

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

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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.² Although he finds “much 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.”³

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

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² In PRODUCTS LIABILITY LAW Professor Owen cites and discusses the writings of a 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 J. Stapleton, PRODUCT LIABILITY ch. 13, at 341 et. seq. (1994); Anita Bernstein, *Restatement Redux*, 48 VAND. L. REV. 1663, 1681 (1995) (expressing sympathy for concerns about products liability as a distinct field of law, but ultimately embracing products liability at a legal category in Anita Bernstein, *How Can a Product be Liable?*, 45 DUKE L. J. 1, 4, 83 (1995)); William Powers, *A Modest Proposal to Abandon Strict Products Liability*, 1991 U. ILL. LAW REV. 639, 639 (1991); Richard Speidel, *Book Review*, 33 VAND. L. REV. 813, 817 (1980); Jane Stapleton, *Bugs in Anglo-American Products Liability*, 53 S.C. LAW REV. 1225, 1254 (2002).

³ Owen, *supra* note 2, at 5.

of its most prominent nurturers. Of course he was not present when Benjamin Cardozo inked *MacPherson v. Buick Motor Co.*,⁴ when Roger Traynor wrote his concurring opinion in *Escola v. Coca-Cola Bottling Corp.*⁵ or his unanimous opinion in *Greenman v. Yuba Power Products*⁶ or when William Prosser drafted section 402A for the American Law Institute.⁷ However, those founding fathers (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 1960’s and 1970’s provided the fundamental elements that enabled thinking about the field as a distinct body of law. However, the work of Owen and other scholars to chronicle, categorize, and critique emerging products liability doctrines provided mortar to hold together the bricks created by courts and legislatures. Scholars such as Owen likely created or shaped some of the bricks, 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,⁸ his

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

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

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

⁷ RESTATEMENT (SECOND) OF TORTS Section 402A (1965).

⁸ See, e.g., David G. Owen, ed., *PHILOSOPHICAL FOUNDATIONS OF TORT LAW* (Oxford Univ. Press, 1995); David G. Owen, *Defectiveness Restated: Exploding the “Strict” Products Liability Myth*, 1996 ILL. L. REV. 743; David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*,

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. In 1980 Owen, along with coauthor John Montgomery, produced the first products liability casebook ever to be published. The casebook, which is perennially among the best-sellers in the field, eventually added Mary Davis as another coauthor and is now in its fourth edition. 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 15 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.⁹ Earlier Owen served as a coauthor on the torts hornbook originated by William Prosser and Page Keeton, *PROSSER & KEETON ON THE LAW OF TORTS*.¹⁰ The famous Prosser hornbook, while preceding Owen's work on treatises more narrowly directed at products liability, significantly added to practitioner's 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.¹¹

68 NOTRE DAME L. REV. 427 (1993); David G. Owen, *The Moral Foundations of Punitive Damages*, 40 ALAB. L. REV. 705 (1989); David G. Owen, *The Intellectual Development of Modern Products Liability: A Comment on Priest's View of the Cathedral's Foundations*, 14 J. LEGAL STUDIES 529 (1985).

⁹ Mary Davis, Stuart Madden, & David Owen, *MADDEN & OWEN ON PRODUCTS LIABILITY* (2000).

¹⁰ W. Page Keeton, Dan B. Dobbs, Robert E. Keeton & David G. Owen, *PROSSER AND KEETON ON THE LAW OF TORTS* (5th Ed. 1984).

¹¹ In *PRODUCTS LIABILITY LAW* Professor Owen cites the following articles he has published as foundations for sections of the book: David G. Owen, *Special Defenses in Products Liability Law*, 70 MO. L. REV. (2005) (forthcoming); David G. Owen, *Proof of Product Defect*, 93 KY. L.J. (2005) (forthcoming);

The work of Owen and others to encourage thinking about products liability as a distinct field of law have met with overwhelming success. An August, 2004 study counted roughly 15,000 products liability decisions “of some significance” in the United States.¹² Since the 1960’s, an explosion of increasingly complex rules and principles have developed in products liability cases.¹³ Practicing lawyers and judges have increasingly 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.¹⁴ When the American Law Institute decided to begin work on its RESTATEMENT (THIRD) OF TORTS in the early 1990’s, it decided to segregate products liability as a distinct project separate from other torts issues. 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.”¹⁵ Professor Owen served as the project’s editorial adviser. In assessing the debate over whether to consider products liability an independent field of law, Owen concludes:

David G. Owen, *Inherent Product Hazards*, 93 KY. L. J.1 (2005); David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L. REV. 1003 (2004); David G. Owen, *The Puzzle of Comment J*, 55 HASTINGS L. J. 1377 (2004); David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411 (2003); David G. Owen, *A Decade of Daubert*, 80 DENVER U.L. REV. 345 (2003); David G. Owen, *Manufacturing Defects*, 54 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 Responsabilita 1999 (Italian trans.); David G. Owen, *Products Liability Law Restated*, 49 S.C. L. REV. 273 (1998); David G. Owen, *American Products Liability Law Restated*, 6 CONSUMER L.J. 161 (1998). Owen, *supra* note 2, at viii. Owen has also coauthored the most recent edition of West’s PRODUCTS LIABILITY IN A NUTSHELL (West 2005) (Jerry J. Phillips and David G. Owen, coauthors).

¹² Owen, *supra* note 2, at 5.

¹³ *Id.* at 6.

¹⁴ *Id.*

¹⁵ Foreword, RESTATEMENT OF TORTS (THIRD): PRODUCTS LIABILITY (Tent. Draft 1, 1994), at xiii.

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 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.¹⁶

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, theoretical law review articles and books, and law review articles 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 among his most significant.

Owen's PRODUCTS LIABILITY LAW, published as part of the West Hornbook Series in 2005, is almost certainly destined to become one of the leading authorities 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."¹⁷ 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."¹⁸

¹⁶ Owen, *supra* note 2, at v.

¹⁷ *Id.*

¹⁸ *Id.*

Along with solid chronicling of products liability doctrines and trends,¹⁹ Owen's elegant and thought-provoking normative analyses add significantly to the hornbook's usefulness. One example may be found in his analysis of *Daubert v. Merrell Dow Pharmaceuticals*,²⁰ 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. 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, perhaps the most significant civil case of any kind in the United States in the past quarter century, provides strong evidence for Professor Owen's view that products liability has developed to the point that it should be considered as a field unto itself. For *Daubert* is a child of products liability. It was conceived in 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. Without products liability, there would have been no *Daubert*, and there would have been relatively little perceived need for a decision like *Daubert*.

¹⁹ 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* (4th ed., 1971), preface, at xi). Owen also notes another metaphor from the 12th Century French priest Bernard of Chartres: "dwarfs on the shoulders of giants." Owen, *supra* note 2, at v (citing Jacques Le Goff, *INTELLECTUALS IN THE MIDDLE AGES 12* (1957, 1985 (T. Fagan trans., Blackwell, 1993, citing Stephen G. Ferrulolo, *THE ORIGINS OF THE UNIVERSITY: THE SCHOOLS OF PARIS AND THEIR CRITICS 1100-1215*, at 154 (Stanford, 1985)).

²⁰ 509 U.S. 579 (1993).

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 issues which lie at the heart of products liability adjudication.²¹

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 be both reflecting and generating 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."²²

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 the prominent products liability scholar Aaron Twerski provides an interesting illustration of how *Daubert* is influencing thought on substantive products

²¹ Owen, *supra* note 2, at 377.

²² *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.

liability law. Dean 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.²³ One academic critic asserted during the RESTATEMENT (THIRD)'s drafting process that "The writings of [Twerski and Henderson] over the past two decades indicate a conservative penchant toward negligence and manufacturer-protective rules."²⁴ Another scholar recently described Twerski and Henderson as "academic critics of judicial expansion of product manufacturer liability."²⁵ Professor Henderson has written that "When I was first appointed [as co-reporter with Twerski for the RESTATEMENT (THIRD)], Plaintiffs' Bar had, collectively, what might pass for an aneurysm."²⁶ In truth, both scholars have not always favored defendants in their writings.²⁷ However, on balance, few would likely

²³ James A. Henderson and Aaron Twerski, *The Politics of the Products Liability Restatement*, 26 HOFSTRA L. REV. 667, 686 (1998) (citing Larry S. Stewart, *The ALI and Products Liability: "Restatement" or Reform?*, TRIAL, Sept. 1994 at 28, 30).

²⁴ Jerry J. Phillips, *Achilles Heel*, 61 TENN. L. REV. 1265, 1265 (1994).

²⁵ Douglas A. Kysar, *The Expectations of Consumers*, 103 COLUM. L. REV. 1700, 1702 (2005).

²⁶ James A. Henderson, *Revising Section 402A: The Limits of Tort as Social Insurance*, 10 Touro L. REV. 107, 111 (1993).

²⁷ See Victor E. Schwartz, *Process, Partisanship, and the Restatements of Law: The RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY – The American Law Institute's Process of Democracy and Deliberation*, 26 HOFSTRA L. REV. 743, 752 (regarding Dean Twerski and Professor Henderson, "a review of all of their written works reveals that neither scholar could be pigeon-holed as "pro-plaintiff" or "pro-defendant"). In 1993, when beginning his work as co-reporter, Professor 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.

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 Dean Twerski and Professor Henderson for design defect claims was, without question, the most controversial aspect of the products liability Restatement. 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.²⁸ This test heightens reliance on expensive expert witnesses, which are usually necessary to establish whether a reasonable alternative design would be feasible.

The expense caused by the test's focus on expert testimony was 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 argued that it would bar access to the courts for all legitimate design defect claims where the claims' value was not high enough to pay the price needed for expensive expert witness testimony.²⁹ Many critics argued instead for a defectiveness test based on whether the product design violated a reasonable consumer's

Henderson, *supra* note 26, at 111-112.

²⁸ RESTATEMENT OF TORTS (THIRD): PRODUCTS LIABILITY Section 2(b) (1998).

²⁹ See, e.g., Jerry J. Phillips, *The Unreasonably Unsafe Product and Strict Liability*, 72 CHI.-KENT L. REV. 129, 147 (1996) ("This requirement of a 'reasonable alternative design' on plaintiff imposes an especially onerous burden on the plaintiff, a burden that she may often be unable to meet"); Frank Vandall, *Design-Based Liability in American Products Liability Law: State Judges Should Reject the Reasonable Alternative Design Standard of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY*, 8 KANS. J. OF L. & ECON. 62, 63-64 (analogizing the RESTATEMENT (THIRD)'s reasonable alternative design requirement to the discrimination against poorer passengers in the movie *Titanic*, and suggesting that the test might share a fate similar to the ship).

expectations of safety, asserting among other things that the consumer expectations test provides greater protection of consumers' interests.³⁰

As Professor 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.³¹ The *Daubert* decision came out at about the same time the debate between reasonable alternative design and consumer expectations began raging in the ALI. *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.

Although probably a majority of courts have adopted the reasonable alternative design test, a substantial minority have 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 section 402A. In the 1960's and 70's courts overwhelmingly adopted 402A; it has been described as the closest thing to "holy writ" ever produced by the ALI.³² The RESTATEMENT (THIRD)'s reception by courts has been much more mixed, and one must

³⁰ 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 a "supporting cast" role and requiring proof of a reasonable alternative design would lead to the "astonishing" result of a plaintiff losing a case even if plaintiff establishes that the 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 the consumer expectations test in favor of a risk-utility test with a reasonable alternative design requirement inappropriately favors manufacturers over consumers).

³¹ See Owen, *supra* note 2, at 356.

³² James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement of Torts (Second)*, 77 CORN. 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).

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, Dean Twerski was one of the most prominent advocates of the perceived as pro-defense, expert-intensive, reasonable alternative design test.³³ As noted previously, he was also perceived by many as having a restrictive view of products liability generally.³⁴ However, this same Dean Twerski, 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. Further, he is directly pinning his argument for an expansion of products liability law on *Daubert*. 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 Dean Twerski coauthored the proposal, but also because of his co-author's prominence in the field of evidence.³⁵

The dramatic Berger/Twerski proposal is presented in an article recently published in November in the *Michigan Law Review* entitled *Uncertainty and Informed Choice: Unmasking Daubert*.³⁶ The Berger/Twerski proposal is that an “informed choice

³³ Indeed, before being named as co-reporters, Dean Twerski and Professor 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 32, at 1514.

³⁴ See *supra* notes 23 through 26 and accompanying text.

³⁵ See David E. Bernstein, *Learning the Wrong Lessons from 'An American Tragedy'* 10 MICH. L. REV. (2006) (forthcoming; available at Social Science Research Network: http://ssrn.com/abstract_id=775065) (“Margaret Berger and Aaron Twerski are among the leading scholars in their respective fields of Evidence and Products Liability”).

³⁶ 104 MICH. L. REV. 257 (2005).

cause of action” should exist for pharmaceutical products even without proof that physical harm was caused when:

- 1) The causal relationship between the toxic agent and P’s harm is unresolved at the time of litigation and will likely remain unresolved;
- 2) The drug is not therapeutic, but rather its purpose is to avoid discomfort or to improve lifestyle;
- 3) It 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) Defendant drug company was aware of the potential risk or should have undertaken Rx testing to discover the risk and failed to provide the requisite information to the patient or physician.³⁷

This Berger/Twerski proposal basically calls for a negligent infliction of emotional distress cause of action in a context far beyond the parameters of where courts have previously allowed such claims. They 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.”³⁸ 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.³⁹

Dean Twerski and Professor 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. Bendectin was marketed between 1957 and 1983 to

³⁷ *Id.* at 259.

³⁸ *Id.*

³⁹ *Id.*

approximately 36 million women to treat morning sickness during pregnancy.⁴⁰ Many lawsuits were filed contending that Bendectin caused stunted limbs in the children of mothers taking the drug, and that the manufacturer did not warn of this risk.⁴¹ 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.⁴² However, there was significant mosaic evidence of potential causation of birth defects that according to Twerski and Berger, 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.⁴³ 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.”⁴⁴

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.⁴⁵ Some users brought lawsuits contending that the drug caused strokes, and that no warning of this risk was provided.⁴⁶ Evidence existed suggesting that Parlodel may cause strokes, but most courts found it too idiosyncratic and unreliable to be presented to a jury.⁴⁷ However, in 1989 Parlodel was withdrawn from the market as an anti-lactation drug because it was

⁴⁰ *Id.* at 268; see also Michael D. Green, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 91, 180 (1996).

⁴¹ Berger & Twerski, *supra* note 36, at 268.

⁴² *Id.*

⁴³ *Id.* at 268-69.

⁴⁴ *Id.* at 268.

⁴⁵ See Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434,442 (W.D. Pa. 2003); Berger & Twerski, *supra* note 36, at 269.

⁴⁶ See Berger & Twerski, *supra* note 36, at 269.

⁴⁷ See *id.*

found to have no greater benefit than aspirin.⁴⁸ Twerski and Berger believe Parlodel is a good illustration of a case in which their proposed new cause of action would be warranted because “It 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.”⁴⁹

Twerski and Berger argue that cases such as Bendectin and Parlodel involving uncertain risk 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 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 “The current state of *Daubert* drug litigation is intolerable,”⁵⁰ 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 v. Merrell Dow Pharmaceuticals, Inc.*⁵¹

They conclude “That 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.”⁵²

⁴⁸ See *Eve v. Sandoz Pharms. Corp.*, No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at *14-20 (S.D. Ind. March 7, 2001); Berger & Twerski, *supra* note 36, at 270.

⁴⁹ Berger & Twerski, *supra* note 36, at 270.

⁵⁰ *Id.* at 288.

⁵¹ *Id.* at 258.

⁵² *Id.* at 288.

I have significant sympathy for these concerns. Who would dispute that 100 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 Professor 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. Plaintiffs must hire an academic or a private consultant.⁵³ Further, manufacturers typically pay for their 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 truly bold proposal, not an evolutionary baby-step. Further, as the authors acknowledge, courts would have difficulty defining with

⁵³ See Owen, *supra* note 2, at 358. Owen notes:

The bulk of experienced and otherwise qualified experts 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 consultants.

Id.

consistency the “lifestyle or discomfort” – i.e., lower utility – drugs for which Berger and Twerski would like to limit their standard to keep it from being too broad.⁵⁴ 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.⁵⁵

Professor David Bernstein recently wrote a paper expressing additional concerns about the Berger/Twerski proposal.⁵⁶ Much of Bernstein’s critique centers on disagreement with an assertion by Twerski and Berger that Bendectin provides, in Professor Bernstein’s words, the “paradigmatic example” of why courts should adopt the Berger/Twerski proposal.⁵⁷ Bernstein argues that if Bendectin, a safe drug in his view, is an example of a situation in which the Berger/Twerski cause of action would be appropriate, the cause of action is clearly overbroad. 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.⁵⁸ He concludes that “by the early 1980’s, there was a solid consensus in the medical community that Bendectin was not a teratogen.” Rather than serving as an illustration of why the Berger/Twerski proposal

⁵⁴ See Berger & Twerski, *supra* note 36, 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”).

⁵⁵ 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 (1994). Similarly to Dean Twerski and Professor Berger, I acknowledged in the article that clearly distinguishing medical products with primarily cosmetic utility from medical products with restorative utility would be difficult. 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 exclusion from strict liability in hybrid sales/services transactions. *See id.* at 911-12.

⁵⁶ See Bernstein, *supra* note 36 (forthcoming; available at Social Science Research Network: http://ssrn.com/abstract_id=775065).

⁵⁷ *Id.* at 2.

⁵⁸ *Id.* at 2-3.

should be adopted, Bernstein sees Bendectin litigation as an illustration of “unreasonable fears of the lay public, stirred by irresponsible interest groups, hired gun delusional experts, credulous media coverage and plaintiffs’ lawyers.”⁵⁹ He adds several additional concerns about the proposal, including assertions that:

- 1) “The proposal invites reliance on unreliable testimony;”⁶⁰
- 2) “Jurors are not competent to determine subtle risk assessment issues;”⁶¹
- 3) “Even assuming juror competence, the proposal asks too much of jurors;”⁶²
- 4) “The proposal ignores the problem inherent in multiple trials;”⁶³
- 5) “The proposal fails to consider the potential costs of informed choice litigation;”⁶⁴
- 6) “The informed choice proposal would lead to a vast surfeit of warning;”⁶⁵
and
- 7) “The informed choice proposal may be barred by the preemption doctrine.”⁶⁶

Without addressing each of Professor Bernstein’s concerns in detail, it may be useful to note that much of his critique could be seen as reflecting broader views about the efficacy or lack of efficacy 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

⁵⁹ *Id.* at 5-6.
⁶⁰ *Id.* at 15.
⁶¹ *Id.* at 20
⁶² *Id.* at 21.
⁶³ *Id.* at 23.
⁶⁴ *Id.* at 24
⁶⁵ *Id.* at 27.
⁶⁶ *Id.* at 28.

nonmeritorious claims – both may implicate products liability cases well beyond those in the limited target area of the Berger/Twerski proposal.

Professor 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 discussions of *Daubert* a launching point for expressions of 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.⁶⁷ 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 Dean 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 has past since *Daubert* was decided, and what we do not know about its full impact on products liability still

⁶⁷ 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 the same trends both in *Daubert* jurisdictions and *Frye* jurisdictions, leading the authors to conclude that defense lawyers may not perceive the federal *Daubert* rule to offer significant advantages over *Frye*).

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 1960's and 1970's, but quick growth spurts such as this are not the end of the story. From a long-term perspective, tort and products liability law are things that usually meander slowly toward, in the words of Judge Andrews in *Palsgraf* quoted previously, a "rough sense of justice."⁶⁸

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 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 them leading to dead ends, and then return back to the main street to meander further along their way toward justice.

I say this with some fondness, not derision, because eventually leisurely tourists 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. Again in the words of Judge Andrews (although he was applying them specifically to proximate cause), tort law's model is

⁶⁸ *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 103 (N.Y. 1928) (Andrews, J., dissenting).

simply seeking to fulfill a rough sense of justice.⁶⁹ The same model applies to products liability. As is the case with those respectful of 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. 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.

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' search 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. However, injustice 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.⁷⁰ 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.

⁶⁹ *Id.*

⁷⁰ See Berger & Twerski, *supra* note 36, at 271 (“Preparing for and litigating *Daubert* has undoubtedly made litigation more expensive than before”).

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 for 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 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.

A factor going the other way 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 manifestation 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 50 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 perhaps courts should follow both impulses discussed above: to enhance objective justice in trials where expert testimony is truly central by keeping something like the current *Daubert* standard, but at the same time applauding and encouraging substantive evolution to make civil litigation less frequently a battle of the increasingly expensive experts, where such evolution is consistent with best-achieving a rough sense of justice.

Although he places caveats on his praise and I place caveats on my criticism, on balance Professor 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.⁷¹

⁷¹ Owen, *supra* note 2, 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 frequency 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, and plaintiffs should have prevailed, except that they could simply not afford to bring their cases to trial had they spent enough on testing and 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, Professor Owen does not leave the assertion quoted above unmitigated. In the same paragraph he notes “the fact remains that only infrequently is *Daubert* invoked to exclude expert testimony proffered by defendants,”⁷² and elsewhere he cautions that “courts must sedulously avoid using this important gate-keeping function to bar evidence that actually may be sound.”⁷³ I would prefer more elaboration on *Daubert*'s significant costs to justice in addition to the discussion of its benefits, but Professor 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 Professor Owen's assertion that products liability has

⁷² *Id.* at 370.

⁷³ *Id.* at 377.

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.