
Believing in Products Liability: Reflections on *Daubert*, Doctrinal Evolution, and David Owen's *Products Liability Law*

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This essay analyzes the implications of Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), for the substantive, doctrinal evolution of products liability law. It begins by chronicling Professor David Owen's contributions to the recognition of products liability as a distinct body of law, with particular emphasis on his recently published hornbook, Products Liability Law, as an introduction to Daubert's impact on the body of law's evolution. Utilizing a recent proposal for a new products liability cause of action by prominent scholars Margaret Berger and Aaron Twerski as illustrative of a Daubert-inspired evolutionary impulse, the essay concludes both that Daubert is a child of products liability's evolution, and that it will also inevitably become a parent to further products liability doctrinal evolution.

David Owen believes in the law of products liability. By this I do not mean that he necessarily supports an expansive approach to products liability litigation. Professor Owen is a thoughtful centrist; in some areas he calls for expansion, and in others he calls for restriction. In asserting that he believes in the law of products liability, I mean that he feels there is value in thinking and writing about it as a distinct field of law rather than as merely bits and parts of tort, contract, and other areas of law. Primarily because products liability relies so heavily on tort and contract law, some respected scholars have seen little benefit, and perhaps harm, in treating products liability as a discrete field of law.¹ Although he finds “much

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¹ In *Products Liability Law* Professor Owen cites and discusses the writings of a

power” in critics’ arguments, Owen supports what he describes as “a major shift away from conceptualizing products liability problems as ‘tort’ or ‘contract’ and toward viewing these problems as functionally distinct.”²

Professor Owen’s enthusiasm for products liability as a distinct area of law is not surprising, given that he is one of the field’s most prominent progenitors, or at least one of its most prominent nurturers. Of course, he was not present when Justice Benjamin Cardozo inked *MacPherson v. Buick Motor Co.*,³ when Justice Roger Traynor wrote his concurring opinion in *Escola v. Coca-Cola Bottling Corp.*⁴ or his unanimous opinion in *Greenman v. Yuba Power Products*,⁵ or when Professor William Prosser drafted section 402A of the Restatement (Second) of Torts for the American Law Institute (“ALI”).⁶ Those founding fathers, however (unfortunately, “fathers” is the gender-correct term due to the era), did not take products liability to maturity as a functionally distinct body of law. This task was left to the next generation of judges and scholars.

Enthusiastic judicial and legislative acceptance and expansion of products liability in the 1960s and 1970s provided the fundamental elements that enabled thinking about the field as a distinct body of law. The work of Owen and other scholars to chronicle, categorize, and critique emerging products liability doctrines, however, provided mortar to hold together the bricks created by courts and legislatures. Scholars such as Owen likely created or shaped some of the bricks,

number of prominent scholars critical of treating products liability as a distinct field of law. See DAVID G. OWEN, PRODUCTS LIABILITY LAW 4-5 (2005). Critical analyses cited by Owen include JANE STAPLETON, PRODUCT LIABILITY 341-59 (1994); William Powers, *A Modest Proposal to Abandon Strict Products Liability*, 1991 U. ILL. L. REV. 639, 639; Jane Stapleton, *Bugs in Anglo-American Products Liability*, 53 S.C. L. REV. 1225, 1254 (2002); Anita Bernstein, *Restatement Redux*, 48 VAND. L. REV. 1663, 1681 (1995) (book review) (expressing sympathy for concerns about products liability as distinct field of law, but ultimately embracing products liability as legal category in Anita Bernstein, *How Can a Product Be Liable?*, 45 DUKE L.J. 1, 4, 83 (1995)); Richard Speidel, *Products Liability and Safety, Cases and Materials*, 33 VAND. L. REV. 813, 817 (1980) (book review).

² OWEN, *supra* note 1, at 5.

³ 111 N.E. 1050 (N.Y. 1916) (relaxing privity restrictions in negligence cases involving defective products).

⁴ 150 P.2d 436 (Cal. 1944) (arguing creatively but unsuccessfully (at least at that time) in concurring opinion that in defective product cases, California Supreme Court should permit cause of action for strict liability in tort).

⁵ 377 P.2d 897 (Cal. 1963) (creating strict liability in tort cause of action for cases involving defective products).

⁶ RESTATEMENT (SECOND) OF TORTS § 402A (1965) (advocating adoption of strict liability in tort).

too, in a field that underwent explosive and confused evolution, and thus was constantly casting about for guidance and for stabilizing influences.

Professor Owen's work without question belongs on any list of the most important scholarship molding and nurturing products liability as a body of law. Although he has written more than his share of outstanding theoretical scholarship, his efforts as a chronicler of judicial trends and rules have been particularly significant in encouraging courts and scholars to think of products liability as a distinct body of law.⁷ In 1980, Owen (along with coauthors Page Keeton and John Montgomery) produced one of the first products liability casebooks ever to be published.⁸ That casebook, which is perennially among the best-sellers in the field, added Michael Green as an author of the second edition and Mary Davis as an author of the fourth edition, and is presently undergoing a revision into its fifth edition.⁹ The casebook's quality in addressing products liability as a body of law is unsurpassed. It was already a well-established source when I began teaching, and I have relied on it each of the approximately fifteen times I have taught products liability as an upper-division course.

Owen's coauthored, three volume treatise with Stuart Madden and Mary Davis, *Madden & Owen on Products Liability*, was published in 2000 and serves as a leading overview of the field useful both to practitioners and scholars.¹⁰ Earlier Owen served as a coauthor on the torts hornbook originated by William Prosser and Page Keeton,

⁷ See, e.g., *PHILOSOPHICAL FOUNDATIONS OF TORT LAW* (David G. Owen ed., Oxford Univ. Press 1995) (collection of essays by several authors, edited by Owen, addressing philosophical foundations of tort law); David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth*, 1996 ILL. L. REV. 743 (challenging idea that strict liability is truly "strict"); David G. Owen, *The Intellectual Development of Modern Products Liability Law: A Comment on Priest's View of the Cathedral's Foundations*, 14 J. LEGAL STUD. 529 (1985) (addressing Professor George Priest's views of products liability law's intellectual foundations, and providing Owen's theoretical perspective); David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*, 68 NOTRE DAME L. REV. 427 (1993) (addressing products liability law's moral foundations); David G. Owen, *The Moral Foundations of Punitive Damages*, 40 ALA. L. REV. 705 (1989) (addressing moral foundations of punitive damages awards).

⁸ W. PAGE KEETON, JOHN MONTGOMERY & DAVID OWEN, *PRODUCTS LIABILITY AND SAFETY: CASES AND MATERIALS* (1980).

⁹ The current edition is DAVID G. OWEN, JOHN E. MONTGOMERY & MARY J. DAVIS, *PRODUCTS LIABILITY AND SAFETY: CASES AND MATERIALS* (4th ed. 2004).

¹⁰ DAVID G. OWEN, M. STUART MADDEN & MARY J. DAVIS, *MADDEN & OWEN ON PRODUCTS LIABILITY* (3d ed. 2000).

Prosser and Keeton on Torts.¹¹ The famous Prosser hornbook, while preceding Owen's work on treatises more narrowly directed at products liability, significantly added to practitioners' understanding of the new and rapidly growing field. Supplementing his outstanding theoretical publications with several articles focused on chronicling the development of case law has expanded Owen's audience and his efforts to address products liability as a functionally distinct field of law.¹²

The work of Owen and others to encourage thinking about products liability as a distinct field of law has met with overwhelming success. Owen's August 2004 study counted roughly 15,000 products liability decisions "of some significance" in the United States.¹³ Since the 1960s, an explosion of increasingly complex rules and principles has developed in products liability cases.¹⁴ Practicing lawyers and judges increasingly have considered products liability as a distinct practice area, and the great majority of American law schools have offered courses specifically focused on products liability as a field of law. Many jurisdictions, both domestic and international, have enacted products liability statutory schemes treating such cases as a distinct subject.¹⁵ When the ALI decided to begin work on its *Restatement (Third) of Torts* in the early 1990s, it chose to segregate products liability as a distinct project separate from other torts issues.¹⁶

¹¹ W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS (5th ed. 1984).

¹² In *Products Liability Law* Professor Owen cites the following articles he has published as foundations for sections of the book: David G. Owen, *American Products Liability Law Restated*, 6 CONSUMER L.J. 161 (1998); David G. Owen, *A Decade of Daubert*, 80 DENV. U. L. REV. 345 (2003); David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411 (2003); David G. Owen, *Inherent Product Hazards*, 93 KY. L.J. 377 (2005); David G. Owen, *Manufacturing Defects*, 53 S.C. L. REV. 851 (2002); David G. Owen, *Products Liability: User Misconduct Defenses*, 52 S.C. L. REV. 1 (2000); David G. Owen, *Products Liability Law in America*, 11 DANNO E RESPONSABILITÀ 1999 (Italy); David G. Owen, *Products Liability Law Restated*, 49 S.C. L. REV. 273 (1998); David G. Owen, *Proof of Product Defect*, 93 KY. L.J. 1 (2005); David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003 (2004); David G. Owen, *The Puzzle of Comment J*, 55 HASTINGS L.J. 1377 (2004); David G. Owen, *Special Defenses in Products Liability Law*, 70 MO. L. REV. 1 (2005). OWEN, *supra* note 1, at viii. Owen has also authored the most recent version of West's *Products Liability in a Nutshell*. JERRY J. PHILLIPS & DAVID G. OWEN, PRODUCTS LIABILITY IN A NUTSHELL (2005). Nominally coauthored with the late Professor Jerry J. Phillips, Owen's edition of the *Nutshell* is in fact an abridged version, as he mentions in his preface to the seventh edition of his hornbook.

¹³ OWEN, *supra* note 1, at 5.

¹⁴ *Id.* at 6.

¹⁵ *Id.*

¹⁶ See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, at xiii (Tentative Draft

Further, it decided to tackle products liability before addressing other torts-related issues, recognizing that “products liability is highest in priority for reformulation, for it is socially significant and technically complicated.”¹⁷ Owen served as the project’s editorial adviser.¹⁸ In assessing the debate over whether to consider products liability an independent field of law, Owen concludes:

There is simply no arguing that products liability draws heavily from tort, contract, and other fields of law. Yet, its separate treatment by courts, academics, practitioners, and legislatures around the world dispels the view that modern products liability simply is bits and pieces of other fields of law, that it has no separate identity of its own. Academics may argue this point until the cows come home, but products liability is a field of law distinct unto itself.¹⁹

As noted above, Owen has himself to thank (although he would be too modest to do so) for some measure of products liability’s victory in attaining status as a functionally distinct field of law through his many years of work with products liability hornbooks, casebooks, law review articles, and books that chronicle trends and rules in products liability case law. One of his most recent contributions to the field of products liability law is also certainly among his most significant. Owen’s *Products Liability Law*, published as part of the West Hornbook Series in 2005, is likely to attain broad recognition as the leading current authority on modern products liability law. Owen explains his goal for the hornbook as being “to trace the evolution of products liability law in America, to examine how legislatures and courts presently define and apply the law, and to explore an array of problematic issues on which courts and commentators disagree.”²⁰ Hornbooks are sometimes perceived as (and in fact often are) merely overview recitations of general legal principles. Owen’s hornbook is much more than that, as it, in his words, “selectively critiques products liability law in America in the early stages of the 21st century.”²¹

Along with solid chronicling of products liability doctrines and trends, Owen’s elegant and thought-provoking normative analyses add

No. 1, 1994).

¹⁷ *Id.*

¹⁸ See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, at v (1998).

¹⁹ OWEN, *supra* note 1, at 6.

²⁰ *Id.* at v.

²¹ *Id.*

significantly to the hornbook's usefulness.²² One example may be found in his analysis of *Daubert v. Merrell Dow Pharmaceuticals*, the 1993 United States Supreme Court case that has been interpreted as significantly raising standards on the admissibility of expert testimony in federal courts, and that has strongly influenced expert testimony standards in state courts as well.²³ I will use a bit of Owen's discussion of *Daubert* as a launching point to share some reflections on the case and on products liability's evolution as a field of law.

Daubert, arguably the most significant civil case in the United States in the past quarter century, provides strong evidence for Owen's view that products liability has developed to the point that it should be considered as a field unto itself; for *Daubert* is largely a child of products liability.²⁴ The case was conceived during the explosive growth in reliance upon expert testimony that came with the equally explosive growth of products liability, and it was birthed in one of products liability's early mass tort morasses: Bendectin litigation.²⁵ Without products liability, there would have been no *Daubert*, and there may have been relatively little perceived need for a decision like *Daubert*.

Professor Owen wisely decided to address *Daubert* in some depth in *Products Liability Law* and, while he sees some grounds for concern about application of the case and its progeny, his overall verdict on *Daubert*'s legacy is fairly supportive:

By requiring experts to provide reasoned bases for their opinions, and by requiring that such opinions be relevant to the legal issues in the case and grounded in reliable methodology, the reliability and relevancy principles of *Daubert*, used properly, provide a firm foundation for the fair and rational resolution of the scientific and technological

²² Owen borrows Prosser's self-deprecating humor in describing the work of a chronicler as analogous to that of a rodent: "Credit belongs to William Prosser for observing that such chroniclers essentially are packrats, 'unblushingly' collecting and assembling bits and pieces from other scholars, judicial and academic." *Id.* (citing WILLIAM PROSSER, *THE LAW OF TORTS*, at xi (4th ed. 1971)). Owen also notes another metaphor from the twelfth century French priest Bernard of Chartres: "[D]warfs on the shoulders of giants." *Id.* at n.* (citing JACQUES LE GOFF, *INTELLECTUALS IN THE MIDDLE AGES* 12 (T. Fagan trans., Blackwell 1993) (1957) (citing STEPHEN G. FERRULOLO, *THE ORIGINS OF THE UNIVERSITY: THE SCHOOLS OF PARIS AND THEIR CRITICS* 1100-1215, at 154 (Stanford 1985))).

²³ 509 U.S. 579 (1993).

²⁴ See *supra* text accompanying note 19.

²⁵ See *infra* notes 50-63 and accompanying text.

issues which lie at the heart of products liability adjudication.²⁶

I will address two aspects of *Daubert* to share some of my own reflections on the case and its relationship to products liability as a distinctive field of law. The first aspect I will examine is the extent to which *Daubert* and its progeny might both reflect and generate evolution in the substantive common law of products liability. I will also provide some thoughts about how *Daubert* has both strengthened and weakened product liability's ongoing quest to achieve a "rough sense of justice."²⁷

The first question, whether *Daubert* and its progeny have and will reflect or influence the substance of products liability law, is easily answered. In a word: yes. A decision perceived as having such a significant impact on the outcome of many products liability cases simply cannot avoid influencing substantive common law to some extent. Substance and procedure are not neatly separated in the real world of products liability. The broader goal of justice renders them inextricably intertwined, and a significant change to one must be felt by the other as well.

The evolution of prominent products liability scholar Dean Aaron Twerski's thinking provides an interesting illustration of how *Daubert* is influencing thought on substantive products liability law. Twerski, co-reporter with Professor James Henderson for the *Restatement (Third) of Torts: Products Liability*, is not known for having a generally expansive approach to products liability. Indeed, Twerski acknowledges that representatives of the plaintiffs' bar, such as the American Trial Lawyers Association, assailed his *Restatement (Third)* as a "tort reform" package.²⁸ One academic critic asserted during the *Restatement (Third)*'s drafting process that "[t]he writings of [Twerski and Henderson] over the past two decades indicate a conservative penchant toward negligence and manufacturer-protective rules."²⁹ Another scholar recently described Twerski and Henderson as "academic critics of judicial expansion of product manufacturer

²⁶ OWEN, *supra* note 1, at 377.

²⁷ *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 103 (N.Y. 1928) (Andrews, J., dissenting). Judge Andrews used the phrase in the context of proximate cause analysis, but it applies equally well in describing the goals of tort law and products liability law generally.

²⁸ James A. Henderson & Aaron Twerski, *The Politics of the Products Liability Restatement*, 26 HOFSTRA L. REV. 667, 686 n.49 (1998) (citing Larry S. Stewart, *The ALI and Products Liability: "Restatement" or "Reform"?*, TRIAL, Sept. 1994, at 28, 30).

²⁹ Jerry J. Phillips, *Achilles' Heel*, 61 TENN. L. REV. 1265, 1265 (1994).

liability.”³⁰ Not long after the project began, Henderson wrote: “When I was first appointed [as co-reporter with Twerski for the *Restatement (Third)*], Plaintiff’s Bar had, collectively, what might pass for an aneurysm.”³¹ In truth, neither scholar always favors defendants in his writings.³² On balance, however, few would likely argue that the balance of Twerski’s (or of Henderson’s) writings lean toward increasing opportunities for plaintiffs to sue product sellers.

The reasonable alternative design test promoted by Twerski and Henderson for design defect claims was, without question, the most controversial aspect of the products liability section in *Restatement (Third)*. Indeed, the debate in the ALI over this topic was fierce. The test requires that as a prerequisite to prevailing in design defects claims, plaintiffs establish proof that a reasonable alternative design exists or could have been created and that failing to utilize the reasonable alternative design rendered the product not reasonably safe.³³ This test heightens reliance on expensive expert witnesses, whose testimony is usually necessary to establish whether a reasonable alternative design is feasible.³⁴

The expense caused by the test’s focus on expert testimony is one of critics’ most significant complaints about the *Restatement (Third)*’s adoption of a reasonable alternative design requirement. Opponents of the expert testimony-driven reasonable alternative design test

³⁰ Douglas A. Kysar, *The Expectations of Consumers*, 103 COLUM. L. REV. 1700, 1702 (2005).

³¹ James A. Henderson, *Revising Section 402A: The Limits of Tort as Social Insurance*, 10 Touro L. REV. 107, 111 (1993).

³² See Victor E. Schwartz, *The Restatement (Third) of Torts: Products Liability — The American Law Institute’s Process of Democracy and Deliberation*, 26 HOFSTRA L. REV. 743, 752 (1998) (regarding Twerski and Henderson, “[a] review of all of their written works indicates that neither scholar could be pigeonholed as ‘pro-plaintiff’ or ‘pro-defendant’”). In 1993, when beginning his work as co-reporter, Henderson addressed the issue as follows:

For years I had written what was widely viewed, and I think fairly viewed, as pro-defendant material. However, I never thought of myself as pro-defendant. I identified what I thought were flaws in the system, and I did it when it was not popular to do so. When I was your age, I was surrounded by people who wanted ever greater expansion. There was no frontier that was not worth crossing. I started my career saying “wait a minute, do we really mean this?” Now, thinking as an academic, I have shifted and I am politically in the middle of the road. Maybe even in my off moments I am more liberal than many writers.

Henderson, *supra* note 31, at 111-12.

³³ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).

³⁴ See OWEN, *supra* note 1, at 356.

argued that it would bar access to the courts for all legitimate design defect claims where the claims' values were not high enough to pay the price needed for expensive expert witness testimony.³⁵ Many critics argued instead for a defectiveness test based on whether the product design violated a reasonable consumer's expectations of safety, asserting among other things that the consumer expectations test provides greater protection of consumers' interests.³⁶

As Owen notes in *Products Liability Law*, reliance on expensive experts is less likely to be needed on the issue of defectiveness when courts adopt the consumer expectation test over the reasonable alternative design test, particularly in cases involving simple consumer goods.³⁷ The *Daubert* decision came out at about the same time the debate regarding reasonable alternative design versus consumer expectations began raging in the ALI.³⁸ *Daubert*, and particularly lower courts' use of it as a tool to significantly toughen standards for experts, arguably provided another basis for critics to maintain that the reasonable alternative design test is simply too expensive to plaintiffs to achieve justice on a broader level.³⁹

Although probably a majority of courts adopted the reasonable alternative design test, a substantial minority rejected it for the consumer expectation approach or other approaches. Courts' reaction to the Henderson-Twerski *Restatement (Third) of Torts: Products Liability* is nothing like courts' reaction to the *Restatement (Second)*'s

³⁵ See, e.g., Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 148 (1996) ("This requirement of a 'reasonable alternative design' imposes an especially onerous burden on the plaintiff, a burden that she may often be unable to meet."); Frank Vandall, *State Judges Should Reject the Reasonable Alternative Design Standard of the Restatement (Third)*, *Products Liability*, Section 2(b), 8 KAN. J.L. & PUB. POL'Y 62, 63-64 (1998) (analogizing *Restatement (Third)*'s reasonable alternative design requirement to discrimination against poorer passengers in movie *Titanic*, and suggesting that test might share fate similar to ship).

³⁶ See, e.g., Marshall Shapo, *In Search of the Law of Products Liability: The ALI Restatement Project*, 48 VAND. L. REV. 631, 668-69 (1995) (relegating consumer expectations to "supporting cast" role and requiring proof of reasonable alternative design would lead to "astonishing" result of plaintiff losing case even if plaintiff establishes that product's risks outweigh its utilities); Ellen Wertheimer, *The Biter Bit: Unknowable Dangers, the Third Restatement, and Reinstatement of Liability Without Fault*, 70 BROOK. L. REV. 889, 933 (2005) (arguing that eliminating consumer expectations test in favor of risk-utility test with reasonable alternative design requirement inappropriately favors manufacturers over consumers).

³⁷ See OWEN, *supra* note 1, at 356.

³⁸ The *Daubert* case was decided in 1993. *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993). The *Restatement (Third)*'s first draft was published in 1994. *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Tentative Draft No. 1, 1994)*.

³⁹ See *infra* note 86 and accompanying text.

section 402A. In the 1960s and 1970s, courts overwhelmingly adopted 402A; it has been described as the closest thing to “holy writ” ever produced by the ALI.⁴⁰ The *Restatement (Third)*’s reception by courts has been much more mixed, and one must wonder how influential *Daubert* may have been in convincing several courts not to adopt the *Restatement (Third)*’s expert intensive approach. Further, if dissatisfaction with *Daubert* expands, it is interesting to wonder whether more courts will adopt the sometimes less expert intensive consumer expectation test or other tests in the future.

Even before becoming a co-reporter for the products liability Restatement, Twerski was one of the most prominent advocates for the reasonable alternative design test, which was perceived as pro-defense and expert intensive.⁴¹ As noted previously, he was also perceived by many as having a restrictive view of products liability generally.⁴² This same Twerski, however, along with prominent evidence scholar Margaret Berger, is now arguing that in some cases involving non-essential drugs, courts should change the law to make it much easier to win by eliminating the causation-of-physical-harm element.⁴³ Further, he is directly pinning his argument for an expansion of products liability law on *Daubert*.⁴⁴ This suggestion for expansion of the common law of products liability directly in response to *Daubert* is significant not only because the prominent and arguably conservative Twerski coauthored the proposal, but also because of his coauthor’s prominence in the field of evidence.⁴⁵

Berger and Twerski’s dramatic proposal is presented in an article recently published in November 2005 in the *Michigan Law Review* entitled *Uncertainty and Informed Choice: Unmasking Daubert*.⁴⁶

⁴⁰ James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1512 (1992); see also Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 76 (1994).

⁴¹ Indeed, before being named as co-reporters, Twerski and Henderson coauthored a law review article proposing a new Restatement of products liability featuring the reasonable alternative design test for design and warning cases. See Henderson & Twerski, *supra* note 40, at 1514.

⁴² See *supra* notes 28-32 and accompanying text.

⁴³ See *infra* notes 46-63 and accompanying text.

⁴⁴ See *infra* notes 46-63 and accompanying text.

⁴⁵ See David E. Bernstein, *Learning the Wrong Lessons from “An American Tragedy”: A Critique of the Berger-Twerski Informed Choice Proposal*, 104 MICH. L. REV. 1961, 1961 (2006) (“Margaret Berger and Aaron Twerski are among the leading scholars in their respective fields of Evidence and Products Liability.”).

⁴⁶ Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice*:

Berger and Twerski's proposal is that an "informed choice cause of action" should exist for pharmaceutical products even without proof that physical harm was caused when:

- (1) [T]he causal relationship between the toxic agent and plaintiff's harm is unresolved at the time of litigation and will likely remain unresolved;
- (2) [T]he drug is not therapeutic, but rather its purpose is to avoid discomfort or to improve lifestyle;
- (3) [I]t is almost certain that a patient made aware of the risk that is alleged to be associated with consumption of the drug would have refused to take it; and
- (4) [T]he defendant drug company was aware of the potential risk or should have undertaken reasonable testing to discover the risk and failed to provide the requisite information to the physician or patient.⁴⁷

This proposal basically calls for a negligent infliction of emotional distress cause of action in a context far beyond the parameters of where courts previously have allowed such claims. Berger and Twerski attempt to limit the usual Pandora's Box concerns that attend efforts to expand negligent infliction of emotional distress claims by restricting their proposed lawsuit to situations involving less important "discomfort" or "lifestyle" drugs rather than "therapeutic" drugs, and by limiting it to situations in which causation is "almost certain."⁴⁸ Restricting the claim to situations in which the question of physical harm is proved to likely remain unproved may also be viewed as an effort to keep the proposal limited and thus more palatable.⁴⁹

Twerski and Berger use Bendectin, the drug at issue in the *Daubert* case, and the drug Parlodel as illustrations of situations in which their proposed cause of action might be appropriate.⁵⁰ Bendectin was marketed between 1957 and 1983 to approximately thirty-six million women to treat morning sickness during pregnancy.⁵¹ Many lawsuits were filed contending that Bendectin caused stunted limbs in children whose mothers took the drug, and that the manufacturer did not warn

Unmasking Daubert, 104 MICH. L. REV. 257 (2005).

⁴⁷ *Id.* at 259.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* at 268-70.

⁵¹ *Id.* at 268; see also MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 91, 180 (1996).

of this risk.⁵² Most courts eventually found as a matter of law that the evidence supporting these allegations of birth defects was not sufficiently strong to permit findings of causation.⁵³ According to Twerski and Berger, however, there was significant mosaic evidence of potential causation of birth defects that was sufficient to create an appropriate and understandable desire on the part of parents to know of the risks for a drug that merely alleviated discomfort.⁵⁴ This mosaic evidence included: “(1) in vitro (test tube) studies, (2) in vivo (animal) studies, (3) similarities between ingredients in Bendectin with chemical structures similar to known teratogens, and (4) retrospective epidemiological studies to support their contention that the drug caused birth defects.”⁵⁵

Parlodel, the second drug cited as an example by Twerski and Berger, was marketed beginning in 1980 to women seeking to end lactation after childbirth.⁵⁶ Some users brought lawsuits contending that the drug caused strokes, and that no warning of this risk was provided.⁵⁷ Evidence existed suggesting that Parlodel may cause strokes, but most courts found it too idiosyncratic and unreliable to be presented to a jury.⁵⁸ However, in 1989 Parlodel was withdrawn from the market as an antilactation drug because it was found to have no greater benefit than aspirin.⁵⁹ Twerski and Berger believe Parlodel is a good illustration of a case in which their proposed new cause of action would be warranted because “[i]t is hard to believe that a woman warned of the risk of strokes and told of the comparative safety of treatment by over-the-counter analgesics would opt to take Parlodel.”⁶⁰

Twerski and Berger argue that cases involving uncertain risk, such as the Bendectin and Parlodel cases, are the hallmark situations in which *Daubert* denies recovery. They are clearly concerned that many cases involving drugs and other toxic agents that may have serious risks are lost because of difficulties proving causation to an acceptable

⁵² Berger & Twerski, *supra* note 46, at 268-69.

⁵³ *Id.*

⁵⁴ *Id.* at 268-69.

⁵⁵ *Id.* at 268.

⁵⁶ See *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 442 (W.D. Pa. 2003); Berger & Twerski, *supra* note 46, at 269.

⁵⁷ See Berger & Twerski, *supra* note 46, at 269.

⁵⁸ See *id.*

⁵⁹ See *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at *28-30 (S.D. Ind. Mar. 7, 2001); Berger & Twerski, *supra* note 46, at 269-70.

⁶⁰ Berger & Twerski, *supra* note 46, at 270.

certainty, rather than because causation does not in fact exist. They are also concerned that *Daubert's* high evidentiary bar exacerbates the problem of proving causation in many legitimate claims. Declaring that “[t]he current state of *Daubert* drug litigation is intolerable,”⁶¹ they note that:

Plaintiffs have, in large part, been stymied by their inability to establish that toxic agents, no matter how potentially dangerous, were actually responsible for the harms they have suffered. Their difficulties in this regard have increased exponentially since the Supreme Court’s decision in *Daubert* . . .⁶²

They conclude “[t]hat a toxic drug cannot be proven to have definitively caused a harm does not mean that plaintiffs should be deprived of the right to choose whether they wish to subject themselves to the material risk of that harm actually taking place.”⁶³

I have significant sympathy for these concerns. Who would dispute that one hundred years from now scientists will have clear knowledge that many drugs currently in use cause serious harm even though plaintiffs are not able to meet the high burden of proving so at present? Further, as Owen points out in *Products Liability Law*, manufacturers have an inherent advantage in expert-reliant cases because they have access to experts naturally, being in the business of making the product: their experts may even be their own employees who designed the product.⁶⁴ Plaintiffs must hire an academic or a private consultant.⁶⁵ Further, manufacturers often pay for their

⁶¹ *Id.* at 288.

⁶² *Id.* at 258.

⁶³ *Id.* at 288.

⁶⁴ See OWEN, *supra* note 1, at 358.

⁶⁵ *Id.* Owen notes:

The bulk of experienced and otherwise qualified specialists in most fields of product design, manufacturing, and labeling are employed by private industry, often by the manufacturing enterprises who are defendants in products liability litigation. Thus, because such persons are already in its employ, a manufacturer usually has little difficulty in finding appropriate engineering and other experts to help defend a products liability case. Indeed, such experts may include the very persons who designed the accident product, advised on appropriate warnings, and designed and supervised the assembly process by which it was produced. Plaintiffs’ lawyers, on the other hand, generally are limited to two principle resource pools for expert witness talent: universities and private consulting expert firms.

experts with insurance money, and have much deeper pockets to foot these bills than do injured consumers, who have to pay out of their own pockets, which are usually shallow rather than deep.

Having expressed sympathy with the concerns voiced by the Berger-Twerski proposal, I will not hold my breath expecting a majority of courts to fall in line with it, despite the prominence of its authors. Eliminating the causation-of-physical-harm element in some products liability cases is a bold proposal, not an evolutionary baby step. Further, as the authors acknowledge, courts would have difficulty consistently defining the “lifestyle or discomfort” — lower utility — drugs for which Berger and Twerski would like to limit their standard to keep it from being too broad.⁶⁶ I myself took a stab in a 1994 article at arguing for a more relaxed liability standard in cases involving prescription products with primarily cosmetic utility, and courts have shown remarkable restraint in not rushing too quickly to follow my suggestion.⁶⁷

Professor David Bernstein recently wrote a paper expressing additional concerns about the Berger-Twerski proposal.⁶⁸ Much of Bernstein’s critique centers on disagreement with an assertion by Twerski and Berger that Bendectin provides, in Bernstein’s words, the “paradigmatic example” of why courts should adopt the Berger-Twerski proposal.⁶⁹ Bernstein argues that if Bendectin, a safe drug in his view, is an example of a situation in which the Berger-Twerski

Id.

⁶⁶ See Berger & Twerski, *supra* note 46, at 288.

We are aware that there is no bright line that can be drawn between lifestyle and therapeutic drugs. Nonetheless, the distinction is important as a beginning point in recognizing a cause of action for informed choice. In the former, the issue of decision-causation, that is, whether the plaintiff would have chosen against taking the drug if informed of the possible serious side effects, is much clearer.

Id.

⁶⁷ See Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Product Transactions*, 21 FLA. ST. U. L. REV. 873, 873-74 (1994). Similarly to Twerski and Berger, I acknowledged in the article that clearly distinguishing medical products with primarily cosmetic utility from medical products with restorative utility would be difficult. *Id.* However, given the rise in use of cosmetic medical products and the lack of special societal utility of such products, I urged courts to make the distinction when possible and to exclude primarily cosmetic products from comment k’s protection from strict liability in hybrid sales/services transactions. See *id.* at 911-12.

⁶⁸ Bernstein, *supra* note 45.

⁶⁹ *Id.* at 1962.

cause of action would be appropriate, the cause of action is clearly overbroad.⁷⁰ He notes that by 1977 fourteen epidemiological studies had been performed on Bendectin, and none of them found an association between the drug and birth defects.⁷¹ He concludes that “[b]y the early 1980s, there was a solid consensus in the medical community that Bendectin was not a teratogen.”⁷² Rather than serving as an illustration of why the Berger-Twerski proposal should be adopted, Bernstein sees Bendectin litigation as an illustration of “unreasonable fears of the lay public — stirred by irresponsible interest groups, hired gun and delusional experts, credulous media coverage, and plaintiffs’ lawyers.”⁷³ He adds several additional concerns about the proposal, including assertions that:

- (1) “The proposal invites reliance on unreliable testimony”;⁷⁴
- (2) “Juries are not competent to determine subtle risk assessment issues”;⁷⁵
- (3) “Even assuming juror competence, the proposal asks too much of juries”;⁷⁶
- (4) “The proposal ignores the problems inherent to multiple trials”;⁷⁷
- (5) “The proposal fails to consider the potential costs of informed choice litigation”;⁷⁸
- (6) “The informed choice proposal would lead to a vast surfeit of warnings”;⁷⁹ and
- (7) “The informed choice proposal may be barred by the preemption doctrine.”⁸⁰

Without addressing each of Bernstein’s concerns in detail, it may be useful to note that much of his critique could be seen as reflecting

⁷⁰ *Id.* at 1962-63.

⁷¹ *Id.* at 1963.

⁷² *Id.* at 1965.

⁷³ *Id.*

⁷⁴ *Id.* at 1971.

⁷⁵ *Id.* at 1974.

⁷⁶ *Id.* at 1975.

⁷⁷ *Id.* at 1976.

⁷⁸ *Id.*

⁷⁹ *Id.* at 1978.

⁸⁰ *Id.* at 1979.

broader views about the efficacy or inefficacy of our current products liability system. For example, Bernstein's concerns that juries are not good at determining subtle risk assessment issues, and his concerns that the dynamics of mass litigation often force defendants to settle even nonmeritorious claims, may both implicate products liability cases well beyond those in the limited target area of the Berger-Twerski proposal.

Bernstein's use of a *Daubert*-related analysis to perhaps reveal some of his more general reservations about modern products liability litigation is not surprising or unique. I perceive that the pattern of courts and commentators finding in *Daubert*, and in discussions of *Daubert*, a launching point for expressing broader concerns that products liability is too expansive or too restrictive is both common and understandable. Professors Ed Cheng and Albert Yoon perhaps make an analogous point in a recent empirical article arguing that *Daubert*'s strongest impact has been its educational function in sensitizing courts to the dangers of junk science generally, regardless of whether a case is tried in a *Daubert* jurisdiction or in a *Frye* jurisdiction.⁸¹ The specifics of *Daubert*'s holding are not what has mattered most for products liability law; what has mattered most is how courts and commentators have used *Daubert* to change and to engage in a broader discussion about what is good and bad for our products liability system.

Where the broader *Daubert*-inspired discussion will lead us of course remains uncertain. However, judicial and scholarly reaction to *Daubert*, such as the sometimes conservative Twerski's call for doctrinal expansion, both reflects and predicts some level of evolutionary impulse in products liability law. We should not expect to be able to fully appreciate the impact it will make quickly. Thirteen years have passed since *Daubert* was decided, and what we do not know about its full impact on products liability still substantially outweighs what we do know about its impact. The common law of products liability and of torts may experience rapid evolutionary jolts, such as the meteoric rise of strict products liability in the 1960s and 1970s, but quick growth spurts such as this are not the end of the

⁸¹ Edward K. Cheng & Albert H. Yoon, *Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards*, 91 VA. L. REV. 471, 503 (2005) (addressing empirical study undertaken by authors in which removal rates to federal court were found to follow same trends both in *Daubert* jurisdictions and *Frye* jurisdictions, leading authors to conclude that defense lawyers may not perceive federal *Daubert* rule to offer significant advantages over *Frye*). For a general discussion of the *Frye* standard, see OWEN, *supra* note 1, at 361-62.

story. From a long-term perspective, tort and products liability law are fields that usually meander slowly toward, in the words of Judge Andrews in *Palsgraf*, a “rough sense of justice.”⁸²

I use the phrase “meander toward” intentionally, rather than “stride crisply toward” or “run toward.” The common law of torts and of products liability meander toward a rough sense of justice perhaps a bit like tourists, who, with little sense of time, meander from one edge of a town they are visiting to the far edge of the town. Torts and products liability move in starts and stops, they wander from one side of the boulevard to the other to investigate the sights, they venture down interesting side streets and alleys only to find dead ends, and then they return to the main street to meander further along their way toward justice.

I say this with some fondness, not derision, because leisurely tourists eventually reach their destination, and along the way they have seen and experienced much more of the town’s important aspects than had they scurried straight across town without any interest in the landscape. I do not perceive the common law of torts or of products liability as consciously following a corrective justice model, a law and economics model, a deterrence model, or any other limited model of justice. Their shared guidance system is broader than any of those models; it is at the same time more complex in its manifestations and more simple in its goals.⁸³ Again in the words of Judge Andrews (although he was applying them specifically to proximate cause), tort law’s model is simply seeking to fulfill a rough sense of justice.⁸⁴ The same model applies to products liability. As is the case with those attracted to a broad range of religions, the common law paths of torts and of products liability find some truth in each of the models academics champion as their proper goal, and their sense of justice is a rough combination of nearly all of the proposed models.⁸⁵ Thus, sometimes the path of the common law toward its sense of justice cannot be easily or neatly explained, but even in such situations its progress can often be vaguely felt.

⁸² *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 103 (N.Y. 1928) (Andrews, J., dissenting).

⁸³ See generally Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801 (1997) (arguing that corrective justice model of tort law and deterrence model of tort law both have elements of truth, and are not mutually exclusive).

⁸⁴ *Id.*

⁸⁵ See generally *id.*

Perhaps what is being felt in courts' and scholars' current grappling with the impact of *Daubert* is that the case and its progeny have at the same time both helped and hurt courts' searches for a rough sense of justice in products liability law. There are of course many roads to justice and injustice, and I will briefly highlight two that are especially relevant to *Daubert*. Objectively uncertain results invite injustice, and this form of injustice arises when courts do not enforce a sufficiently strenuous evidentiary threshold. Injustice, however, also exists when there are thousands, or perhaps hundreds of thousands, of meritorious cases that can never be undertaken because it is too expensive to do so or because, although the plaintiff is correct, she cannot prove she is correct with sufficient certainty under a particularly demanding standard.⁸⁶ The more strictly courts apply *Daubert* to avoid injustice from junk science, the more courts also create injustice by pricing out valid claims where expensive expert fees are not economically viable or where the high standard makes proving valid cases impossible. This conflict presents a balancing question, and how we feel about the balance may say as much about our personal leanings as it does about justice itself.

In products liability cases, the most interesting questions about *Daubert* might relate less to specific evidentiary standards than to whether we think products liability law simply expanded too much in the latter half of the twentieth century. *Daubert* may be, in effect, a reform tool for those who think we have too much products liability litigation, and a powerful impediment to those who think our level of products liability litigation helps rather than hurts society.

When pondering how reaction to *Daubert* reflects broader views, it is interesting to contemplate judicial psychology. It is easy to imagine that judges might feel most strongly the injustice of watching a jury reach the wrong conclusion because unreliable evidence was slickly marketed to them. Judicial frustration and indignation over repeatedly witnessing such results is understandable and of course appropriate. Another form of injustice, however, is neatly hidden from direct judicial view. Judges see the undeserving plaintiffs who sometimes win under looser rules, but they do not have to see the thousands of injured plaintiffs with legitimate cases who never get to a

⁸⁶ See Berger & Twerski, *supra* note 46, at 267 ("Preparing for and litigating *Daubert* issues has undoubtedly made litigation more expensive than before."); see also OWEN, *supra* note 1, at 29 (noting study which revealed that "the plaintiff's bar is increasingly limiting its clients to those with serious injuries and a greater likelihood of success, and that it is refining its litigation techniques and skills, including the effective use of expert witnesses").

courtroom because of the financial or evidentiary burden *Daubert* imposes. However, just because the injustice against deserving plaintiffs is less visible does not make it any less real. Having an especially demanding standard that leads to a tidy sense of justice for judges presiding over trials can cause significant structural unfairness that is conveniently easy not to contemplate.

An opposing factor is that visible injustice in the judicial system has the additional cost of eroding the public's confidence in the courts. If citizens believe that trials with flimsy expert evidence are an exercise in snake oil salesmanship rather than objective justice, the civil justice system is harmed. But perhaps we should be concerned about the possibility of courts favoring a more visible manifestation of justice over a less visible but equally real manifestation of justice based on the very issue of public visibility. Such favoritism may represent a form of snake oil salesmanship in itself, ironically utilized, in this context, to limit snake oil salesmanship at trials.

Those who do not believe products liability's expansion over the past fifty years has been on the whole more negative than positive have several choices in reacting to *Daubert*. One is to oppose its current application and argue that it causes more harms than benefits to justice. This may not be the same thing as opposing *Daubert* itself, because so much of *Daubert's* impact seems to be in how it has been interpreted and applied. Another approach could be to argue that courts should follow both impulses discussed above: enhance objective justice in trials where expert testimony is truly central by keeping something like the current *Daubert* standard, but at the same time applaud and encourage substantive evolution to make civil litigation less frequently a battle of the increasingly expensive experts.

Although he places caveats on his praise and I place caveats on my criticism, on balance, Owen's assessment of *Daubert* and its implications may be more positive than my own. In *Products Liability Law*, after citing a large number of cases in which courts excluded plaintiffs' expert testimony based on *Daubert*, he writes:

It may well be that the experts in each case in which the testimony was excluded propounded bad science, or perhaps the plaintiffs' attorneys simply failed to adequately prepare their experts on the *Daubert* requirements before the trial, or perhaps they failed at trial (or at a *Daubert* hearing) to provide the court with a sufficient offer of proof.⁸⁷

⁸⁷ OWEN, *supra* note 1, at 370.

In my thinking this fails to pay sufficient attention to some important possibilities that must be factors in many lawsuits involving *Daubert* exclusions. For example, given the regularity with which drugs approved by the Food and Drug Administration, and once considered safe, are eventually recognized as being in fact dangerous, in many cases plaintiffs' excluded expert testimony is doubtless correct in its assertions. In these cases plaintiffs should have prevailed, except that they simply could not afford to bring their cases to trial due to the prohibitive costs of testing and establishing other indicia of reliability to meet the very high *Daubert* standard.

Further, even in situations in which financial costs are not an insurmountable barrier, the scientific conclusions of plaintiffs' experts in many cases are likely correct, and plaintiffs should have prevailed, except that the scientifically correct conclusion was not a scientifically provable conclusion — at any cost — under the very high *Daubert* standard. However, Owen does not leave the assertion quoted above unmitigated. In the same paragraph he notes, “[T]he fact remains that only infrequently is *Daubert* invoked to exclude expert testimony proffered by defendants,”⁸⁸ and elsewhere he cautions that “courts must sedulously avoid using this important gate-keeping function to bar evidence that actually may be sound.”⁸⁹ I prefer more elaboration on *Daubert*'s significant costs to justice in addition to the discussion of its benefits, but Owen at least acknowledges that the standard may be subject to abuse.

Regardless of one's views about *Daubert* and its progeny, the lavish attention paid to the case by courts and scholars and its unique importance to products liability serve as powerful evidence for Owen's assertion that products liability has come of age as a body of law, and that its inevitable future changes will be viewed as evolution of a functionally distinct legal field. His belief in the law of products liability is, with time, becoming increasingly irrefutable.

⁸⁸ *Id.*

⁸⁹ *Id.* at 377.