so shoddy in fact that plaintiffs' lawyers scored many favorable points at trial when cross-examining Merrell's witnesses about it.³⁴ Toxicological studies by Merrell were quite poorly done, and one generated a "smoking gun." After thalidomide revealed that drugs could cross the placental barrier, Merrell began reproductive testing of Bendectin.³⁵ A Merrell researcher conducted a teratology study on rabbits and found minor malformations (shifted ossification centers) in the kits of high-dose Bendectin rabbits that were similar to the effects previously found in studies with thalidomide. The researcher warned in his report that more studies were required to determine whether higher doses of Bendectin might produce more severe anomalies.³⁶ Merrell did not follow up on the researcher's suggestion; it did not submit the report to the FDA for three years, and when it did, it deleted the sections about the malformations and the recommendation for further research.³⁷ In short, this episode and others uncovered by plaintiffs' lawyers assisted plaintiffs in painting Merrell as a company that was at the very least cavalier about safety, if not malicious about concealing evidence of teratogenicity in its drug.³⁸ Plaintiffs' lawyers painted this picture well enough to obtain a number of punitive damage awards against Merrell, including one for \$75 million.³⁹

So when the litigation began in 1977, there was very little evidence available about Bendectin and the effect that it had (or did not have) in causing birth defects. Because 3-5% of all live births involve a birth defect and with one-third of the approximately four million pregnant women in the United States taking the drug, there were tens of

32. 11 FDA DRUG BULLETIN, INDICATIONS FOR BENDECTIN NARROWED 1 (1981).

33. See generally Robert R. Brent, *The Bendectin Saga: Another American Tragedy*, 27 TERATOLOGY 283 (1983) (estimating that as of that time 30 million fetuses had been exposed to Bendectin).

34. *Id.*

35. *Id.* at 283-84.

36. *Id.* at 284.

37. Merrell's explanation for the omission of the malformations was that this was a good-faith reclassification of data.

38. See MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 128-29 (1996); JOSEPH SANDERS, *BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION* 8-9 (1998).

39. See *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990).

thousands of pregnant women each year who had taken Bendectin and borne children with birth defects. That, of course, does not mean there is a causal relationship any more than the fact that many people who die are bald means that baldness causes death.⁴⁰

With no strong evidence either way, and the damaging evidence of Merrell's culpability that emerged in discovery, plaintiffs had some modest success in the first several cases.⁴¹ This success spawned a great deal of publicity, including a front page article in the *National Enquirer*,⁴² much solicitation of additional claimants by the early lawyers in the litigation, including Melvin Belli, and hundreds of additional cases.

For our purposes, we can quasi-fast forward the story.⁴³ By the mid-1980s there were three important developments in the Bendectin litigation: (1) around 2,000 cases had been filed against the manufacturer; (2) plaintiffs were winning almost one-half of the trials that occurred;⁴⁴ and (3) the scientific evidence on Bendectin's teratogenicity was becoming robust and tending to exonerate the drug as a teratogen.⁴⁵

What was to be done? Tort reform legislation would not make a dent in the problem that Bendectin (and similar mass tort) litigation posed. The most popular tort reform measures,⁴⁶ such as imposing caps on noneconomic damages, modifying joint and several liability,

40. Actually, there is a better case for baldness causing death than Bendectin causing birth defects based on the incidence of birth defects in the offspring of women who took Bendectin. Baldness is associated with death in the sense that there is a higher proportion of baldness among those who die than in the remainder of the population. The number of birth defects after Bendectin usage does not suggest anything about the comparative incidence of birth defects among those who did not use Bendectin. Of course, the reason that baldness is associated with death, even though it is not a cause of it, is that baldness is associated with other attributes, age and serious diseases, that do cause death. See, e.g., Linda A. Bailey et al., *Reference Guide on Epidemiology*, in FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 121, 158-60 (1994) (discussing confounding relationships).

41. See generally Richard A. Nagareda, *Outrageous Fortune and the Criminalization of Mass Torts*, 96 MICH. L. REV. 1121, 1136-37 (1998) (explaining that jurors' moral condemnation of outrageous conduct by manufacturing defendants has diminished the role of causation in deciding tort cases).

42. *New Thalidomide-Type Scandal—Experts Reveal . . . COMMON DRUG CAUSING DEFORMED BABIES*, NAT'L ENQUIRER, Oct. 9, 1979, at 1.

43. For anyone who wants to rewind the tape and play back the story more slowly, there are several case studies of the Bendectin litigation. See GREEN, *supra* note 38; SANDERS, *supra* note 38.

44. See SANDERS, *supra* note 38, at 119.

45. See Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HAST. L.J. 301, 394-95, 403-06 (1992).

46. See Joseph Sanders & Craig Joyce, "Off to the Races": *The 1980s Tort Crisis and the Law Reform Process*, 27 Hous. L. REV. 207, 217-18 (1990).

reforming medical malpractice liability, changing the collateral source rule, limiting contingent attorneys' fees, imposing fee shifting, and restricting punitive damage recovery and awards, would not cut to the core of the difficulty with the way Bendectin litigation was playing out.⁴⁷

The problem was a lack of causation and increasing scientific evidence that causation did not exist, but juries often reached a contrary conclusion, sometimes spectacularly so. The most notable example of plaintiff success occurred in *Ealy v. Richardson-Merrell Inc.*,⁴⁸ in which a jury in the District of Columbia awarded Sekou Ealy, an eight-year-old with severe arm and hand deformities, \$20 million in compensatory damages and \$75 million in punitive damages.⁴⁹

So long as the plaintiff introduces sufficient evidence, we all know that causation (like other factual elements of a case) is a question for the finder of fact.⁵⁰ Plaintiffs managed to cobble together plausible theories about why Bendectin was a teratogen, having no trouble finding expert witnesses who would testify in support of it.⁵¹ Of course, Merrell had its experts who testified to the lack of evidence of teratogenicity and the safety of Bendectin.

What to do? The courts might have continued as they had for many years, merely leaving the question of causation and resolution of the battle of the experts to the jury.⁵² This approach is exemplified by the

47. One tort reform that would have made an impact on Bendectin litigation is abrogation of the Child Savings Acts, which toll the statute of limitations for minors. See John H. Derrick, Annotation, *Tolling of Statute of Limitations, on Account of Minority of Injured Child, as Applicable to Parent's or Guardian's Right of Action Arising Out of Same Injury*, 49 A.L.R. 4th 216 (1993). The policy behind these Savings Acts is questionable because parents or guardians, who may have claims in their own rights, have adequate incentives to make a decision to sue on behalf of the child. Yet this potential reform never got onto the tort reform movement's radar.

48. 897 F.2d 1159 (D.C. Cir. 1990).

49. *Id.*

50. See *McDermott v. Midland Management Inc.*, 997 F.2d 768, 771 (10th Cir. 1993); *Miller v. American President Lines, Ltd.*, 989 F.2d 1450, 1463 (6th Cir. 1993); *Ingram v. AC & S, Inc.*, 977 F.2d 1332, 1340 (9th Cir. 1992); *Arkwright Mut. Ins. Co. v. Philadelphia Elec. Co.*, 427 F.2d 1273, 1275 (3d Cir. 1970); *Petroleum Carrier Corp. v. Carter*, 233 F.2d 402, 405 (5th Cir. 1956); *Kurak v. AP Green*, 689 A.2d 757, 765-66 (N.J. Super. Ct. App. Div. 1997).

51. See SANDERS, *supra* note 38, at 91-116. As the epidemiological studies of Bendectin grew, Dr. Alan Done, the primary expert witness for plaintiffs, developed a "mosaic" theory that stipulated that while none of four different types of evidence—epidemiologic, in vitro and in vivo toxicologic, and chemical structure analysis—was sufficient to prove causation, the whole was greater than the sum of the parts and demonstrated causation. See *id.* at 106-07; GREEN, *supra* note 38, at 277, 283.

52. See *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995) (stating the weight of scientific evidence is within the province of the jury); *Graham v. Wyeth Lab.*, 906 F.2d 1299, 1404 (10th Cir. 1990) (stating that the court is precluded from "weighing the evidence, passing on the credibility of the [expert] witnesses, or substituting a court's judgment for that of the jury"); *Wilson v. Merrell Dow Pharms., Inc.*, 893 F.2d 1149, 1155 (10th Cir. 1990) (stating

District of Columbia Circuit Court of Appeals in *Ferebee v. Chevron Chemical Corp.*,⁵³ which concluded: "Judges, both trial and appellate, have no special competence" to review and decide complex scientific questions of causation.⁵⁴ Indeed, in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*,⁵⁵ one of the early Bendectin cases, that is precisely what the Court of Appeals for the District of Columbia did. Plaintiff's expert, Dr. Alan Done, testified based on structure-activity information (the chemical similarity of Bendectin to known teratogens), in vivo studies (tests on live animals), in vitro studies (tests on living cells to determine whether a substance affects the cells and their development), and reanalyses of epidemiological studies (studies on human beings that compare the incidence of disease in different groups), that Bendectin caused the plaintiff's shortened right forearm, missing two fingers on her right hand, and fusion of the three remaining fingers.⁵⁶ Quoting *Ferebee*, the court reversed the trial court's granting judgment notwithstanding the verdict to Merrell, declaring that "if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony."⁵⁷

Continuing as before is not what happened. The response of courts to Bendectin cases beginning in the latter half of the 1980s reveals that courts actively examined the scientific record on birth defects and their connection with Bendectin, found succor in prior Bendectin decisions, even though those decisions were based on sufficiency of the evidence grounds that should have been limited to the evidence in those cases, critiqued the bases for experts' opinions, declaring them inadmissible when those bases were found wanting, and created scientific evidentiary thresholds for toxic tort plaintiffs. With hindsight, we could characterize the courts as having established a rule of law that plaintiffs cannot prevail on causation in a Bendectin case. This rule is not the sort of legal rule that we commonly understand courts to be engaged in making, but judicial lawmaking is. In addition, Bendectin, with some help from Judge Weinstein in *In re "Agent Orange" Prod-*

that when expert testimony is in conflict, "the jury alone has the power to weigh that evidence and assess the credibility of witnesses"); *McMahon v. Eli Lilly & Co.*, 774 F.2d 830, 835 (7th Cir. 1985) (stating that the jury must decide whether to credit experts' testimony on the existence of causation); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1534 (D.C. Cir. 1984).

53. *Ferebee*, 736 F.2d at 1534.

54. *Id.* at 1534-35.

55. 506 A.2d 1100 (D.C. 1986).

56. *Id.* at 1104.

57. *Id.*

uct Liability Litigation,⁵⁸ produced two rules that have had a significant impact outside the Bendectin litigation.⁵⁹

Lawmaking by Bendectin courts consisted of two different approaches with a couple of variations. The first entailed courts that examined the state of the scientific evidence regarding Bendectin and birth defects, often in substantial detail. Refusing to defer to the judgment of plaintiff's expert witnesses, who concluded from the evidence that Bendectin had caused the plaintiff's birth defect, the courts found the scientific record inadequate to permit such proof, despite an expert's contrary opinion.

The first such court to employ a sufficiency-of-the-evidence approach was the trial court in *Richardson v. Richardson-Merrell, Inc.*,⁶⁰ after a jury awarded \$1.2 million to an infant plaintiff with severe limb reduction birth defects and her parents.⁶¹ Although the court had denied defendant's motion for summary judgment, it granted a motion for judgment notwithstanding the verdict.⁶² Evidence of Bendectin's

58. 611 F. Supp. 1223 (E.D.N.Y. 1985). The contribution of Judge Jack Weinstein, whose lawmaking forays are well-known and legendary to the developments described in the text, must be acknowledged. In the *Agent Orange* litigation, which occurred in parallel with some of the early Bendectin cases, Judge Weinstein granted defendants summary judgment in individual suits brought by veterans who opted out of the class action settlement. *Id.* In the course of an opinion that discounted the value of animal studies and emphasized the importance of human epidemiology, Judge Weinstein resurrected *Frye* and expanded it to address novel opinions, even if derived from conventional scientific methodologies and principles. Judge Weinstein sounded a clarion call for careful examination of expert witness testimony in toxic substances cases:

Such careful scrutiny of proposed evidence is especially appropriate in the toxic tort area. The uncertainty of the evidence in such cases, dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gatekeeping under Rules 403 and 703 by the court.

Id. at 1260. Judge Weinstein's admonition was absorbed and repeated in subsequent Bendectin cases, such as *Brock v. Merrell Dow Pharmaceuticals, Inc.*, which remarked on the "growing realization among academics, lawyers, and judges that cases such as this present special problems and challenges to traditional ideas regarding the role of the jury as a decision maker." 874 F.2d 307, 309 (5th Cir. 1989). *Brock* acknowledged that

[u]nder the traditional approach to scientific evidence, courts would not peer beneath the reasoning of medical experts to question their reasoning. Confronted, as we now are, with difficult medical questions, courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them.

Id. at 309-10. Peter Schuck has admirably chronicled the *Agent Orange* litigation and Judge Weinstein's role in lawmaking and outcome determining. See PETER H. SCHUCK, *AGENT ORANGE ON TRIAL: MASS TOXIC DISASTERS IN THE COURTS* 111-42 (1987); see also Michael D. Green, *Expert Witnesses and Sufficiency of the Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. REV. 643, 675-77 (1992).

59. See *infra* text accompanying notes 70-75, 109-123.

60. 649 F. Supp. 799 (D.D.C. 1986).

61. *Id.*

62. *Id.*

teratogenicity was introduced based on animal studies, in vitro studies, and chemical structure similarity, but the court focused on the epidemiological evidence: "The ominous hypothesis of two decades ago, namely, that Bendectin might be another Thalidomide, has been reduced to the status of a perdurable superstition by the worldwide epidemiological investigations it provoked"⁶³

Referring to the published studies introduced by the defendant, the court concluded that "the literature on Bendectin, individually and in the aggregate, fails to demonstrate Bendectin's teratogenicity to a scientifically acceptable degree of accuracy."⁶⁴ The court added another important slant to the evaluation of scientific evidence. Dr. Alan Done and Shanna Swan testified as experts on plaintiffs' behalf based on their reanalysis of an epidemiological study to account for their criticism of the methodology employed in the original study. The court discounted this work because it had not been subjected to the standard crucible for scientific work—publication and peer review.⁶⁵ This failure to publish was adopted by the court of appeals in *Richardson* and later by other courts. And, as we all know, Justice Blackmun subsequently adopted it in his flexible four factors for evaluating the scientific methodology of experts in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*⁶⁶

Another version of this sufficiency-of-the-evidence approach, championed by the Fifth Circuit in *Brock v. Merrell Dow Pharmaceuticals, Inc.*,⁶⁷ is to require plaintiffs to meet an evidentiary threshold in order to satisfy their burden of production. Like the *Richardson* case, a jury found for the plaintiff, but unlike *Richardson*, the trial judge had entered judgment for the plaintiff.⁶⁸ Despite acknowledging the traditional deference accorded experts, the *Brock* court expressed the view, first set forth by Judge Weinstein in *Agent Orange*, that toxic substances cases are different.⁶⁹ A new day of careful scrutiny of scientific evidence had dawned:

Under the traditional approach to scientific evidence, courts would not peer beneath the reasoning of medical experts to question their reasoning. Confronted as we now are, with difficult medical questions, courts must critically evaluate the reasoning process by which

63. *Id.* at 803.

64. *Id.* at 802.

65. *Id.*

66. 509 U.S. 579, 592-94 (1993).

67. 874 F.2d 307, 311-13 (5th Cir. 1989).

68. *Id.* at 313.

69. *Id.* at 310.

the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them.⁷⁰

Yet the court did not base its decision on the admissibility of expert testimony, as had Judge Weinstein. Instead, the court recognized the primacy of epidemiological evidence as proof of causation and adopted an evidentiary threshold for plaintiffs.⁷¹ Without a statistically significant epidemiological study finding Bendectin to be a teratogen, the court declared that the plaintiff could not satisfy her burden of proof.⁷² The Fifth Circuit's evidentiary threshold scheme has the attraction of being simple in application: it requires very little review or understanding of the scientific record, no analysis of an expert witness's opinion or its bases, and no consideration of the strength of the evidence tending to exonerate the alleged toxic agent. Not only has the Fifth Circuit's approach been employed in subsequent Bendectin litigation,⁷³ as well as other toxic agent cases in the Fifth Circuit,⁷⁴ it has proven an attractive rationale in a number of other toxic substances cases, including those in which there was very little epidemiology that had been conducted examining the agent at issue.⁷⁵

The final method, one that culminated with the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,⁷⁶ entails examination of the basis of an expert's opinion. The First Circuit, one of the first to address the matter, reviewed the scientific literature on birth defects—their known and unknown causes—canvassed the studies of Bendectin, and critiqued the reanalyses performed by plaintiff's

70. *Id.* at 309-10 (citation omitted).

71. *Id.* at 313.

72. *Id.*; see also *Lynch v. Merrell-National Labs., Div. of Richardson-Merrell, Inc.*, 830 F.2d 1190 (1st Cir. 1987) (rejecting non-epidemiologic evidence as inadequate and thereby implying an epidemiological threshold). For a critique of the court's reasoning in reaching this conclusion, see Green, *supra* note 58, at 667-68.

73. See *Daubert v. Merrell Dow Pharms., Inc.*, 727 F. Supp. 570, 575 (S.D. Cal. 1989); *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 724 (Tex. 1997); *Oxendine v. Merrell Dow Pharms., Inc.*, Civ. No. 82-1245, 1996 WL 680992, at *32 (D.C. Super. Ct. Oct. 24, 1996).

74. See *Bartley v. Euclid, Inc.*, 158 F.3d 261, 269 (5th Cir. 1998); *Thomas v. Hoffman-La-Roche*, 731 F. Supp. 224, 227-28 (N.D. Miss. 1989); *Christophersen v. Allied-Signal Corp.*, CA-W-88-98 (W.D. Tex. 1990); *Kelley v. Am. Heyer-Schulte Corp.*, 957 F. Supp. 873, 878 (W.D. Tex. 1997) (lower end of confidence interval must be above 1.0—equivalent to requiring that a study be statistically significant—before a study may be relied upon by an expert).

75. See *Renaud v. Martin Marietta Corp.*, 749 F. Supp. 1545, 1555 (Colo. 1990) (quoting *Brock* approvingly); *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 198 (Tex. Ct. App. 1998) (requiring reliable epidemiological evidence in order to satisfy burden of producing sufficient evidence on causation); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1485-86 (D.V.I. 1994).

76. 509 U.S. 579 (1993).

experts in *Lynch v. Merrell-National Laboratories*.⁷⁷ The court, in a passage that shakes what edifice *Ferebee* might represent, concluded:

We face then a situation in which limb reductions are a fairly unusual subspecies of defect, in which the origin of most limb reduction is unknown, in which world-wide scientific investigations of Bendectin have produced no evidence establishing that Bendectin causes limb reduction, and in which the irrelevance of Bendectin to the incidence of limb defects has been demonstrated. The ignorance that prevails as to the etiology of most birth defects does not mean causation in a given case could not be proven; it does mean that there is a large *terra incognita* where gossip and guess work abound, so that courts must carefully control the basis for testimony pointing to a particular cause. A new study coming to a different conclusion would be admissible evidence. Without such a study there is nothing on which expert opinion on Bendectin as a cause may be based. The plaintiffs offered no new study.⁷⁸

Without such scientific evidence, the court declared, the opinions of the plaintiff's experts were inadmissible because they lacked any legitimate basis.⁷⁹ Once those opinions are found inadmissible, the plaintiff is left without any evidence to prove causation, and the trial judge's grant of summary judgment can be affirmed. The *Lynch* opinion augured poorly for Bendectin plaintiffs but appeared to have little direct application for other toxic substances cases given the court's focus on the scientific record specific to Bendectin.

The District of Columbia Court of Appeals continued this expert-witness-inadmissibility approach one year later on appeal in *Richardson*.⁸⁰ Eschewing the trial judge's comparative assessment of the strength of the respective parties' cases, the court of appeals decided, after conducting a three-page assessment of plaintiff's primary expert witness and his testimony, that expert testimony contrary to mainstream scientific thinking and extant epidemiologic evidence is inadmissible.⁸¹ Once again, as with *Lynch*, the decision appeared to have its most significant impact within the congregation of Bendectin cases and did not provide a trans-toxic substances legal rule.⁸²

The *Richardson* court distinguished its *Ferebee* "battles of experts are for juries" decision by explaining that *Ferebee* involved a drug, paraquat, for which there was little scientific evidence about its toxic-

77. 830 F.2d 1190 (1st Cir. 1987).

78. *Id.* at 1194.

79. *Id.*

80. See *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988).

81. *Id.* at 829-32.

82. That assessment is borne out by a number of subsequent cases in the District of Columbia Court of Appeals. See *infra* note 84.

ity, while Bendectin had become a much-studied drug, with a mature body of scientific evidence available.⁸³ That distinction is persuasive—though more relevant to a sufficiency of the evidence analysis—and reveals the new body of law being developed and applied to Bendectin cases.⁸⁴

Richardson was, however, one of the early decisions concluding that the plaintiff could not prevail. As Joe Sanders has written, the court was not entirely confident of its analysis of the evidence and sought to bolster its opinion by explaining that even if plaintiff's expert's testimony were credited, it would not support a finding that Bendectin was the cause of birth defects.⁸⁵

When the District of Columbia Court of Appeals was faced with its next Bendectin case, *Ealy v. Richardson-Merrell, Inc.*,⁸⁶ it confronted a judgment in favor of the plaintiff. Despite the jury and trial judge's view, the court of appeals had no qualms in overturning the judgment. The court's brief opinion reads like one relying on stare decisis:

We find that this case is squarely within the binding rule articulated in *Richardson*: an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific

83. *Richardson*, 857 F.2d at 831-32.

84. That the District of Columbia Circuit meant what it said about the distinction between *Ferebee* and *Richardson* was brought home in a suit brought on behalf of a child born with birth defects whose mother had taken both Bendectin and Depo-Provera during pregnancy. *Ambrosini v. Labarraque*, 966 F.2d 1464 (D.C. Cir. 1992). The case against Merrell was dismissed based on *Richardson*. *Ambrosini v. Richardson-Merrell Inc.*, Civ. No. 86-278, 1989 WL 298429, at *1 (D.D.C. June 30, 1989). Later, the district court also dismissed the case against the manufacturer of Depo-Provera after concluding that the plaintiffs' causation experts' testimony was inadmissible in light of *Richardson*. The District of Columbia Court of Appeals reversed, concluding that unlike the experts in the Bendectin cases, the plaintiffs' causation experts with regard to Depo-Provera had employed conventional scientific methodology to reach their novel conclusions, thus employing the methodology/conclusion distinction later adopted by the Supreme Court in *Daubert*. *Ambrosini*, 966 F.2d at 1464. After remand for further inquiry into the bases of the plaintiffs' experts' opinions, the district court once again concluded the testimony was inadmissible and entered summary judgment. *Ambrosini v. Upjohn Co.*, Civ. A. No. 84-3483, 1995 WL 637650, at *8 (D.D.C. Oct. 18, 1995). Once again, the court of appeals reversed, despite expert testimony by a teratologist that was quite similar to Dr. Done's testimony in *Richardson* that was found inadmissible. The most persuasive ground that the court of appeals offered for distinguishing the two cases was that Bendectin "had been the subject of extensive scientific research . . . none of which has concluded that the drug is teratogenic." while "there is no 'overwhelming body of contradictory epidemiological evidence' to [the expert's] conclusion." *Ambrosini v. Labarraque*, 101 F.3d 129, 138 (D.C. Cir. 1996).

When a post-*Ambrosini* Bendectin case was once again before the Court of Appeals, it gave short shrift to plaintiff's argument that *Ambrosini* had changed the law established in *Richardson* and affirmed the trial judge's conclusion that, because plaintiff's expert's testimony was inadmissible, judgment as a matter of law for defendant was required. *Raynor v. Merrell Pharms. Inc.*, 104 F.3d 1371, 1376 (D.C. Cir. 1997).

85. See SANDERS, *supra* note 38, at 163.

86. 897 F.2d 1159 (D.C. Cir. 1990).

foundation under Federal Rules of Evidence 703 in the face of a "wealth of published epidemiological data" to the contrary. . . . Because *Richardson* provides a binding legal precedent governing the admissibility of expert opinion on the ability of Bendectin to cause human birth defects, the Ealys can only avoid that decision by showing that the record here is materially different from that in *Richardson*. We find no such difference.⁸⁷

In the words of Joe Sanders, *Ealy* declared that "[a]s a matter of law, Bendectin does not cause birth defects."⁸⁸

One of the more interesting examples of cross-case influence in the Bendectin litigation occurred in the long saga of *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*⁸⁹ Recall that this is the case in which the appellate court reinstated a jury verdict. In this, one of the earliest Bendectin cases, the trial judge granted judgment notwithstanding the verdict based on the inadequacy of the plaintiff's causation expert. The court of appeals reversed in an opinion that relied heavily on *Ferebee*: judges have no special ken in dealing with complex, scientific issues; if experts have conflicting views, the matter is one to be resolved by the jury.⁹⁰

That might have been the end of it, but it was not. The case developed into a struggle between the trial court (albeit different judges) and the appellate court, with the trial court determined to overturn the jury's verdict and the appellate court equally resolute about upholding it. Another decision by the trial court overturned the jury verdict, this time on a different ground, because the appellate court had previously ruled the expert's evidence admissible and sufficient.⁹¹ Seizing on mischaracterizations by the expert of his credentials, the trial court accused the expert of perjury, and found it so egregious that the verdict had to be overturned.⁹² Refusing to brook this thinly veiled attempt to get around its earlier decision, the court of appeals once again reversed.⁹³

One might have thought that this second emphatic decision by the court of appeals would be the end of *Oxendine*, some seven years after it was filed. On the contrary, this was the point at which *Oxendine* became most interesting for our purposes. Because punitive damages remained to be resolved, no final judgment could be entered, and

87. *Id.* at 1160-62.

88. See SANDERS, *supra* note 38, at 164. See also *Lee v. Richardson-Merrell, Inc.*, 961 F.2d 1577 (6th Cir. 1992); *Elkins v. Richardson-Merrell, Inc.*, 842 F. Supp. 996 (M.D. Tenn. 1992).

89. 506 A.2d 1100 (D.C. 1986).

90. *Id.* at 1110.

91. *Id.* at 1114.

92. See *Oxendine v. Merrell Dow Pharms., Inc.*, 563 A.2d 330, 331 (D.C. 1989).

93. *Id.* at 337-38.

Merrell took the opportunity to argue that developments occurring after the 1983 trial required that the verdict be reconsidered.⁹⁴ After having been told twice by the court of appeals that the verdict should not be overturned, the trial court declined. On yet another appeal, the court of appeals changed its mind. Recognizing the scientific evidence that had developed regarding Bendectin's teratogenicity since the time of the verdict, the court of appeals permitted the trial court to reconsider whether to provide Merrell relief from the 1983 verdict.⁹⁵ While the court of appeals paid obeisance to finality concerns, its decision could not have been in more flagrant disregard of them. Permitting Merrell to challenge a verdict rendered some eleven years previously based on scientific studies that did not exist at the time, would, if applied more generally, create never-ending cases forever subject to reconsideration as science better understood natural phenomena.⁹⁶

The trial court accepted the court of appeals' invitation and wrote an opinion in 1996, almost two decades after the Bendectin litigation began, but with a now mature body of scientific evidence.⁹⁷ The court's opinion is more revealing, at least for our purposes, in its structure than its outcome. While the invitation by the court of appeals

94. *Id.* at 333.

95. *Id.* at 337-38.

96. Before a new trial or relief from a judgment on the grounds of newly discovered evidence may be granted, hornbook law requires that the new evidence concern "facts existing at the time of trial." 11 CHARLES A. WRIGHT ET AL., *FEDERAL PRACTICE AND PROCEDURE* § 2808, at 86-87 (2d ed. 1995). Otherwise, judgments would constantly be subject to reconsideration if post-trial facts could be employed to show that the judgment is erroneous. The *Oxendine* court reasoned that although the studies that defendants sought to introduce did not exist at the time of trial, they concerned a "fact"—whether Bendectin caused birth defects—that existed at the time of trial. The difficulty with this argument is that it proves too much: new scientific evidence will always be about a fact that existed and was contested at trial, thereby eliminating this constraint on consideration of new evidence. Thus, the question must be not whether the fact existed at the time of trial but whether the evidence did. *See* *Hobbs v. United States*, No. 90-1861, 1991 U.S. A. LEXIS 27696, at *19 (4th Cir. Nov. 3, 1991) (letter that did not exist at time of trial); *McCathern v. Toyota Motor Corp.*, 985 P.2d 804, 825 (Or. Ct. App. 1999) ("Thus, the phrase 'newly discovered evidence' implies that the evidence existed but was not known or knowable at the time of trial."); *see also* WRIGHT, *supra*, § 2859, at 302 ("the same standard applies to motions on the ground of newly discovered evidence whether they are made under Rule 59 or Rule 60(b)(2) . . . Under both rules, the evidence must have been in existence at the time of the trial . . ."); *cf.* *National Bank of Commerce v. Dow Chem. Co.*, 1 S.W.3d 443 (Ark. 1999) (new research on connection between chemical and plaintiff's birth defect irrelevant to defendant's *res judicata* defense); *Strack v. Pelton*, 637 N.E.2d 914, 916 (Ohio 1994) (holding that plaintiff could not challenge paternity judgment with HLA genetic testing that established conclusively that plaintiff was not the father and observing: "We are not unaware that our decision in effect declares as static a state of facts that reliable scientific evidence contradicts.").

97. *See* *Oxendine v. Merrell Dow Pharms., Inc.*, Civ. No. 82-1245, 1996 WL 680992, at *2-4 (D.C. Super. Ct. Oct. 24, 1996).

was quite limited and tentative—indeed one judge specially concurred and expressed concern that the remand would prolong a case then twelve years old, with no change in the outcome—the trial court concluded that newly developed evidence not only would probably produce a different result in a new trial but that the plaintiff should not even be afforded the opportunity for a new trial and granted judgment for Merrell.

The court began its opinion with a survey of other appellate opinions (nine) on the merits in Bendectin cases. The court summarized its conclusion: “In all of these cases it was the lack of admissible, statistically significant epidemiological evidence that doomed each plaintiff’s case.”⁹⁸ The court proceeded to explain the primacy and therefore necessity of epidemiological evidence to prove causation, the necessity not only of epidemiological studies but statistically significant ones,⁹⁹ to summarize each of the epidemiological studies of Bendectin and birth defects and meta-analyses of these studies that had been published after the *Oxendine* jury verdict, to elaborate on several sources on teratogenic agents and their treatment of Bendectin, and to critique the nine expert affidavits submitted by the plaintiff before concluding that it must enter “judgment mandated by the state of scientific knowledge.”¹⁰⁰

Throughout its critique of plaintiff’s expert affidavits, the court relied on other court opinions and their treatment of that expert’s testimony. The court employed the analyses and conclusions of several court-appointed experts in *DePyper v. Navarro*,¹⁰¹ a state court case in Michigan and the only Bendectin case with court-appointed experts. I think it is not an inaccurate assessment of *Oxendine* to say that the court found its conclusions, methodology, operative rule (statistically significant epidemiological evidence is required for a plaintiff to present a prima facie case), and critical analysis in the prior Bendectin appellate opinions, none of which, the court took pains to note, favored a ruling for the plaintiff.¹⁰²

98. *Id.* at *7.

99. The demand for statistically significant epidemiological evidence began with the Fifth Circuit in *Brock*. See *supra* notes 67-74 and accompanying text.

100. *Oxendine*, 1996 WL 680992, at *34.

101. No. 83-303467-NM, 1995 WL 788828 (Mich. Cir. Ct. Nov. 27, 1995).

102. *Oxendine*, 1996 WL 680992, at *7 n.16. One might quibble with the court on this point. In *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, the court vacated the trial court’s granting of summary judgment to Merrell, concluding that the trial judge had inadequately explained why plaintiff’s expert testimony was inadmissible. 911 F.2d 941, 958 (3d Cir. 1990). The *DeLuca* court expressed its concern that courts were creating “special rules to address the problems posed by continued Bendectin litigation.” *Id.* at 952. On remand, the trial court held a hearing on the admissibility of plaintiff’s scientific evidence, once again found plaintiff’s expert’s testi-

Ten years after *Richardson*, the *Oxendine* court exhibited no uncertainty, no doubts that it had reached both a correct and justified decision. To be sure, the *Oxendine* court had a considerably more extensive body of exonerative epidemiological evidence before it, but the influence on the court of other Bendectin cases, like *Richardson*, was substantial.¹⁰³

These decisions were not, as Joe Sanders has observed, a "series of isolated, atomistic events."¹⁰⁴ Rather, they are best understood as part of the "congregation of Bendectin cases," in which courts were, with their eyes on each other, working out substantive rules to resolve this significant body of cases.¹⁰⁵ "A question to be asked about case congregations is whether, at some point, courts are prepared to act on [issues common to all cases] and make substantive determinations in individual cases based upon knowledge drawn from the congregation as a whole. With respect to Bendectin, the answer is yes."¹⁰⁶

The move toward resolving Bendectin cases through expert testimony admissibility decisions can be understood as the courts rationing judicial and court resources. While directed verdicts and judgments notwithstanding the verdict were devices that could be employed to correct errors by juries, expert witness rulings had the additional effect of saving the time of conducting a trial. Once again, Joe Sanders explains that the courts were, after several lengthy, complicated trials, seeking devices to limit the resources devoted to resolving Bendectin cases.¹⁰⁷ This resource-preservation lawmaking is also revealed by the failure of courts to recognize the distinction between admissibility and

mony inadmissible, and reentered summary judgment; the Court of Appeals affirmed. *DeLuca v. Merrell Dow Pharms., Inc.*, 791 F. Supp. 1042 (D.N.J. 1992).

103. With the judgment for Merrell in *Oxendine*, there has yet to be a final judgment on behalf of a plaintiff in the Bendectin litigation, and it is unlikely that there will be. There are only three live Bendectin cases remaining in the United States. The judgment in *Oxendine* is on appeal before the District of Columbia Court of Appeals. In another case, Merrell has been granted summary judgment, but the judgment is not final because of a claim against a co-defendant. The final case has the greatest potential to be resolved against Merrell, but that outcome is still a long shot. In *Blum v. Merrell Dow Pharmaceuticals, Inc.*, the plaintiffs obtained a jury verdict of \$4.2 million in compensatory damages and \$15 million in punitive damages that the Pennsylvania Superior Court overturned on the ground that the trial court abused its discretion by admitting plaintiffs' experts' testimony on causation. 705 A.2d 1314, 1323-24 (Pa. Super. Ct. 1998). The court concluded that judgment notwithstanding the verdict should have been granted. *Id.* at 1324. That decision is currently pending on appeal before the Pennsylvania Supreme Court. See *Blum v. Merrell Dow Pharms., Inc.*, 735 A.2d 1267 (Pa. 1999); Telephone Interview with W. Glenn Forrester, Senior Corporate Counsel for Hoechst Marion Roussel (the successor to Merrell Dow Pharmaceuticals, Inc.) (Aug. 9, 1999).

104. See SANDERS, *supra* note 38, at 144.

105. *Id.*

106. *Id.* at 158.

107. *Id.*

sufficiency of the evidence when ruling on the admissibility of expert testimony. It may be that animal toxicology evidence alone should be insufficient to support a determination of causation in a toxic substance case. But, surely, extraordinary circumstances aside, it is relevant to the question of whether a toxic substance causes disease in human beings.¹⁰⁸ Another telling omission in the Bendectin courts' assessments of plaintiffs' experts and the flaws in their reanalyses is the frequent jury-deferring device of leaving criticisms and errors to the "weight to be given the [evidence], rather than bearing on admissibility."¹⁰⁹

The judicial lawmaking that occurred in Bendectin was not limited to that congregation of cases, however. Initially, it encouraged the imposition of a higher threshold for sufficient evidence of causation in

108. 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, 230 (1993); Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Context-Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 16 VA. ENVTL. L.J. 1 (1996); Susan R. Poulter, *Reference Guide on Toxicology: Fitting Science to Law*, 36 JURIMETRICS J. 169, 176 (1996) ("On balance, because toxicological methods in general have some validity for predicting the existence and magnitude of human effects, there would seem to be toxic tort cases in which toxicological evidence ought to be deemed admissible on the issue of general causation."); Ellen Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, 1 CTS. HEALTH SCI. & L. 374 (1991).

109. Thus, in *Lynch v. Merrell-National Laboratories, Inc.*, the court held the testimony of plaintiff's witness, Shanna Swan, inadmissible. 830 F.2d 1190 (1st Cir. 1987). The court began its criticism of her testimony by observing that the subjects of the study that she reanalyzed were "an entirely abnormal set—1,231 children with birth defects and their mothers." *Id.* at 1195. In this criticism, the court failed to appreciate that one well-established epidemiological methodology is to conduct a study with those who have the disease of interest and compare their rates of exposure to suspected agents. See Linda A. Bailey et al., *Reference Guide on Epidemiology*, in FEDERAL JUDICIAL CENTER, REFERENCE GUIDE ON SCIENTIFIC EVIDENCE 121, 136-38 (1994). Next, the court criticized Swan's work because she compared her cases (those with limb reduction birth defects) with a control group of only those children with birth defects known to be caused by genetics. *Id.* Once again, that reflected a reasonable methodology to exclude those with birth defects of unknown origin because Bendectin might be a cause of those birth defects, and, if it were, any association between Bendectin and limb reduction defects would be diluted by birth defects it might cause in the control group. See SANDERS, *supra* note 38, at 181. Third, the court criticized Swan for failing to consider whether genetic birth defects might protect against other birth defects, a little like criticizing a study of the rate of crime for failing to consider the effect of substituting nonaspirin analgesics such as Tylenol and Advil for aspirin. See *id.* at 181-82. Sure, it might, but there is no reason to believe that it does and therefore include that variable in a study. Finally, the court criticized Swan for failing to publish or have peer reviewed her reanalysis and concluded that her work therefore could not be the basis of an expert opinion on the causal relationship between Bendectin and limb reduction defects. *Id.* at 182-83. The critical point is not the validity of the court's critique, but its failure to consider that these deficiencies be considered by the jury for its assessment of the strength of Swan's testimony. See also *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 725-26 (Tex. 1997); *cf. Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1229 (9th Cir. 1998); *Ambrosini v. Labarraque*, 101 F.3d 129, 140 (D.C. Cir. 1996) (failure of experts to rule out all other possible causes goes to weight and not admissibility of their opinions); *Dipetrillo v. Dow Chemical Co.*, 729 A.2d 677, 689 (R.I. 1999).

other toxic substances cases. Ultimately, however, the greatest impact it spawned was enhanced judicial scrutiny of expert witness testimony—initially to other toxic substances litigation—and ultimately to the entire panoply of expert witness testimony in products liability cases.

Judge Kozinski of the Ninth Circuit Court of Appeals played a critical role in this development by instigating the Supreme Court to address the question of the appropriate standard by which trial judges should determine the admissibility of expert witness testimony.¹¹⁰ This accelerated the influence of Bendectin decisions in other products liability cases, beyond the sufficiency influence of cases like *Brock*. Judge Kozinski employed *Frye v. United States*,¹¹¹ for the first time in a Bendectin case in the November of Bendectin litigation.¹¹² Heavily influenced by the earlier decisions of *Lynch*, *Richardson*, and *Brock*, Judge Kozinski, in a casual, two-page opinion decided that plaintiffs' expert witnesses' reanalyses of other studies could not support their opinions because they had not been subjected to peer review or published, both of which were required to satisfy generally accepted scientific methodology under *Frye*.¹¹³

The invocation of *Frye* in a Bendectin case and the potential for a legal methodology for the review of expert witnesses had profound implications beyond Bendectin. Confronted with the narrow, yet important question of whether *Frye* survived the adoption of the Federal Rules of Evidence, the Supreme Court replaced *Frye* with a focus on reliability and fit, and a list of four factors for trial judges to employ.

To say that the Supreme Court replaced *Frye* in its *Daubert* opinion is misleading. What the Court did in *Daubert* was to adopt a test for scrutinizing an expert's methodology and reasoning that filled a previously extant void. *Frye* and its general acceptance test was virtually nonexistent in civil cases and toxic substances litigation until Judge

110. See *Daubert v. Merrell Dow Pharms., Inc.*, 951 F.2d 1128 (9th Cir. 1991).

111. 293 F. 1013 (D.C. Cir. 1923).

112. *Frye* had earlier been cited, but not employed, by Judge Higginbotham in his dissent to the denial of rehearing en banc in *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 884 F.2d 167 (5th Cir. 1989). Judge Higginbotham cited *Frye* in support of the proposition that the issue of whether courts "should accept opinions of experts not based upon a generally accepted scientific principle and the more broadly stated concern that substantive principles such as tort law are not handling science issues in a rational manner" "has, of course, been debated in varying intensity since the 1923 decision" in *Frye*. *Id.* at 168-69, 169 n.2. *Frye* was also cited in *Deluca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1991), but only by way of explaining that an earlier criminal case had rejected use of it, because of its problematical aspects.

113. *Daubert*, 951 F.2d at 1129-31. See also *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 312-13 (5th Cir. 1989); *Lynch*, 830 F.2d at 1193-96; *Richardson*, 857 F.2d at 831; *Frye*, 293 F. at 1013.

Kozinski employed it in *Daubert*.¹¹⁴ Prior to the revolution wrought by the Bendectin litigation, expert testimony in products liability cases simply was not judicially screened.

Suffice to say that *Daubert* made a sea change in the law of expert witnesses, and this new law has had a profound impact on products liability law. Expert witnesses testifying about alternative designs,¹¹⁵ the causes of accidents,¹¹⁶ the adequacy of warnings,¹¹⁷ and the existence of defects,¹¹⁸ have been subjected to the “gatekeeping” mandated by *Daubert*, with their opinions frequently found inadmissible. Those of us who thought *Daubert* would produce more of the laissez-

114. Professor Paul Gianelli reports: “The civil cases, spurred by toxic tort litigation, also came later. *Frye* had been applied almost exclusively to criminal cases and was not applied in a federal civil case until 1984.” Paul C. Giannelli, *Daubert: Interpreting the Federal Rules of Evidence*, 15 CARDOZO L. REV. 1999, 2008 (1994) (citations omitted). See also MICHAEL H. GRAHAM, *HANDBOOK OF FEDERAL EVIDENCE* § 703.2 (3d ed. 1991) (“The *Frye* test has been applied most frequently over the years in criminal cases”); 1 DAVID W. LOUISELL & CHRISTOPHER B. MUELLER, *FEDERAL EVIDENCE* § 105, at 853 (1977) (“The *Frye* standard . . . is rarely applied in civil litigation; *Frye* itself has been cited only in a very few civil cases, principally in state courts in connection with blood tests to determine paternity.”); FAUST F. ROSSI, *EXPERT WITNESSES* 36 (1991) (The *Frye* standard traditionally has been applied almost exclusively in criminal cases.”).

A Westlaw search for all non-criminal cases that cited *Frye* and were decided before 1990 produced 25 cases. Of those 25 cases, eight were habeas corpus cases, seven employed the narrow holding of *Frye* to decide that lie detector evidence is inadmissible, four cases cited to *Frye* generally without employing it as a precedent in the case, and five cases employed *Frye* to deal with traditional criminal forensic evidence (e.g., fingerprinting) whose admissibility was at issue in a civil case. The only one of these 24 cases that was a toxic substances case was *Brock*, in which Judge Higginbotham cited *Frye* in his dissent to the denial of rehearing en banc. See *supra* note 112. The final case, *Ellis v. International Playtex, Inc.*, cited *Frye* critically and concluded that the dispute over the validity of the methodology in certain epidemiological studies should be submitted to the jury, rather than be decided by the judge. 745 F.2d 292, 303-04 (4th Cir. 1984).

Indeed, on one view of *Frye* it was inapplicable to the conventional scientific methodologies employed in cases like *Daubert*. *Frye* was understood to be limited to novel scientific techniques. See Cuevas v. E.I. DuPont de Nemours & Co., 956 F. Supp. 1306, 1308 (S.D. Miss. 1997). *Daubert* made plain that the gatekeeping obligation it imposed included all scientific expert witnesses regardless of how conventional their scientific tools may be. See 509 U.S. 579, 592 n.11 (1993) (“Although the *Frye* decision itself focused exclusively on ‘novel’ scientific techniques, we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence.”).

115. See, e.g., *Pries v. American Honda Motor Co., Inc.*, 31 F.3d 543, 545 (7th Cir. 1994); *Stanczyk v. Black & Decker, Inc.*, 836 F. Supp. 565, 567-68 (N.D. Ill. 1993) (excluding expert opinions under the *Daubert* approach in design defect cases).

116. See, e.g., *Vadala v. Teledyne Indus., Inc.*, 44 F.3d 36 (1st Cir. 1995); *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1043-45 (2d Cir. 1995); *Roback v. V.I.P. Trans. Inc.*, No. 91 C 5902, 1994 WL 548197 (N.D. Ill. Oct. 4, 1994) (finding experts’ opinions regarding causation inadmissible under *Daubert*); *Golod v. LaRoche*, 964 F. Supp. 841, 857 (S.D.N.Y. 1997).

117. See, e.g., *Robertson v. Norton Co.*, 148 F.3d 905 (8th Cir. 1998).

118. *Jaurequi v. John Deere Co.*, 173 F.3d 1076, 1084 (8th Cir. 1999); *Diviero v. Uniroyal Goodrich Tire Co.*, 114 F.3d 851 (9th Cir. 1997).

faire status quo have been proved desperately wrong, as courts have aggressively examined proposed expert testimony and ruled it inadmissible without hesitation.¹¹⁹

The Supreme Court's decision in *Kumho Tire Co. v. Carmichael*¹²⁰ confirms this revolution in products liability law and extends the law-making begun in the Bendectin litigation beyond toxic substances litigation to the full range of products liability cases. The *Kumho* decision makes plain that the *Daubert* framework is applicable not only to the epidemiologists and toxicologists who testify about causation in toxic substances cases, but also to the accident reconstruction experts, human factors experts, engineering experts from all disciplines, and physicians who provide essential evidence in virtually every products liability case.¹²¹

And let us not underestimate the impact of this development. Extending *Daubert* to virtually all experts who testify in products liability cases will increase the costs of litigating a products case in both obvious and nonobvious ways,¹²² provide additional strategic opportuni-

119. I have a weekly Lexis Eclipse search that provides me with all reported federal cases in which *Daubert* is invoked to challenge the admissibility of an expert's testimony. I generally see 10-12 cases per week, of which 2/3 are civil, and the vast majority of which hold the challenged expert's testimony inadmissible. While this is surely not a representative sample of *Daubert* matters, it does reflect at least a portion of the federal judiciary in active examination of expert testimony. See also 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.").

120. 119 S. Ct. 1167 (1999).

121. *Id.* at 1174-75.

122. The obvious way in which *Daubert* and *Kumho* will increase the costs of litigation is through the pretrial motions and hearings to determine the admissibility of a challenged expert's testimony. Cf. *United States v. Katz*, 178 F.3d 368, 370 (5th Cir. 1999). ("We would be remiss if we did not note that we are troubled by the amount of judicial resources that were devoted to the *Daubert* hearing. In a case capable of being tried start to finish in a day and one half, not only the court but the lawyers were engaged for the better part of five days in a hearing to determine the reliability of testimony and potential prejudice of exhibits involving a well known test that is applied in a quite straightforward manner. *Daubert* hearings in cases much more complex than this one are customarily conducted with dispatch consuming only a few hours at best.") The latent impact of these cases on costs occurs for additional reasons. First, experts will be required to spend more time specifying the bases of their opinions so as to permit an assessment of the validity of their methodology. See *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 416-17 (3d Cir. 1999) (reversing trial judge who held expert's opinion inadmissible because the report contained only "conclusory statements" and remanding for a hearing pursuant to Federal Rules of Evidence 104(a), at which the expert's reasoning could be fully presented). Second, the demands of scrutinizing expert testimony will push forward the time when experts will have to perform and complete their work. Frequently, lawyers, especially plaintiffs' lawyers, attempt to defer expert efforts and their associated costs until late in the pretrial process, so as to avoid paying for them unnecessarily in the event that a case settles. Third, scrutiny of an expert's methodology and reasoning will frequently require that experts spend more time, effort, and resources in conducting their investigation and preparing their reports than previously. See Wat-

ties for expert discovery, and have a significant impact on which cases are brought and how they are resolved.

Another area in which judicial lawmaking is now emerging, spurred by the developments in *Bendectin* and *Daubert* is in the silicone gel breast implant cases. This lawmaking may ultimately lead to decisions that bar plaintiff's expert witnesses from testifying, thereby rendering the plaintiffs unable to prove causation. But the breast implant litigation has not quite reached the end-stage that *Bendectin* has been through.

The lawmaking in the breast implant cases entails the appointment of court-appointed experts to assist in resolving *Daubert* challenges to the admissibility of plaintiffs' experts' testimony. To date, panels consisting of experts in several relevant sciences were appointed by Judge Jones in *Hall v. Baxter Corp.*,¹²³ which consisted of seventy consolidated cases in federal court in Oregon, and by Judge Sam Pointer in the multidistrict breast implant consolidated pretrial proceedings in Alabama.¹²⁴ The frequency with which court-appointed experts have been recommended by commentators in the past has been exceeded only by the frequency with which the advice is ignored.¹²⁵ In ap-

kins v. Telsmith, Inc., 121 F.3d 984, 992 (5th Cir. 1997) (expert proposing alternative design for holding conveyor arm must do more "than just conceptualizing possibilities"). The district court appropriately noted the lack of testing of any of the proposed alternatives. See also *Cummins v. Lyle Indus.*, 93 F.3d 362, 368 (7th Cir. 1996) (emphasizing the importance of testing of alternative designs as prerequisite to the admissibility of an expert's opinion, easing off a bit as to whether it is always required and observing "Rule 702 is designed to ensure that, when expert witnesses testify in court, they adhere to the same standards of intellectual rigor that are demanded in their professional work."); *Byrnes v. Honda Motor Co.*, 881 F. Supp. 279, 281 (S.D. Fla. 1994) (ruling plaintiff's expert's testimony about an alternative design for a motorcycle to provide lower body crash protection inadmissible because alternative design had not been built, tested, or accepted by the industry); *McCollin v. Synthes Inc.*, 50 F. Supp. 2d 1119, 1127 (D. Utah 1999) ("It is clear that no expert orthopedic surgeon would attempt to make a diagnosis without examining the patient, without considering the entirety of a patient's records, by allowing a non-doctor to select records before she considered them, or by allowing non-medical personnel to conduct patient interviews used for diagnostic purposes"); cf. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. e (1998):

In many cases, the plaintiff must rely on expert testimony. Subsection 2(b) does not, however, require the plaintiff actually to produce a prototype in order to make out a prima facie case. Thus, qualified expert testimony on the issue suffices, even though the expert has produced no prototype.

Id. *Daubert* and *Kumho* were not crafted to foster economical litigation.

123. 947 F. Supp. 1387, 1415 (D. Or. 1996).

124. *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 996 F. Supp. 1110 (N.D. Ala. 1997). For a listing of the specific orders related to the appointment of and charge to the panel of experts, see Howard M. Erichson, *Mass Tort Litigation and Inquisitorial Justice*, 87 GEO. L.J. 1983, 1983 n.2 (1999).

125. See Joe S. Cecil & Thomas E. Willging, *Accepting Daubert's Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1004 (1994); E. Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific*

pointing expert panels¹²⁶ to consider the evidence of silicone gel breast implants' causal connection with immune system disease, these courts are breaking new ground in finding ways to assist in the resolution of mass toxic substances cases.¹²⁷

I do not consider the conclusion I have reached to the question posed to be surprising or provocative. Courts have been "making law" in response to changes in the social, political, economic, and scientific landscape for centuries and will, no doubt, continue to do so. Tort law, as the American Bar Association explained in its thorough review of the subject, "provides an important front-line weapon for the law" as courts "confront novelty and change: new products, processes and techniques, and changing conceptions of justice in a society whose ideas of justice continue to evolve"¹²⁸ or waver over time. Mass toxic substances litigation has, since the mid-1970s, presented courts with a panoply of challenges to traditional products liability law that has required rethinking of many well-accepted principles, including the respective role of judge and jury, acceptable proof of causation, and a host of other issues of substantive and procedural law.¹²⁹

Evidence, 69 B.U. L. REV. 487, 501 (1989); Sameul R. Gross, *Expert Evidence*, 1991 WIS. L. REV. 1113, 1191 (study of over 500 civil trials in the California in which of 1,748 expert witnesses who testified, none was court appointed); Tahirih V. Lee, *Court-Appointed Experts and Judicial Reluctance: A Proposal to Amend Rule 706 of the Federal Rules of Evidence*, 6 YALE L. & POL'Y REV. 480, 494-95 (1988) ("Even with Rule 706 in place, judges rarely appoint experts."). See also Michael Saks, *Court-Appointed Experts: Defining the Role of Experts Appointed Under Federal Rule of Evidence 706*, 35 JURIMETRICS J. 233, 234 (1995) (Rule 706 "is a rule that was never really intended to be used. And not using it is what most judges do with it most of the time").

126. Judge Jones' experts were for the purpose of assisting him in resolving the motions to exclude expert testimony, rather than to testify in the case. *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996). The expert panel in the Multidistrict Litigation was appointed to provide expert testimony for the federal courts to which the multidistrict cases are remanded upon completion of the multidistrict proceedings. The Order establishing the panel did not specify to what use these experts would be put, presumably leaving that to the judgment of the remand court. Order No. 31, May 31, 1996, *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 996 F. Supp. at 1112.

127. See Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. (forthcoming 1999).

128. See SPECIAL COMMITTEE ON THE TORT LIABILITY SYSTEM, TOWARDS A JURISPRUDENCE OF INJURY: THE CONTINUING CREATION OF A SYSTEM OF SUBSTANTIVE JUSTICE IN AMERICAN TORT LAW 11-12 (1984).

129. Other areas in which the courts have engaged in lawmaking include: (1) reconsidering the role of class actions for mass torts, *Ortiz v. Fibreboard Corp.*, 119 S. Ct. 2295 (1999); *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997); *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227 (9th Cir. 1996); (2) substantially modifying of the single judgment rule, *Jackson v. Johns-Manville Sales Corp.*, 781 F.2d 394 (5th Cir. 1986); (3) determining which of several alleged "injuries" are legally cognizable (asymptomatic pleural plaque, medical monitoring), *Herber v. Johns-Manville Corp.*, 785 F.2d 79 (3d Cir. 1986) (enhanced risk); *Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795 (Cal. 1993); *In re Moorenovich*, 634 F. Supp. 634 (D. Me. 1986) (cancerphobia); (4) using sampling techniques to determine individual personal injury dam-

That judges made and continue to make law in these new cases which pose difficult scientific issues and large numbers of claimants with different types of injuries is no surprise. That new law has emerged is unsurprising. That dispositive new law has developed in the Bendectin litigation in the shadowy underworld of admissibility and sufficiency of evidence areas may be less well appreciated, but it is no less real in its impact on the outcomes of these cases.

I would like to conclude by confessing that I have avoided the most difficult issue implicated in my assignment. I have hewed to the descriptive and ignored the normative. Is the lawmaking that I have described the much-castigated "judicial activism" that my colleague Arthur Bonfield so well defined, or is this the genius of the common law process, making the necessary adjustments that social, technological, and political winds require?¹³⁰ Answering that is an endeavor more difficult, I think, than learning riverboat piloting on the Mississippi. Without a figurative Mr. Bixby¹³¹ to guide me on this journey, I shall leave it to others to answer this question.

ages, *Cimino v. Raymark Industries, Inc.*, 751 F. Supp. 649 (E.D. Tex. 1990), *rev'd*, 151 F.3d 297 (5th Cir. 1998); (5) deciding whether to adopt a market-share basis of liability, *compare* *Smith v. Eli Lilly*, 560 N.E.2d 324 (Ill. 1990), *with* *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y. 1989); (6) making efforts to impose limits on the repetitive punitive damage awards for the same conduct, *Dunn v. HOVIC*, 1 F.3d 1362 (3d Cir. 1993); *Juzwin v. Amtorg Trading Corp.*, 705 F. Supp. 1053 (D.N.J. 1989); (7) polyfurcating trials to separate out the general causation issue or other issues for distinct consideration, *In re Bendectin Litigation*, 857 F.2d 290 (6th Cir. 1988).

130. *Compare* KENNETH R. FOSTER & PETER W. HUBER, *JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS* (1997), and David E. Bernstein, *Junk Science in the United States and the Commonwealth*, 21 *YALE J. INT'L L.* 123 (1996), *with* Lucinda 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 (1999); Michael H. Gottesman, *From Barefoot to Daubert to Joiner: Triple Play or Double Error?*, 40 *ARIZ. L. REV.* 753 (1998); Anthony Z. Roisman, *Conflict Resolution in the Courts: The Role of Science*, 15 *CARDOZO L. REV.* 1945 (1994).

131. Mr. Bixby was the riverboat captain who taught Twain how to pilot a steamboat.

