Science and Uncertainty in Mass Exposure Litigation

Heidi Li Feldman
Georgetown University Law Center, feldmanh@georgetown.edu

This paper can be downloaded free of charge from:
https://scholarship.law.georgetown.edu/facpub/1713

74 Tex. L. Rev. 1
Articles

Science and Uncertainty in Mass Exposure Litigation

Heidi Li Feldman*

The task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability. As the record in this case illustrates, scientists often have vigorous and sincere disagreements as to what research methodology is proper, what should be accepted as sufficient proof for the existence of a "fact," and whether information derived by a particular method can tell us anything useful about the subject under study.

—Judge Alex Kozinski

I. Introduction

Critics of the tort system have condemned courts for their alleged leniency in admitting scientific expert testimony, especially in mass exposure litigation. Claiming that this has resulted in an epidemic of "junk science" in the courtroom, these commentators have urged a more

* Assistant Professor of Law, University of Michigan. B.A. 1986, Brown University; J.D. 1990, Ph.D. (Philosophy) 1993, University of Michigan. Thanks to Terry Sandalow, Jeff Lehman, Jim Joyce, J. Subramanyam, Kent Syverud, Rebecca Eisenberg, Kyle Logue, Steve Croley, William Miller, Richard Lempert, Eileen John, Chris Whitman, James Boyd White, Sam Gross, Fritz Juenger, Peter Steiner, Avery Katz, and Robert Harris. Thanks to the participants in a University of Pennsylvania Law School faculty workshop at which an earlier version of this paper was presented. Thanks to Sam Feder and Robert Tierney for able research assistance.

1. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995).
2. See Peter W. Huber, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 2 (1993). Huber's views have influenced commentators and courts. See, e.g., Stuart v. United States, 23 F.3d 1483, 1486 (9th Cir.) (criticizing a trial judge for "intemperate bench behavior" because the judge quoted from Galileo's Revenge during the trial), cert. denied, 115 S. Ct. 357 (1994); Antevski v. Volkswagenwerk Aktiengesellschaft, 4 F.3d 537, 541 & n.3 (7th Cir. 1993) (upholding exclusion of plaintiff's expert testimony that the Audi 5000 automobile unexpectedly accelerates and citing Huber's criticism of such claims); Carter v. Great Am. Ins., No. Civ. A. 94-0139, 1994 WL 374283, at *1 (E.D. La. July 1, 1994) (citing Huber in granting defendant's motion to exclude plaintiff's expert
scientific approach to admissibility, intimating that employing more scientific standards would exclude scientific evidence favorable to plaintiffs, thereby demonstrating to factfinders that litigated substances are in fact safe or at least not unsafe.³

In 1993, the Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,⁴ articulating a new set of standards for admitting scientific expert witness testimony. This Article argues that just as conservatives have urged, *Daubert* incorporates into law a scientific attitude toward selecting scientific testimony. Contrary to conservatives' expectations, however, this new, more scientific approach to admissibility will not typically lead to greater certainty at trial about the causal powers of substances litigated in mass exposure cases. Rather, at the time of litigation, a reasonable factfinder will often be left in a state of strong uncertainty about general causation, unable to conclude that it is more likely than not that a litigated substance is safe, or that it is more likely than not that the substance is unsafe.

In this Article, I argue that the *Daubert* Court adopted an approach to determining the admissibility of scientific opinion that reflects scientists' own approach to deciding which information to consider when deciding questions of scientific fact.⁵ In fact, I argue that the *Daubert* approach reflects the scientific one more closely than the Court may even have realized.⁶ Yet, whatever the wisdom of bringing legal standards for admissibility in line with scientific standards for respectable science, doing so forces to the forefront a problem that lawyers, judges, legislatures, and citizens have not confronted squarely: the problem of how to satisfactorily dispose of lawsuits involving thousands of plaintiffs in the face of genuine scientific uncertainty regarding the toxicity or safety of the litigated substance or product. The more closely legal standards hew to scientific ones for selecting information worth considering, the more often it will be apparent that science is severely uncertain about the causal effects of the


3. See, e.g., HUBER, supra note 2, at 15-17 (describing a decrease in the stringency of admissibility rules as a boon for plaintiffs and their lawyers); Kenneth R. Foster et al., *A Legal Perspective, in PHANTOM RISK* 35-36 (Kenneth R. Foster et al. eds., 1993) (arguing that uncertain science fuels speculative litigation and that tentative studies benefit plaintiffs even though the studies are not determinative).


5. See infra subpart III(A).

6. See infra Part III.
substances and products that figure so prominently in contemporary tort litigation. When scientists are severely uncertain about the general causal powers of a substance, legal factfinders will lack a basis either for concluding that the substance is more likely than not to cause harm to humans or for concluding that it is more likely than not to be safe for humans.

To demonstrate the point, I consider the state of current scientific understanding of the effects of silicone breast implants in the context of assessing the admissibility of scientific testimony in a hypothetical breast implant lawsuit. Then, I explain the role of certainty about causation in tort litigation in order to consider how the tort system might respond to severe uncertainty about causation, particularly in mass exposure litigation. I conclude that it will be difficult, if not impossible, to respond satisfactorily to severe uncertainty about causation without resolving certain fundamental substantive issues that lie at the heart of tort law. I also conclude that at least in mass exposure litigation, we need to mute the impact of strong uncertainty about causation. I briefly survey three possible revisions of the current system to illustrate how the problem of recurrent strong uncertainty requires us to reconsider traditional tort goals, consider new alternatives, and ascertain how to accomplish our chosen ends.

Now that the Supreme Court has adopted a sensible approach to the admissibility of scientific evidence, it is time for scholars and other commentators to shift their attention to more substantive issues, such as the regulation of products whose causal powers are ill-understood and expensive to ascertain, and the compensation of people with injuries of unknown origin.

II. Daubert

*Daubert* conjoins the issues considered in this Article: the question of admissibility standards for scientific expert witness testimony and the role of science in mass exposure litigation. *Daubert* itself was part of the mass exposure litigation involving the anti-nausea drug Bendectin. From 1956 to 1983, Merrell Dow marketed Bendectin as a cure for morning sickness

---

7. See infra subpart III(B).
8. See infra Part IV.
9. See infra Part VI.
10. Unfortunately, scholars have already begun to criticize the *Daubert* standards, sustaining the academic focus on admissibility. See, e.g., Margaret G. Farrell, *Daubert v. Merrell Dow Pharmaceuticals, Inc.: Epistemology and Legal Process*, 15 CARDOZO L. REV. 2183 (1994) (arguing that *Daubert* is internally inconsistent); Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After Daubert*, 78 MINN. L. REV. 1387, 1391 (1994) (arguing that *Daubert’s* guidelines are too vague to be useful in assessing the validity of scientific testimony).
During pregnancy.11 Since 1977, there have been approximately thirty trials litigating the question of whether Bendectin causes birth defects in the offspring of women who took the drug.12 Of these cases, only one verdict has been returned in favor of the plaintiff and survived appeal.13 In general, the trend in Bendectin litigation has been toward summary judgment,14 resulting in fewer trials. The main explanation for this trend is that during the lifetime of the litigation, an unusually quick and extensive scientific consensus emerged to the effect that Bendectin does not cause birth defects.15 This meant that the later Bendectin cases, including *Daubert*, presented ripe targets for complaints about the use of "junk science" to create spurious issues of fact on the causation question.16

Plaintiff Daubert sought to introduce scientific expert testimony to support the claim that Bendectin caused his limb-reduction birth defects.17 The testimony in question consisted of expert opinions based on animal tests, chemical structure analyses, and the reanalysis of previous epidemiological studies.18 The trial court excluded the testimony, determined that without it the plaintiff could not meet the burden of proof on the causation question, and awarded summary judgment for Merrell Dow.19 On appeal, the Ninth Circuit upheld the trial court’s rulings,20 relying

---

15. See Sanders, supra note 12, at 18-27 (surveying the published studies on Bendectin and concluding that there is substantial evidence that it is safe).
16. See HUBER, supra note 2, at 111-29 (depicting the Bendectin litigation as being whipped up by lawyers and fueled by bad science); see also Louis Lasagna & Sheila R. Shulman, *Bendectin and the Language of Causation*, in PHANTOM RISK, supra note 3, at 101, 101-05 (outlining the results of various studies failing to show any significant elevation of malformations in infants exposed to Bendectin).
18. *Id.* at 574.
19. *Id.* at 575-76.
upon an admissibility rule formulated in *Frye v. United States*, the most prominent appellate decision regarding admissibility of scientific testimony. When the Supreme Court in *Daubert* reviewed the question of the admissibility of the plaintiff's evidence, it ruled that the Federal Rules of Evidence superseded previous appellate holdings regarding the standards for admitting scientific expert testimony and replaced the *Frye* rule with new admissibility standards.

The Supreme Court's ruling in *Daubert* accomplishes two things. First, it strips *Frye* of its authority. Second, it provides the basis for a new set of admissibility standards based on Federal Rule of Evidence 702. In this Part, I explain why the shift from *Frye* to *Daubert* is a shift toward a more scientific approach to admissibility.

A. The Frye Rule

In *Frye*, the D.C. Circuit held that scientific expert testimony is admissible only if it is based on techniques generally accepted within the relevant scientific community. Over the years, the *Frye* rule attracted much scholarly attention, most of it critical. Lower courts interpreted its general acceptance standard more and less expansively, with some

---

21. 293 F. 1013 (D.C. Cir. 1923).
22. For a discussion of the *Frye* rule, see infra subpart II(A).
23. *Daubert* v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2793-96 (1993). On remand, applying *Daubert*, the Ninth Circuit affirmed the district court's original grant of summary judgment to the defendants. *Daubert* v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1322 (9th Cir. 1995). Although the appellate court expressed unease about judicial competence in applying *Daubert*, id. at 1315-16, it applied the decision quite ably. Following the Supreme Court's guidelines, see infra subpart III(B), the court ruled the plaintiff's expert testimony inadmissible. Interestingly, the Ninth Circuit opinion repeatedly alluded to the problem specified in this Article: recurrent strong uncertainty about causation. *Daubert*, 43 F.3d at 1313-14; see infra subpart III(B).
24. *Frye*, 293 F. at 1014.
26. Restrictive courts increased *Frye*'s stringency in a number of ways. Some interpreted the relevant community of scientists broadly, thereby requiring extensive acceptance. See, e.g., People
circuits eventually rejecting it altogether. As scientific opinion came to play an important role in high-profile, high-impact tort litigation, however, some scholars and courts began to call for a recommitment to Frye, interpreted so as to restrict the range of scientific opinion admitted in the courtroom.

If we grant that when a legal outcome turns on a question of scientific fact, it makes sense for the legal factfinder to consider information scientists would think relevant, we can appreciate the initial attractiveness of the Frye rule. If scientists thought that the only research relevant to

v. King, 72 Cal. Rptr. 478, 488 (Ct. App. 1968) (holding voiceprint identification inadmissible because it was not "generally recognized by the scientific disciplines in the related fields of speech, phonetics, linguistics and acoustics"). Others required plaintiffs to show that background theory, as well as a particular technique, enjoyed explicit general acceptance. E.g., United States v. Alexander, 526 F.2d 161, 163 n.3 (8th Cir. 1975); United States v. Addison, 498 F.2d 741, 743 (D.C. Cir. 1974). Finally, some courts insisted that plaintiffs provide fairly extensive evidence of general acceptance. See, e.g., People v. Kelly, 549 P.2d 1240, 1248-51 (Cal. 1976) (finding that neither the testimony of a single expert nor that of the creator of a technique is sufficient to establish general acceptance); Commonwealth v. Topa, 369 A.2d 1277, 1282 (Pa. 1977) (holding that at least two experts must testify to establish general acceptance).

More liberal courts interpreted Frye to impose less stringent requirements. Some courts described the relevant community more narrowly. See, e.g., People v. Williams, 331 P.2d 251, 254 (Cal. App. Dep't Super. Ct. 1958) (requiring only that a test "has been generally accepted by those who would be expected to be familiar with its use"). Other courts did not require acceptance of background theory. See, e.g., United States v. Stifel, 433 F.2d 431, 438 (6th Cir. 1970) (upholding the admission of neutron activation analysis despite the lack of support for the theory underlying the technique), cert. denied, 401 U.S. 994 (1971); Reed v. State, 391 A.2d 364, 370, 369-70 (Md. 1978) (interpreting Frye to demand only "a scientific judgment on the reliability of [a particular] process"). Finally, some courts allowed parties to establish general acceptance on the basis of judicial opinions. See, e.g., State v. Olderman, 336 N.E.2d 442, 447-48 (Ohio Ct. App. 1975) (looking to other courts' conclusions to determine the admissibility of a voice exemplar).

27. See, e.g., United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985) (rejecting the Frye test in determining the admissibility of expert testimony regarding the reliability of eyewitness identifications); United States v. Williams, 583 F.2d 1194, 1198 (2d Cir. 1978) ("Difficulty in applying the 'Frye' test has hassled a number of courts to its implicit modification.")., cert. denied, 439 U.S. 1117 (1979).

28. E.g., Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128, 1129-30 (9th Cir. 1991); Huber, supra note 2, at 14-17, 176-77.

29. Throughout this Article, I assume that it does make sense to present the legal factfinder who is deciding a question of scientific fact with scientific evidence that scientists would consider relevant. This assumption, however, is not obviously correct. If the legal factfinder is usually a jury of laypeople (as it currently is in mass exposure litigation), it might make sense to admit only the scientific evidence that scientists would think laypeople ought to consider when deciding issues of scientific fact. Alternatively, if the evidence is to include any relevant science, it might make sense to use a jury of scientists. I follow other scholars in starting from the position that lay factfinders should consider all relevant science when deciding issues of scientific fact. See generally Huber, supra note 2, at 225 (stating that courts achieve an optimal result through a "disciplined pursuit of scientific fact" and "by affirming true science"); Peter Schuck, Multi-Culturalism Redux: Science, Law, and Politics, 11 Yale L. & Pol'y Rev. 1, 35-40 (1993) (arguing that issues that are essentially scientific, such as causation, should be decided from a scientific perspective). But see Peter Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 Colum. L. Rev. 277, 329-37 (1985) (arguing that in mass torts, courts should defer to expert administrative agencies).
scientific matters of fact was research based on generally accepted techniques, the *Frye* rule would fit the bill. This standard of relevance, however, is too stringent. Although scientists might agree that all research based on generally accepted techniques is relevant, they would not all agree that only such research is relevant. When scientists describe the state of scientific understanding, they draw ideas from the cutting edge as well as from the bank of established findings. Research based on an innovative technique, not yet generally accepted, may well be relevant to scientific inquiry. In fact, a blanket prohibition on testimony based on cutting-edge techniques, methods, and ideas runs contrary to a scientific approach to gathering information.30

B. The *Daubert* Admissibility Standards, in Brief

Concluding that the Federal Rules of Evidence superseded earlier appellate rulings on the admissibility of scientific evidence,31 the *Daubert* Court relied upon Federal Rule of Evidence 702 to develop an account of how trial courts should decide which scientific opinions to admit and which to exclude. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.32

From the phrase “scientific . . . knowledge,” the Court derived a standard of reliability.33 To be admissible, scientific testimony must have a “grounding in the methods and procedures of science,” that is, be “derived by the scientific method” and must amount to more than “subjective belief or unsupported speculation.”34 Based upon the phrase “assist the trier of

---

30. This is not to deny that scientists are sometimes quite conservative. Famous examples of such conservatism include Einstein’s reluctance to accept quantum mechanics, see JEREMY BERNSTEIN, *Einstein* 175, 175-76 (Frank Kermode ed., 1973) (attributing Einstein’s rejection of quantum mechanics in part to his “incredible stubbornness”), and geologists’ unwillingness to accept the continental-drift hypothesis, see MARTIN SCHWARZBACH, ALFRED WEGENER: THE FATHER OF CONTINENTAL DRIFT 106 (Carla Love trans., Science Tech, Inc. 1986) (1980) (stating that the reaction to the theory of continental drift was “overwhelmingly negative” for several decades after its proposal). Nonetheless, when quantum mechanics and continental drift were relatively new theories, a scientist describing the state of physics or geology would not have ignored these theories altogether, even if she treated them dismissively.


32. FED. R. EVID. 702.

33. *Daubert*, 113 S. Ct. at 2795.

34. *Id.*
fact," the Court set a standard of relevance.\textsuperscript{35} The expert testimony must "fit" the case for which it is proffered; for the testimony to aid the factfinder appropriately, there must be a "valid scientific connection" between the testimony and the facts of the case.\textsuperscript{36} With these remarks, the Court singled out the methods and procedures of science as well as the relationship between scientific information and legal disputes, suggesting that the reliability and relevance of scientific information differ in kind from the reliability and relevance of other sorts of information.

After proposing the distinctiveness of scientific knowledge, the Court offered some guidance in identifying characteristically scientific testimony.\textsuperscript{37} \textit{Daubert} articulates four factors to guide courts in evaluating whether proffered scientific expert testimony constitutes scientific knowledge that will assist the trier of fact to understand or determine a fact in issue: testability, peer review and publication, rate of error, and general acceptance.\textsuperscript{38} The Court makes it clear that these criteria are simply guidelines for determining whether information is genuinely scientific; no single criterion nor any combination of criteria establishes a necessary or sufficient condition for admissibility.\textsuperscript{39}

The Court explains the purpose of each factor as follows. Testability guarantees that putative scientific knowledge consists of hypotheses whose likely truth or falsity can be assessed through systematic comparison to the actual state of the world.\textsuperscript{40} Peer review and publication ensure reliability because independent scientists have checked the soundness of an individual investigator's work.\textsuperscript{41} Rate of error more directly attests to the reliability of any particular technique or method.\textsuperscript{42} Finally, whether a method enjoys general acceptance within "the relevant scientific community" has some bearing on reliability because general acceptance, like peer review,
presumably demonstrates agreement among scientists as to the soundness of a particular technique.\textsuperscript{43}

C. Frye and Daubert: A Preliminary Comparison

The meaning of the guidelines set out in \textit{Frye} and \textit{Daubert} and the relationships between them requires clarification, which I provide in subpart III(A). For now, I want simply to note that \textit{Daubert} endeavors to guard against the admission of pseudo-scientific testimony while avoiding the problems with \textit{Frye} that I discussed previously.\textsuperscript{44}

As I will discuss more thoroughly in Part III, \textit{Daubert's} testability criterion ensures that scientific testimony will have an empirical basis, one of the central distinguishing features of science. In addition, \textit{Daubert's} retention of general acceptance as one factor in admissibility allows courts to consult scientific opinion as to whether the methods on which scientific testimony is based are indeed genuinely empirical.

By allowing trial judges to consider testability, peer review, and publication in addition to general acceptance, however, \textit{Daubert} makes room for testimony based on innovative research developed with techniques not yet generally accepted so long as they are genuinely empirical methods or have received some scrutiny from other scientists. Just by adding these criteria to general acceptance, \textit{Daubert} comports with a scientific approach to admissibility more closely than \textit{Frye} did. To fully understand just how accurately \textit{Daubert} captures the nature of modern science requires a more detailed understanding of the \textit{Daubert} guidelines.

III. Digging More Deeply into \textit{Daubert}

In this section, I argue for two claims. First, the best interpretation of \textit{Daubert} resolves a potential tension between the testability guideline and the peer review and publication and general acceptance guidelines. Second, once we fully understand the vision of science that informs \textit{Daubert}, it becomes evident that in many mass exposure lawsuits, scientific expert testimony will reveal severe uncertainty among scientists.

A. Two Kinds of Empiricism and the Daubert Guidelines

Philosophers, as well as jurists, have sought to distinguish science from other human enterprises. According to logical empiricism, the

\textsuperscript{43} \textit{Id.} at 2798.

\textsuperscript{44} See supra subpart II(A). \textit{Daubert's} significance as a bar to the use of fishy science has already been noted by commentators. See Sheila L. Birnbaum & J. Russell Jackson, \textit{Almost a Year After the Daubert Ruling, Courts Start to Recognize and Apply the Strict New Standard on Scientific Expert Testimony}, \textit{NAT'L L.J.}, May 16, 1994, at B5 (discussing two cases in which courts excluded testimony under \textit{Daubert}).
dominant philosophy of science in the mid-twentieth century, testability is the sole distinguishing feature of science. When the Daubert Court cited Carl Hempel and Karl Popper, two distinguished logical empiricists, as authorities for the testability guideline, the Court seemed to be committing itself to logical empiricism and its position on the distinctiveness of science. If this were the case, however, it would not have made sense for the Court to assign peer review, publication, and general acceptance equal and independent weight as guidelines for identifying respectable science. A Court fully in the grips of logical empiricism would, at most, have treated these guidelines as indicia of testability. Instead, the Daubert Court suggested that they possess independent significance.

Guidelines such as peer review, publication, and general acceptance are more compatible with revised empiricism, a philosophical revision of logical empiricism that dominates late-twentieth-century philosophy of science. As I will demonstrate subsequently, revised empiricism developed in response to shortcomings in the logical empirist account of testability. While revised empiricists continue to regard a version of testability as one distinctive feature of science, they stress the definitive role of scientists' collective judgment in making testability work. On this view, scientists' collective judgments—facilitated and established through devices such as peer review and publication and measured by general acceptance—are as distinctively characteristic of science as testability itself. Despite its citations to logical empiricism, the Daubert Court ultimately, if unintentionally, endorsed revised empiricism by putting peer review, publication, and general acceptance on an equal footing with testability, treating all as equally distinctive features of science. To fully understand each guideline, and the relationships between them, we must explore the evolution from logical to revised empiricism.

Logical empiricists sought to describe scientific beliefs as logically structured systems in an effort to distinguish "real science" from


46. Id. at 254, 254-55 (describing the logical empiricists' goal of distinguishing "real science" from "its phony pretenders" through testing).

47. The contours of logical empiricism can be described in various ways, including some that would categorize Hempel, but not Popper, as a logical empiricist. For purposes of understanding Daubert, it is useful to focus on the logical empirist commitment to testability understood in a particular way. See infra text accompanying notes 54-57. Popper shared this commitment, which is why, for present purposes, I count him a logical empiricist.

"unconstrained speculation, metaphysical posing and assorted mush." The logical empiricists held that scientifically justified beliefs either followed logically from sensory beliefs or simply were sensory beliefs. According to the empiricists, sensory beliefs are expressed in observation sentences, such as "red here now" or "there is a red chair there," which report privately experienced sense impressions in a most minimal fashion. When a scientist wants to test a hypothesis, she should deduce from it observation sentences and initial conditions and then determine through experimentation whether the deduced observations issue under the specified conditions. If so, the hypothesis is "confirmed," a term of art specified by Hempel. If, for instance, we wanted to test the hypothesis that ice melts in the sun, we would deduce the expected observation that ice will turn to water in initial conditions of direct sunlight. If, when we perform the experiment of placing an ice cube directly in the sun, the cube turns to water, we will have confirmed the original hypothesis.

This example hints at Popper's major contribution to logical empiricism. Actual scientists do not proceed simply by experimentally testing noncontroversial or trivial hypotheses, such as "ice melts in the sun," which are readily and unsurprisingly confirmed. Doing so contributes little to the growth of knowledge. If, however, a scientist demonstrates experimentally the falsity of a seemingly uncontroversial yet significant hypothesis, we learn a great deal. When Columbus proved that the earth was not flat, for example, he and his contemporaries added importantly to their stock of learning. If today a scientist were to confirm that the earth is round, his findings would be trivial in the extreme. Popper taught that falsifying hypotheses was at least as important as confirming them. Eventually, more sophisticated Popperian philosophers of science recognized that science progresses either when an unlikely hypothesis is confirmed or when a likely one is falsified. In either case, the scientist learns, relative to current belief. For present purposes, note that whether a scientist aims to confirm or to falsify a hypothesis, she will proceed through empirical testing. What shifts is the

49. CHURCHLAND, supra note 45, at 254. Given that the Daubert Court's goals mirrored the logical empiricists' objective of distinguishing "real science," it is not surprising that the Court found the empiricists' work congenial.
50. Id.
51. Id. at 254-55.
52. CARL G. HEMPEL, ASPECTS OF SCIENTIFIC EXPLANATION 3-51 (1965). It is important to note that confirmation is never conclusive. No matter how many times a hypothesis is experimentally confirmed, there is no guarantee that it will be confirmed again the next time. Thus, no hypothesis about the physical world can be conclusively confirmed.
53. POPPER, supra note 48, at 40-42.
54. ALAN F. CHALMERS, WHAT IS THIS THING CALLED SCIENCE? 54-55 (2d ed. 1982).
initial likelihood of her hypothesis. Because science progresses both by confirming the unlikely and falsifying the likely, neither an unlikely hypothesis nor a surprising result is contrary to good science.

Logical empiricism oversimplifies scientific experimentation, regardless of whether the scientist aims at confirmation or falsification. The logical empiricist account presupposes that both initial conditions and observational results can be specified in basically incontestable terms, thereby enabling the straightforward experimental confirmation or falsification of the tested hypothesis. Here is the logical empiricist model of testability, presented schematically:

1. Hypothesis.
2. Initial conditions, including background assumptions.
3. Expected observational results.
4. Experiment.
5. Observed results.

If (5) coincides with (3), the hypothesis is confirmed. If (5) contradicts (3), the hypothesis is falsified. Presented in this form, it is easy to see that if the observed results contradict the expected results, it is logically possible for either the hypothesis or one of the propositions in the specification of the initial conditions to be false. This complicates both confirmation and falsification. Suppose a scientist performs an experiment, and the observed results contradict expected results. Confirmation is not ruled out, nor is falsification established: the falsehood may lie not in the hypothesis, but in the initial conditions, specifically within the background theories and assumptions that underpin any experiment.55

Moreover, observations and observation sentences are themselves theory-dependent.56 Our theories shape what we notice and which observations we find significant; they mold how we conceptualize and articulate our observations. This means that observations do not provide a perfectly independent test for measuring the truth of our theories or hypotheses. How we interpret our observations and whether we do or do not attach significance to a particular result are at least partially determined by our background assumptions, rather than purely determined by how the world actually is. Confirmation and falsification are, therefore, shot through with scientific judgment: the world is not the exclusive determinant of the content and interpretation of the observed result; background theory and assumptions contribute significantly. This means that observations

55. Id. at 32-34.
themselves are revisable not only in response to additional empirical data, but also in the name of preserving a hypothesis or a background theory.\textsuperscript{57}

To preserve the idea of testability, there must be some principled way of distinguishing observation sentences from theoretical ones, along with a principled way of deciding what to reject and what to revise when hypotheses and observation clash. Much post-logical empiricist philosophy of science attacks these problems. Like the logical empiricists, many contemporary theorists—including Thomas Kuhn, Imre Lakatos, and Helen Longino—maintain commitments to empiricism and to the idea that science is a distinctive human enterprise.\textsuperscript{58} Unlike logical empiricism, however, revised empiricism vindicates these commitments by emphasizing the holistic nature of scientific theory and the sociology of scientific practice.\textsuperscript{59} Note particularly that the revised empiricist account of science portrays "ordinary, normal" science. It is not primarily an account of "revolutionary science," nor does it depict science as a series of drastic "paradigm shifts."

Revised empiricists start from the recognition that logic alone cannot distinguish observation sentences from theoretical ones, nor can it determine what to revise or reject in a clash between hypothesis and observation. These premises motivate a picture of scientific theories as holistic accounts of the world, each theory generating concepts, hypotheses, and experimental programs that possess meaning and significance in the context of the original theory.\textsuperscript{60} On this view, "there is no such thing as

\begin{itemize}
\item \textsuperscript{57} KUHN, supra note 56, at 114-17, 120-22; LONGINO, supra note 56, at 46-48.
\item \textsuperscript{58} See, e.g., IMRE LAKATOS, THE METHODOLOGY OF SCIENTIFIC RESEARCH PROGRAMMES 1-7 (John Worrall & Gregory Currie eds., 1978).
\item \textsuperscript{59} Revised empiricism holds sway among contemporary scientists, physicians, and historians of science as well as contemporary philosophers of science. See Brief Amici Curiae of Physicians, Scientists, and Historians of Science in Support of Petitioners, Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) (No. 92-102) (arguing for a Kuhnian conception of science) (listing among the amici curiae Stephen Jay Gould, Alexander Agassiz Professor of Zoology, Professor of Geology, and Professor of the History of Science at Harvard University and Fellow of the American Association for the Advancement of Science, the American Academy of Arts and Sciences, and the National Academy of Sciences; Gerald Holton, Mallinckrodt Professor of Physics and Professor of the History of Science at Harvard University and past Secretary of the American Academy of Arts and Sciences; and Peter Infante, an epidemiologist who has worked at the Centers for Disease Control and is a Fellow of the American College of Epidemiology). See generally Brief of the Carnegie Commission on Science, Technology, and Government as Amicus Curiae in Support of Neither Party at 11, Daubert (No. 92-102) (arguing that distinctively scientific knowledge possesses features in addition to testability); Brief for the American Association for the Advancement of Science and the National Academy of Sciences as Amici Curiae in Support of Respondent at 18, Daubert (No. 92-102) (arguing for the centrality of the scientific community's collective judgment in evaluating scientific claims); Brief of the New England Journal of Medicine, Journal of the American Medical Association, and Annals of Internal Medicine as Amici Curiae in Support of Respondent at 2, Daubert (No. 92-102) (arguing for the joint importance of peer review and experimental testing in producing "good science").
\item \textsuperscript{60} CHALMERS, supra note 54, at 77 (describing scientific theories as "structured wholes"). Kuhn calls the complex of theory, concepts, hypotheses, and experimental program a "paradigm." KUHN,
a once-and-for-all crucial experiment in which a hypothesis is conclusively demonstrated to be false. A test for a hypothesis is crucial not absolutely, but relative to background assumptions. In principle, the truth of any sentence can be maintained by making adjustments elsewhere in the theory. Neither logic nor empirical observation can completely clinch the truth or falsity of any hypothesis.

Such a picture threatens to detach science from its empirical base and to plunge any given theory into a sea of ever-possible revision. Revised empiricists, with their sensitivity to scientific practice, recognize that under most circumstances scientists do not—and do not feel free to—whimsically revise and reject hypotheses or observations. The puzzle for revised empiricism is to reconcile the absence of conclusive logical or empirical constraint with the sense that the construction of scientific theories is neither arbitrary nor a matter of unfettered personal choice.

According to revised empiricists, scientists make a series of reasoned—but always revisable—commitments that constrain theory choice and development. First, scientists commit to a theory and its concomitant concepts, hypotheses, and experimental program. Second, within a theory, scientists commit to certain assumptions and premises, working to preserve these regardless of the outcome of future research. In a clash between these assumptions or premises and an experimental result, the scientist tries to interpret the data so as to preserve the privileged assumptions or premises.

These commitments are not existential leaps. They are based on considerations born of the scientific aspiration to understand the world in a way that enables prediction. Scientists prefer theories—and within theories, assumptions and premises—that further this goal. Subsidiary considerations that help enable prediction include simplicity, unity of theory, and the availability of better alternatives. Selecting theoretical commitments on the basis of such considerations calls for human judgment.

supra note 56, at 43-51. Lakatos terms the complex a “research programme.” LAKATOS, supra note 58, at 47-52, 86-90. For present purposes, we need not isolate or compare the specifics of paradigms and research programs.

61. CHURCHLAND, supra note 45, at 262 (emphasis in original); see also Brief of the Carnegie Commission, supra note 59, at 9, 11 (stressing the provisional nature of scientific findings); Brief of the American Medical Association et al. as Amici Curiae in Support of Respondent at 12, Daubert (No. 92-102) (“Hypotheses are framed in terms of the relationship between two variables.”); Brief Amici Curiae of Physicians, Scientists, and Historians of Science, supra note 59, at 11-13 (arguing against the immutability of scientific “truths”).

62. CHURCHLAND, supra note 45, at 263.

63. CHALMERS, supra note 54, at 80-81.

64. Id.

65. Id.

66. CHURCHLAND, supra note 45, at 263.
Despite occasional suggestions to the contrary, revised empiricists generally emphasize that the judgment in question is collective, not individual. Selecting a theory and privileging certain of its assumptions and premises is a collective process comprised of institutionalized educational and scholarly practices that shape and check individual judgment. This collective process imposes an additional constraint on a scientist's theoretical commitments.

According to revised empiricist accounts, science progresses as scientists trade in one theory for another, as they collectively come to recognize that a rival to the established theory better satisfies the various scientific desiderata—predictive power, simplicity, unity of theory, fruitfulness, and so on. Sometimes an established theory is wholly replaced by a new contender; sometimes, the successor is a recognizable version of its predecessor. The impetus for change arises from shortcomings in the settled view. As scientists work with a theory, they find that there are phenomena it either cannot explain or can explain only by adding ad hoc premises and assumptions. Or, they find that the theory provides little or no guidance as to how to proceed experimentally to acquire further understanding. As scientists become disenchanted with the resources of the prevailing theory, they consider alternatives more carefully. Some scientists begin working with alternative frameworks. If one of these outstrips the previously entrenched view, it gradually becomes mainstream—the view into which novice scientists are educated and within which they work, until its shortcomings become apparent and motivate exploration of new rivals. At any given time, alternatives to mainstream theory will be available, and one of them may emerge as a replacement, even if it seems at the time that the mainstream view is the obviously superior one.

Revised empiricism retains but transforms the idea of testability. Logical empiricists viewed testability as a product of straightforward observation and deductive inference; revised empiricists see testability as

67. See, e.g., KUHN, supra note 56, at 122-23 ("On [some] ... occasions the relevant illumination comes in [a single scientist's] sleep.").

68. See, e.g., KUHN, supra note 56, at 176-91 (noting the importance of the community structure of science in establishing and defining a paradigm); LONGINO, supra note 56, at 66-81 (arguing that theories that fail to take into account the effect of community involvement in developing scientific thought do not adequately describe the process by which hypotheses are formed).

69. LONGINO, supra note 56, at 68-69, 76-77; see KUHN, supra note 56, at 43, 167-70 (explaining the role that the community plays in determining shared rules).

70. CHURCHLAND, supra note 45, at 263; see also Brief for the American Association for the Advancement of Science, supra note 59, at 7-9 (explaining the cumulative nature of scientific inquiry).

71. CHALMERS, supra note 54, at 94; KUHN, supra note 56, at 52-65, 69.

72. CHALMERS, supra note 54, at 95-96; KUHN, supra note 56, at 108, 111, 153-59.

73. CHALMERS, supra note 54, at 84, 90-92; LONGINO, supra note 56, at 38-40, 53-56.
a matter of theory-dependent observation, deductive inference, and a hefty dose of contingent judgment. The revised empiricist preserves empiricism by using the standard of collective judgment to establish the distinction between theory and observation that the logical empiricist took for granted. The revised empiricist also relies on the standard of collective judgment to select which tenets will be maintained despite recalcitrant experimental outcomes, at least for the time being. This establishes which propositions will qualify as testable hypotheses. Once scientists collectively stipulate certain sentences as fixed assumptions and others as fixed observations, testability can get off the ground. So long as scientists agree upon these stipulations, they will interpret experimental data in essentially the same way, deductively inferring the truth or falsity of proposed hypotheses.\textsuperscript{74}

In the scheme of revised empiricism, peer review and publication foster agreement on fixed assumptions and observations; general acceptance reflects the choices the scientific community has made. Viewed in this light, \textit{Daubert}’s emphasis on these factors is not inconsistent with its commitment to testability, contrary to at least one scholar’s argument.\textsuperscript{75} In fact, in recognizing the roles of peer review, publication, and general acceptance in the production of science, the Court preserves the meaningfulness of testability.

\textbf{B. Revised Empiricism and Scientific Uncertainty}

Science is dynamic. This is the central lesson of the switch from logical to revised empiricism. In science, revisability is always an option. As scientists acquire new data and change their collective judgments about which background assumptions to hold constant, they revise and replace even well-established scientific theories.\textsuperscript{76} Scientific theory does not achieve absolute finality. Even when one theory enjoys preeminence, other theories are available for consideration. Rival views are a valuable and usual part of the scientific process, providing fodder and stimulation for

\textsuperscript{74} In principle, however, rational scientists can disagree over these matters, even after accumulating large amounts of data, if they disagree over which assumptions and observations to hold fixed. \textit{See, e.g.,} CHURCHLAND, supra note 45, at 263 (“[N]o sentence has special epistemic properties that protect it from revision. Accordingly, it is possible for rational scientists ... to continue to disagree even after a great deal of data is accumulated.” (citation omitted)).

\textsuperscript{75} Margaret A. Berger, \textit{Procedural Paradigms for Applying the Daubert Test,} 78 MINN. L. REV. 1345, 1375 (1994).

\textsuperscript{76} Brief \textit{Amici Curiae} of Physicians, Scientists, and Historians of Science, supra note 59, at 7-16 (describing science as an incomplete process forwarded by the revolutionary discarding of old theories for new ones). One of the most famous historical examples of this process is the Copernican Revolution, the switch from Ptolemaic to Copernican astronomy. \textit{See generally} THOMAS S. KUHN, \textit{THE COPERNICAN REVOLUTION: PLANETARY ASTRONOMY IN THE DEVELOPMENT OF WESTERN THOUGHT} (1985).
those researching in the mainstream. Even when scientific research is totally embedded in the prevailing theory, investigators seek to confirm novel hypotheses and falsify received ones. Starting from unusual suppositions and producing surprising results are integral parts of science, although they add to its instability.

A dynamic enterprise like science does not produce fixed, unassailable conclusions. It produces a range of opinions, some more widely shared than others. A rigid general acceptance standard for the admissibility of scientific testimony pretends otherwise. That sort of standard gives the legal factfinder an edited version of science. Strip away the editing, as Daubert has done, and the factfinder will more often encounter scientific uncertainty. If courts admit scientific expert testimony according to revised empiricist criteria, rather than relying exclusively on general acceptance, often the proper conclusion for the legal factfinder to reach will be that the answer is uncertain. On a revised empiricist view of science, uncertainty among scientists is a natural state of affairs. Shifting from Frye to Daubert brings legal standards into line with revised empiricist standards for selecting information worth considering. Now legal factfinders will have access to the same range of information scientists would consider. Uncertainty in science will show up at trial.

This will be especially true in mass exposure litigation. Scientific research into causation is a slow, arduous process, often barely begun when litigation commences. At that time, rival theories about the toxicity of the litigated substance or device will have respectable adherents, all operating in good faith. Eventually, one theory may garner the endorsement of most scientists—and this may constitute sufficient “certainty” for legal purposes—but in most cases this will not happen during the lifetime of tort litigation. In many cases, trials will occur in the period when scientists have developed several promising alternatives but no one theory has become well established. At that point, opposing parties each can present scientific testimony that gives them a chance at winning, so plaintiffs have incentive to bring suit and defendants have incentive not to

77. Brief Amici Curiae of Physicians, Scientists, and Historians of Science, supra note 59, at 15-16 (asserting that heretical and eccentric views have often facilitated the advance of science); see Brief of the Carnegie Commission, supra note 59, at 5 (noting the role of dissenting researchers in furthering scientific progress).

78. See Brief for the American Association for the Advancement of Science, supra note 59, at 7 (“The scientific community has a special interest in encouraging innovative thinking while simultaneously ensuring that new ideas are subject to rigorous review.”).

79. Under the best of circumstances, scientific study of general causation proceeds slowly. It is delayed by long latency periods and the absence of unique correlations between particular substances and specific diseases. Poulter, supra note 37, at 1307 n.4; see also Jonathan Harr, A Civil Action 132-40 (1995) (describing the early stages of scientific research relevant to a lawsuit brought by plaintiffs suffering from leukemia all living near a possibly contaminated source of drinking water).
settle. If the case goes to trial, Daubert's revised empiricist criteria for admissibility will allow the factfinder to hear the full range of scientific opinion on the issue of cause-in-fact. Often, the only reasonable conclusion for the factfinder to draw will be that, according to science, the causal powers of the litigated substance or device are basically unknown.

IV. Daubert Applied: The Case of Silicone Breast Implants

In this section, I will argue that, as the revised empiricists would expect, there is currently disagreement among scientists over the toxicity of silicone breast implants; that scientists who have performed research into the question regard their own findings as highly tentative; that research in different scientific subdisciplines indicates opposing conclusions on the question of toxicity; in sum, among scientists there is genuine uncertainty about the causal effects of silicone when implanted in the human body. In specific breast implant trials, scientific expert testimony admissible under Daubert will reveal this state of the science to the legal factfinder whether the factfinder is presented simply with rival conclusions or with a more detailed picture of the scientific bases for these conclusions. Presented with testimony that attests to the uncertainty among scientists, a reasonable legal factfinder would, it seems, have to conclude that the causal powers of silicone implants are unknown. To illustrate the point, I will focus on the current silicone breast implant litigation and the specific example of a hypothetical case brought on behalf of a child of an implant recipient. Then, I will specify the relationship between revised empiricism and the current inability to draw conclusions about the safety of silicone breast implants.

A. An Overview of the Breast Implant Litigation

In 1962, manufacturers began marketing silicone breast implants in the United States. These implants have since been associated with a variety of health problems; however, some of these associations are more settled than others. For example, it is uncontroversial that a significant number of women with implants suffer from capsular contracture, a painful and aesthetically displeasing hardening of the tissue around the implants. Treatment for capsular contracture includes techniques that increase the

likelihood of the implant's rupture. Whether intact or ruptured, silicone implants interfere with mammography and therefore may impede the early detection and prompt treatment of breast cancer. More controversial are the links between medical problems such as connective-tissue disorders and autoimmune diseases and exposure to silicone leaked from intact implants or escaped from ruptured ones.

From the late 1970s through 1991, Dow Corning Wright, the leading producer of implants in the United States, received thousands of complaints about the silicone implants and settled numerous actions brought by women who had received the implants. Because these settlements always contained nondisclosure clauses, their precise terms remain unavailable to the public.

In the early 1990s, three plaintiffs won large verdicts against implant manufacturers. A jury awarded Anna Livshits almost $4.5 million, of which just less than $3 million was set aside on defendant's motion for judgment notwithstanding the verdict. Marianne Hopkins recovered $840,000 in compensatory damages and $6.5 million in punitive damages from Dow Corning. The Ninth Circuit upheld Hopkins's award.

82. See Council on Scientific Affairs, American Med. Ass'n, Silicone Gel Breast Implants, 270 JAMA 2602, 2604 (1993) (stating that there is a risk of rupture with the closed capsulotomy treatment of capsular contracture).

83. See D. David Dershaw & Ted A. Chaglassain, Mammography After Prosthesis Placement for Augmentation or Reconstructive Mammoplasty, 170 RADIOLOGY 69, 72-73 (1989) (stating that silicone implants may obscure tissue masses); Neal Handel et al., Factors Affecting Mammographic Visualization of the Breast After Augmentation Mammoplasty, 268 JAMA 1913, 1915-16 (1992) (reporting that breast implants reduce the area of tissue visualized by both compression and displacement mammography).

84. See Kelley P. Douglas et al., Roentgenographic Evaluation of the Augmented Breast, 84 S. MED. J. 49, 53 (1992); Melvin J. Silverstein et al., Breast Cancer Diagnosis and Prognosis in Women Following Augmentation with Silicone Gel-Filled Prostheses, 28 EUR. J. CANCER 635, 639 (1992) (both finding a decreased capability of mammography to detect palpable breast cancer in women with breast implants).

85. As early as the 1970s, scientific research indicated a possible connection between silicone implants and autoimmune diseases. Philip J. Hilts, Strange History of Silicone Held Many Warning Signs, N.Y. TIMES, Jan. 18, 1992, at 1. This connection is still a matter of dispute among scientists. See infra subpart IV(B).

86. Steinbrook, supra note 80, at A24. Dow Corning Wright is a subsidiary of Dow Corning Corporation. Id.

87. Patricia Anstett, Legal Deals Silence Pain: Breast-Implant Settlements Kept Health Problems Quiet, DET. NEWS & FREE PRESS, Feb. 15, 1992, at 1A, 12A.

88. Livshits v. Natural Y Surgical Specialties, Inc., 35 Fed. R. Evid. Serv. (Callaghan) 433, 433-34 (S.D.N.Y. 1991). Livshits's implants had to be removed due to chronic infection; upon removal the implants ruptured. Id. at 434. Shortly thereafter, Livshits was diagnosed with breast cancer in her right breast. Id. Due to the lumps of silicone in her breasts, her physician concluded that mammography would not be a reliable monitor of her condition, and Livshits underwent a radical mastectomy of one of her breasts. Id. at 435. Her physician also concluded that a prophylactic mastectomy of the other breast would probably be necessary. Id. Livshits recovered on a breach of warranty theory. Id. at 436.

89. Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1119-20 (9th Cir. 1994), cert. denied, 115 S. Ct. 734 (1995). Hopkins's implants, which she received in post-mastectomy breast reconstruction
specifically rejecting Dow Corning's argument that the trial court had erred in admitting Hopkins's expert testimony on causation; applying Daubert, the Court of Appeals upheld the trial judge's admissibility decision. 90 Finally, a jury voted to award Brenda Toole $350,000 in compensatory damages and $5 million in punitive damages in her suit against Baxter Healthcare Corporation, the successor to Heyer-Schulte, the manufacturer of Toole's implants. 91 The Eleventh Circuit subsequently granted Baxter's motion for a new trial on liability and damages on the ground that federal agency reports had been improperly admitted into evidence at trial. 92

After the Hopkins verdict, the Food and Drug Administration imposed a temporary moratorium on cosmetic silicone breast implants and opened an investigation into the safety of the implants. 93 The moratorium was later made permanent except for purposes of clinical study. 94 After the imposition of the temporary moratorium, the rate and number of case filings against implant manufacturers increased dramatically. 95 In February 1992, Dow Corning reorganized its top management, assigning its new chief executive officer, Keith R. Mennon, full-time responsibility for handling breast implant-related issues. 96

Following a highly publicized dispute within the plaintiffs' bar about the appropriate forum and procedure for handling the cases, 97 the federal Judicial Panel on Multidistrict Litigation consolidated pending federal breast implant litigation under Judge Sam Pointer, Jr., in the Northern Surgery, ruptured. She alleged that silicone from the ruptured implants caused her mixed connective tissue disease, and she recovered on theories of fraud, strict products liability, and breach of implied and express warranties. Id. at 1118-19.

90. Id. at 1124-25.
91. Toole v. McClintock, 778 F. Supp. 1543, 1545 (M.D. Ala. 1991). Toole suffered severe capsular contracture. Treatment of the condition ruptured her implants, and she required repeated surgeries to remove silicone lumps in her breasts. Id. at 1546. She recovered in a negligence action for failure to warn. Id. at 1547.
92. Toole v. McClintock, 999 F.2d 1430, 1433-35 (11th Cir. 1993).
97. See, e.g., Mark Hansen, Lawyers Spar Over Implant Litigation, A.B.A. J., June 1992, at 16; Tracey Schroth, Breast Implants: Latest Toxic Tort; Plaintiffs' Bar Launches Aggressive Drive for Clients, N.J. L.J., Apr. 13, 1992, at 1, 28 (both describing the debate within the plaintiffs' bar as to whether the litigation should proceed as a nationwide class action or should be consolidated as multidistrict litigation for discovery only).
District of Alabama.98 Pointer later certified a class action for purposes of settlement,99 confirmed the certification,100 and approved a settlement negotiated by the class and selected defendants, including Dow Corning and Baxter Healthcare.101

Implant manufacturers committed nearly $4.25 billion to the compensation fund, rendering it the largest medical product liability settlement in history.102 Nonetheless, Judge Pointer recently announced that the amount cannot provide adequate compensation given the rising number of claimants,103 despite evidence suggesting that Dow Chemical—Dow Corning's parent company—was sufficiently involved in the research and marketing of the breast implants to justify making Dow Chemical a party to the global settlement, thereby increasing its funding.104

On September 8, 1995, in a recording played over the court-operated breast-implant settlement hotline, the Judge stated there was no reason to keep the plan in place.105 More than 400,000 have claimed the right to compensation under the fund; more than 70,000 might qualify for immediate benefits.106 Paying these women the proposed minimum benefit would cost $7.3 billion.107 Only drastic reductions in payments

---

101. Id. at *1. The highly detailed $4,225,070,000 settlement included a program for receiving claims over a 30-year period and for making payments that did not depend on the amount of contributions or financial resources of the defendant that supplied the particular claimant's implants; a simplified claims procedure that did not involve adversarial proceedings or require examinations by court-appointed physicians; the initial identification of certain diseases for which compensation would be paid without requiring proof of causation; a procedure for adding to this list other diseases should this have been warranted by scientific research; and the creation of funds to pay costs other than compensation for officially recognized diseases, including compensation for ruptured implants and medical evaluations. Id. at *1-*2. The disease compensation program did not include any diseases contracted by the natural children of women with silicone breast implants. Id. at *8. Children were, however, members of the settlement class. Id. at *24-*25. Children were able to opt out of the settlement until two years after attaining majority or two years after manifesting symptoms of illness claimed to result from a maternal implant, whichever came later. Id. at *9.
105. Brooks & Weinstein, supra note 102, at D1.
106. Id.
107. Id.
would enable the fund to cover the eligible claims. The recording announced:

The Court believes that the extreme reduction in benefit amounts would result in so many class members opting out that the settling manufacturers would in turn withdraw from the settlement. . . . In light of this, as well as the complications presented by the Dow Corning bankruptcy proceeding, Judge Pointer has preliminarily concluded that there is no justification for keeping the current settlement in place.

On October 2, the Judge was scheduled to issue a court order restructuring or dissolving the global settlement. As of October 4, 1995, however, the court had not issued such an order because three implant manufacturers had submitted a new settlement proposal to the court and plaintiffs’ class counsel. As of October 4, it seems impossible to predict whether any type of settlement will result from the multidistrict litigation or whether the class will be dissolved with any future cases to be litigated on an individual basis.

Breast implant plaintiffs who have opted out of the federal class action have been pursuing their claims in state courts. The most significant recent state court litigation is unfolding in Texas: in two recent trials, the same jury awarded $5.2 million to one plaintiff but no damages to the other. In both of these suits, Dow Chemical, Dow Corning’s parent, is a named defendant.

As the saga of the global settlement fund unfolded, there were several developments in the scientific research on silicone breast implants and the litigation involving Dow Corning Wright. On May 15, Dow Corning sought bankruptcy protection in the Eastern District of Michigan.

108. Id.
109. Id.
110. Fiely, supra note 103, at 3C.
111. According to the settlement information hotline, women with 3M, Baxter, or Bristol-Myers implants who submit claims under the Current Disease Compensation Program could either accept a fixed amount based on disease criteria and severity levels in the present settlement or choose to receive a possible higher payout if they developed more serious diseases in the future and could meet more restrictive standards for establishing a causal connection between their health problems and the implants.
113. $5 Million for Implant Leak, N.Y. TIMES, Feb. 16, 1995, at A20 (claiming that the jury awarded nothing to one plaintiff because they concluded that “sufficient information of problems had become available when she had her implants 10 years after the [other] woman”).
114. Id.
Subsequently, the Bankruptcy Court denied Dow’s request to halt litigation pending against Dow Chemical116 and denied Dow’s request to transfer the opt-outs from the global settlement who were bringing suit against Dow Corning.117 With the demise of the global settlement, the Eastern District of Michigan has ordered the transfer to its jurisdiction of both opt-in and opt-out claims against Dow Corning.118 Meanwhile, on the scientific front, various studies have been published indicating a lack of association between silicone gel breast implants and connective-tissue disorders;119 however, critics ranging from scientists to plaintiffs’ lawyers have faulted these studies for bias due to connections between the researchers and Dow Corning.120

B. Scientific Research into the Toxicity of Breast Implants

Research addressing the effects of silicone breast implants on the human body is tentative. Some research indicates that silicone breast implants may cause harmful effects, and some research suggests that implants cause no harmful effects.

The scientific evidence suggesting that silicone implants may cause harmful effects comes mainly from animal studies showing that silicone causes inflammatory and immunological reactions121 and from human

120. While the Nurses’ Health Study was being done, Dow Corning contributed $7 million to the hospital and received a copy of the study questionnaire before it was distributed. Silicone Implants Pose No Danger, Nurse’s Health Study Shows, 3 Breast Implants Litig. Rep. (Mealey’s) No. 16, at 18, 19 (June 29, 1995). Additionally, two authors of the study were paid consultants of several implant manufacturers during the time the authors were conducting this research. Two Authors of Harvard Nurses’ Study Were Paid Consultants of Implant Makers, 3 Breast Implants Litig. Rep. (Mealey’s) No. 8, at 10, 10 (Feb. 23, 1995).
121. See, e.g., Nahum Ben-Hur et al., Local and Systemic Effects of Dimethylpolysiloxane Fluid in Mice, 39 Plastic & Reconstructive Surgery 423, 423 (1987) (summarizing studies discovering atypical inflammatory cells in mice and rats injected with silicone fluid); Gerald L. Brody & Charles F. Frey, Peritoneal Response to Silicone Fluid, 96 Archives Surgery 237, 238 (1968) (describing the formation of a silicone-induced peritoneal inflammatory infiltrate in rats); John O. Naim et al., The Adjuvant Effect of Silicone-Gel on Antibody Formation in Rats, 22 Immunological Investigations
case studies showing an association between silicone and serious diseases. The scientific evidence suggesting that silicone implants do not cause harmful effects comes primarily from epidemiological studies.

All three types of research suffer from methodological difficulties that reduce the conclusiveness of their results. In general, animal studies do not provide conclusive results because of the many inferences that must be made in extrapolating from animal study results to effects on humans. Animal studies involve giving animals extremely large doses of the substance in question in order to maximize the chances of producing a significant impact upon a large number of the animal population exposed to the toxin. Thus, in order to determine the typical effects on humans, researchers must first extrapolate from high-dose effects to low-dose effects in animals, and then estimate the low-dose effects on human beings. The combination of inferences creates considerable uncertainty.

151 (1993) (concluding, based on rat experiments, that "the probability exists that silicone-gel is able to mediate an auto-immune reaction"); Jerome S. Nosanchuk, *Injected Dimethyldiphenylsiloxane Fluid: A Study of Antibody and Histologic Response*, 42 PLASTIC & RECONSTRUCTIVE SURGERY 562, 563-65 (1968) (finding modular inflammation in animals receiving silicone injections); R.H. Rigdon & Alfred Dricks, *Reaction Associated With a Silicone Rubber Gel: An Experimental Study*, 9 J. BIOMEDICAL MATERIALS RES. 645, 645 (1975) (concluding that the injection of silicone oil and a partly oxidized catalyst into mice, rats, and rabbits caused an inflammatory reaction).

122. See Frank B. Vasey et al., *Clinical Findings in Symptomatic Women with Silicone Breast Implants*, 24 SEMINARS ARTHRITIS & RHEUMATISM 22, 22 (Supp. 1, 1994) (citing 21 case studies showing a connection between connective-tissue disease and silicone breast implants).


125. See CRANOR, supra note 124, at 17-21; Green, supra note 25, at 654-56; Sanders, supra note 12, at 20-21.
Because they involve a relatively small number of persons exposed to a substance, case studies cannot provide conclusive evidence. Due to their small scale, their results may be purely coincidental rather than a reflection of any causal mechanism.\textsuperscript{125}

Epidemiological studies suffer from a number of problems that make them inconclusive. First, epidemiological studies are generally unable to detect small increases in the risk of harmful effects from a substance, especially if the background risks of the same harmful effects are extremely low.\textsuperscript{127} Second, epidemiological studies typically lack follow-up times long enough to ensure that diseases with long latency periods are discovered.\textsuperscript{128} Third, epidemiological studies may suffer from a number of biases such as selection bias, which occurs when the exposed group is selected in a way that makes it more or less susceptible to disease for reasons independent of exposure; diagnostic bias, which occurs when the disease in question is not accurately determined; exposure bias, which is the danger of selecting a study population especially likely or unlikely to have been exposed to the disease; and recall bias, which is the tendency of those who are in a study to recall incorrectly whether they were exposed to the agent being studied.\textsuperscript{129} Fourth, epidemiological studies may be flawed because of the presence of unaccounted-for confounders—undiscovered factors that independently affect disease rates in the studied population.\textsuperscript{130}

\textbf{C. The Breast Implant Litigation and a Hypothetical Lawsuit}

Against this background, suppose a woman who received silicone breast implants brings suit against the manufacturer on behalf of her child, whom she breast-fed and who now suffers from a disease of the esophagus that makes it difficult for the child to swallow and results in digestive disorders. The case turns on scientific testimony about whether silicone

\begin{flushleft}
\textsuperscript{125} Green, supra note 25, at 658; see also Jorge Sánchez-Guerrero et al., Silicone Breast Implants and Rheumatic Diseases: Clinical, Immunologic, and Epidemiologic Studies, 37 \textsc{Arthritis} \& \textsc{Rheumatism} 158, 165-66 (1994) (attributing the failure of most studies to identify a “consistent pattern of immune response [to silicone gel breast implants]” to “inadequate sample size”).

\textsuperscript{127} Green, supra note 25, at 653. The recent Mayo Clinic epidemiological study made this point explicit in noting its limited power to detect an increased risk of rare connective-tissue diseases such as systemic sclerosis: “Indeed, we calculated that it would require a sample of 62,000 women with implants and 124,000 women without implants, followed for an average of 10 years each, for a doubling of the relative risk of this condition to be detected among women with implants, assuming that the annual incidence of systemic sclerosis is 1.6 cases in 100,000 women.” Gabriel et al., Risk of Connective-Tissue Diseases, supra note 123, at 1701.

\textsuperscript{128} See Shanna H. Swan, Epidemiology of Silicone-Related Disease, 24 \textsc{Seminars Arthritis} \& \textsc{Rheumatism} 38, 41-42 (1994) (criticizing two epidemiological studies for inadequate follow-up).

\textsuperscript{129} Green, supra note 25, at 649-51; see Swan, supra note 128, at 40 (noting the many possible sources of bias in any study design).

\textsuperscript{130} Green, supra note 25, at 651.
\end{flushleft}
implants cause this disorder in children who were breast-fed by mothers with implants. The plaintiff seeks to put on experts who will testify that, to a reasonable medical certainty, the implants cause the disorder, and the defendant seeks to put on experts who will testify that, to an equally reasonable medical certainty, the implants do not cause the disorder.

To properly perform the gatekeeping function assigned to her by Daubert, the trial judge must assess the studies that provide the basis for the various experts’ testimony not to determine whether the studies support the conclusions to which the experts plan to testify, but to decide whether the studies constitute genuine scientific knowledge as defined in Daubert. The admissibility decision should not turn on the judge’s own evaluation of the relationship between the strength or content of the expert’s opinion and the strength or content of the research on which it is based. Daubert specifically assigns the task of identifying any deficiency in the support for an expert witness’s conclusions to “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.” The admissibility determination must “focus ... solely on principles and methodology, not on the conclusions they generate.”

The plaintiff seeks to introduce scientific expert testimony based on case studies made by Dr. Jeremiah Levine and Dr. Norman T. Ilowite.\textsuperscript{131}

\textsuperscript{131} Contrast the judge’s admissibility decision with a decision on the sufficiency of evidence. A judge might evaluate the adequacy of support for an expert’s conclusions on causation in deciding motions for summary judgment, directed verdict, or judgment notwithstanding the verdict. When considering such motions, it is appropriate for the judge to consider sufficiency of evidence. If the basis for an expert’s opinion is unduly flimsy, a court could judge one party’s expert testimony insufficient to support a verdict for that side and grant the motion against that party, assuming no other evidence sufficiently supports the party’s case. This would be an unusual outcome in a mass exposure case, in which questions of causation are usually left to the jury. \textit{But see In re Agent Orange Prod. Liab. Litig.}, 611 F. Supp. 1223, 1259-60 (C.D.N.Y. 1985) (holding that summary judgment for the defendant was proper because the plaintiff had failed to meet the burden of proving causation), aff’d, 818 F.2d 187 (2d Cir. 1987), cert. denied, 487 U.S. 1234 (1988).


\textsuperscript{133} Id. at 2797. When it comes to testability, the object of this focus is a bit obscure. Is the trial judge to ask whether case studies are testable? Strictly speaking, this question makes little sense. It is hypotheses, not methods, that are testable—subject to confirmation or falsification through experimentation. Speaking more precisely, the question could mean one of three things. It could mean that the judge should ask whether case studies proceed by testing hypotheses, or it could mean that the judge should ask whether case studies generate testable hypotheses, or it could mean that the judge should check for both.

The third alternative best serves the goal of distinguishing respectable science from crank science. Respectable science both tests hypotheses and generates hypotheses. Practically any method or theory can generate testable hypotheses—a seer staring into a crystal ball may be inspired to formulate predictions that can be confirmed or falsified. What is distinctive about genuine science is that it generates hypotheses through experimentation that tests prior hypotheses. This cycle of hypothesizing and experimenting lies at the heart of the empiricist vision.

\textsuperscript{134} Jeremiah J. Levine & Norman T. Ilowite, \textit{Sclerodermalike Esophageal Disease in Children Breast-Fed by Mothers with Silicone Breast Implants}, 271 JAMA 213 (1994). Scleroderma is a...
Levine and Ilowite examined eleven children born to women with silicone breast implants. Of the eight who were breast-fed, six suffered from the esophageal disease. The physicians concluded that the children's problems could be caused by silicone itself, by other by-products of the implants, or by the mother's antibodies—developed in reaction to the implants—transmitted via breast milk. The doctors also stated that because the children in the study come from four families, genetic factors cannot be excluded as causes despite the rarity of inherited scleroderma. Finally, Levine and Ilowite concluded:

The true incidence of this disorder among breast-fed children is unknown and cannot be estimated from our study because of selection bias. Studies examining greater numbers of BFSI [breast-fed silicone implant] children are needed to confirm these results and to determine the long-term outcome of these children.

A trial judge deciding whether to admit testimony based on the Levine and Ilowite case studies must decide whether case studies are a permissible methodology according to Daubert. She must consider testability, rate of error, peer review and publication, and general acceptance. Case studies fulfill the criterion of testability; they follow the empiricist cycle of experimentally testing hypotheses to generate additional experimentally testable hypotheses. Levine and Ilowite's case studies tested the hypothesis that "breast-fed children of mothers with silicone implants are at increased risk for the development of sclerodermalike esophageal involvement compared with children not exposed to silicone implants."

They did so by examining a group of children with gastrointestinal problems. Some children's mothers had implants, while other children's mothers did not. Among the children of the women with implants, some had been breast-fed, some bottle-fed. The esophageal disease afflicted only children breast-fed by mothers with silicone breast implants that causes thickening of the skin and has been linked to exposure to silicone through silicone breast implants. Id. at 213. Some of the children in the Levine and Ilowite study suffered from a sclerodermalike disease of the esophagus that made it difficult for them to swallow. Id. at 215.

---

135. Id.
136. Id. at 216.
137. Id.
138. Id.
139. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2796 (1993) (requiring judges to make a preliminary assessment of whether the methodology is scientifically valid and whether that methodology properly can be applied to the facts at issue).
140. Levine & Ilowite, supra note 134, at 216.
141. Id. at 213.
142. Id.
implants.\textsuperscript{143} The study generated—or regenerated—the hypothesis it tested. That is, the authors concluded that based on their results, the hypothesis merits further testing. This is a fruitful outcome.\textsuperscript{144} Levine and Ilowite's research fulfills the testability criterion. The study also meets two more of the \textit{Daubert} factors: it appeared in a peer-reviewed journal and followed a method that enjoys legitimacy in the scientific community. Therefore, it would seem that a trial judge should admit testimony based on Levine and Ilowite's work.

Although admissible, Levine and Ilowite's case studies are hardly conclusive on the issue of causation, as the authors themselves recognize.\textsuperscript{145} Cognizant of the dangers of cross-examination, our hypothetical plaintiff seeks to introduce additional evidence to bolster her child's claim. Although to date no animal or epidemiological studies specifically address the links between silicone breast implants, breast-feeding, and sclerodermalike disease in children, some studies address the more general issue of the association between silicone implants and various connective-tissue disorders, including scleroderma.\textsuperscript{146}

In 1993, Dr. John Naim and colleagues published a study investigating the hypothesis that silicone provokes immune responses.\textsuperscript{147} The study demonstrated that when rats were injected with silicone and a known antigen (a substance that provokes an immune response), the mixture provoked a strong antibody response.\textsuperscript{148} Because the level of the known antigen was too low to produce such response by itself, the researchers concluded that silicone may act as an adjuvant, stimulating immune response when combined with other immune-provoking substances.\textsuperscript{149} The authors recommended further investigation of this hypothesis.\textsuperscript{150}

If the plaintiff whose child has suffered esophageal disease seeks to introduce scientific testimony based on the Naim study,\textsuperscript{151} it should be admitted under \textit{Daubert}. The study empirically tested a hypothesis and generated a further one; it appeared in a peer-reviewed journal; and,

\begin{itemize}
\item \textsuperscript{143} \textit{Id.} at 215.
\item \textsuperscript{144} On the revised empiricist view of science, fruitfulness distinguishes worthwhile science from poor science. \textit{See} text accompanying notes 60-72.
\item \textsuperscript{145} Levine & Ilowite, \textit{supra} note 134, at 216.
\item \textsuperscript{146} For present purposes, I am going to assume that these studies meet the relevance requirement articulated in \textit{Daubert} despite the somewhat attenuated connection between the studies and the facts of the hypothetical case.
\item \textsuperscript{147} Naim et al., \textit{supra} note 121, at 151.
\item \textsuperscript{148} \textit{Id.} at 153-54.
\item \textsuperscript{149} \textit{Id.} at 157.
\item \textsuperscript{150} \textit{Id.} at 160.
\item \textsuperscript{151} Since one of Levine and Ilowite's postulated hypotheses developed on the basis of their case studies is that antibodies produced by women with implants are transmitted to their children through breast milk, the Naim study bears on the hypothetical plaintiff's case.
\end{itemize}
although the general relevance of animal studies to human health is difficult to ascertain, they are a generally accepted research methodology. The research fulfills three of the four factors discussed in *Daubert*; this should suffice for admissibility.

The defendant-manufacturer in our hypothetical lawsuit seeks to admit testimony based on a recently published large-scale epidemiological study, the first epidemiological study of the effects of silicone breast implants. Its authors reportedly found no evidence of an association between breast implants and connective-tissue disorders including scleroderma. The authors, however, do not regard the study as conclusive on the issue of the toxicity of silicone implants and urge additional research on the question.

This epidemiological study, like the other two discussed above, meets three of the four *Daubert* criteria and merits admission. Gabriel and her colleagues tested a hypothesis and regenerated it. Through a comparative survey of the health records of women with and without silicone breast implants, the authors tested for a statistical correlation between receiving implants and developing connective-tissue disorders. This empirical process generated the conclusion that more rigorous epidemiological studies are needed to test whether a connection between implants and connective-tissue disorder exists. Before publication in a refereed journal, the

152. Gabriel et al., *Risk of Connective-Tissue Diseases*, *supra* note 123.

153. See Marcia Angell, *Do Breast Implants Cause Systemic Disease?*, 330 NEW ENG. J. MED. 1748 (1994) (contending that before the Gabriel study "there had been almost no reliable evidence bearing on the subject" of purported links between silicone gel breast implants and connective-tissue disorders). Since the publication of this study, the findings of two other epidemiological studies have been presented to the American College of Rheumatology. See Philip J. Hilts, *2 Studies Find No Breast-Implant Tie to Connective-Tissue Illness*, N.Y. TIMES, Oct. 26, 1994, at A23 (reporting the findings of a study conducted by Dr. Marc C. Hochberg and another by researchers at the Harvard Medical School). These studies did not detect an association between nonruptured implants and connective-tissue disorders. *Id.* Due to sample size, one of the studies, according to its author, would not detect an increase in risk created by the implants unless the increase were 70% or more. *Id.*


155. Gabriel et al., *Risk of Connective-Tissue Diseases*, *supra* note 123, at 1697-98. The authors note the methodological shortcomings of their study, which are the usual problems confronted by epidemiological research. *Id.* at 1701-02.

156. *Id.* at 1697.

157. *See id.* at 1701 (predicting that the results of ongoing studies will help determine the link between silicone breast implants and connective-tissue disorder).
study received extensive peer review, resulting in extensive revisions. Finally, a significant number of scientists accept the methods of epidemiological research.

D. Revised Empiricism Realized, Recurrent Strong Uncertainty Recognized

As the foregoing applications illustrate, Daubert's interpretation of Federal Rule of Evidence 702 leads to the admission of scientific expert testimony on both sides of the cause-in-fact issue in our hypothetical case. The factfinder will hear testimony that maternal implants can cause sclerodermalike disease in breast-fed infants and testimony that implants do not cause scleroderma at all. If each side's attorneys are skillful cross-examiners, the factfinder will also receive some information about the underlying basis of each expert's opinion. Taken all together, the testimony will reveal that scientists have not reached any firm conclusions regarding the causal powers of silicone breast implants; researchers have drawn extremely tentative conclusions in opposite directions depending on their subdisciplines.

In this subpart, I address two interesting implications of the above hypothetical case. First, the state of scientific research, and therefore the scientific expert testimony admissible under Daubert, is just what the revised empiricist would expect it to be. Second, this testimony provides an insufficient basis for concluding either that the mother's implants did not cause the child's esophageal disease or that they did. This is a specific case of a recurrent type of uncertainty in which the reasonable factfinder will be unable to conclude that it is more likely than not that a litigated substance is unsafe or that it is more likely than not that the substance is safe. Procedurally speaking, whenever strong uncertainty about general causation exists, the party bearing the burden of proof on the causation question should lose. In the next section of this Article, I will show how this sort of strong uncertainty systematically interferes with realizing the goals of tort law.

158. Angell, supra note 153, at 1749 ("The paper by Gabriel and colleagues was reviewed by three outside experts and twice by one of our statistical consultants, and it was revised extensively.").

159. In Hopkins v. Dow Corning Corp., 33 F.3d 1116 (9th Cir. 1994), the Ninth Circuit sustained a jury verdict finding Dow liable for the plaintiff's mixed connective-tissue disease. The court did not reach the issue of the sufficiency of the evidence on the question of causation; the opinion addressed only the admissibility of plaintiffs' expert testimony on the issue. Id. This may have been because, as the plaintiffs argued, Dow failed to preserve an objection to the sufficiency of the evidence on causation when it failed to move for directed verdict on this ground. See Brief of Plaintiff-Appellee at 55-56, Hopkins (No. 92-16132). Furthermore, it appears that unlike the hypothetical defendant discussed in the text, Dow did not present expert testimony rebutting the plaintiff's evidence of causation; instead, Dow relied solely on its objections to the admissibility of plaintiff's expert testimony. See Appellant's Opening Brief at 44-50, Hopkins (No. 92-16132).
Revised empiricism teaches us to regularly expect strong uncertainty about causation in mass exposure litigation. According to revised empiricism, science is dynamic, non-dogmatic, theory-dependent, and empirical. The science presented in the hypothetical case possesses these characteristics. The testimony indicates that the science investigating the causal powers of silicone is still developing, with all researchers drawing only tentative conclusions and calling for further study. Depending upon the scientific discipline in which they work, different researchers urge the pursuit of the negative or the positive hypothesis on the causal connection between silicone implants and disease in humans. Clinicians like Levine and Ilowite, educated to place weight on clinical experiences with patients, conclude on the basis of such experiences that the hypothesis that implants cause esophageal disease is sufficiently likely to be true that it warrants further study. John Naim, an animal researcher working from the background assumption that animal effects have implications for human health, concludes that the effects of silicone on rats tend to suggest a connection between implants and autoimmune disease. Sherine Gabriel and other epidemiologists, schooled in a correlative understanding of causation, conclude that statistical evidence, although not wholly reliably gathered, reinforces the hypothesis that breast implants do not cause autoimmune disorders in humans. While these scientists all regard their findings as tentative, they also judge that the experimental research in their respective disciplines suggests the correct understanding of the causal powers of silicone.

The testimony in the esophageal disease hypothetical is insufficient to provide a basis for a conclusive finding on causation. The scientists whose studies provide the basis for the fictional experts' testimony do not commit to firm positions on the question because at this stage, competing scientific evidence points in different directions. If scientists cannot draw firm conclusions, the jury cannot do so in any principled fashion, even if the expert witnesses claim to have conclusive opinions on the question of causation. A jury confronted with conflicting scientific testimony, none of

160. This may be especially true in cases such as Daubert which involve suspected teratogens (chemicals known to cause limb reduction defects). On remand of Daubert, Judge Alex Kozinski noted:

[S]cientists simply do not know how teratogens . . . do their damage: They cannot reconstruct the biological chain of events that leads from an expectant mother's ingestion of a teratogenic substance to the stunted development of a baby's limbs. Nor do they know what it is about teratogens that causes them to have this effect.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1311-12 (9th Cir. 1995).

161. Levine & Ilowite, supra note 134, at 216.

162. Naim et al., supra note 121, at 151.

163. See, e.g., Gabriel et al., Risk of Connective-Tissue Diseases, supra note 123, at 1697 (finding "no association between breast implants and the connective-tissue diseases . . . that were studied").
which rests on scientific research that even purports to be conclusive, might decide to find one way or the other on the question of causation. In such cases, however, we should be suspicious of the accuracy of the jury's choice. Scientists' genuine uncertainty renders it a matter of luck whether the jury answers the causation question correctly.¹⁶⁴

We provide juries with expert testimony in areas requiring expertise because we doubt that jurors can accurately decide matters of fact in such areas without assistance. We expect the jury's conclusions to piggyback on those of the experts. In a case in which the experts have not reached strong conclusions, the jury cannot meet this expectation. Jurors will be left to their own devices, forced to draw conclusions in situations in which those with superior knowledge and understanding of the field decline to do so.

The situation confronting a jury in a case like the esophageal disease hypothetical is not one in which the jury is asked to make a probabilistic judgment on the basis of competing statistical information from a variety of experts. Animal studies and case studies do not straightforwardly provide probabilistic information about causation. Even if, theoretically speaking, any information presented affects the probability of the truth of a hypothesis about causation, the jury is not in a position to compute that probability. To do so would require extensive background knowledge of the likelihood of the truth of that hypothesis without the addition of the new information. Laypeople do not possess this background knowledge. Furthermore, even with that knowledge, it can be extremely difficult to decide how new information affects the likelihood of the truth of the hypothesis. This is one reason why scientists, who may arguably possess the necessary background knowledge, do not draw strong conclusions from isolated research results.¹⁶⁵

¹⁶⁴. The problem is the same whether jurors are presented with conflicting scientific opinions, all couched conclusively, or with individual testimony, expressing uncertainty: the jury has no principled way of deciding the underlying issue. This is sometimes discussed in terms of the jury's inability to accurately assess the credibility of experts. See Samuel R. Gross, Expert Evidence, 1991 WIS. L. REV. 1113, 1182 (1991) (stating that the problem with expert testimony is that "[w]e call expert witnesses to testify about matters that are beyond the ordinary understanding of lay people... and then we ask lay judges and jurors to judge their testimony"); Richard Lempert, Civil Juries and Complex Cases: Taking Stock After Twelve Years, in VERDICT: ASSESSING THE CIVIL JURY SYSTEM 181, 202 (Robert E. Litan ed., 1993) ("A... difficulty the jurors had in some cases was understanding esoteric facts when the parties offered conflicting expert testimony from apparently credible sources."). But it can also be understood as a result of the jury's inability to independently assess the meaning and plausibility of the substance of the testimony. Richard Lempert suggests that when experts present firm but conflicting conclusions, credibility is not the important question because in such cases it is likely that both positions are reasonably maintained. Id. at 194. When this is so, a case presents the problem of strong uncertainty.

¹⁶⁵. I am arguing that a resort to Bayesianism will not resolve the practical problems typically raised by scientific evidence in mass toxic tort litigation. For a similar argument addressed to another legal context, see Richard Lempert, Some Caveats Concerning DNA as Criminal Identification
A case like the esophageal disease hypothetical exemplifies the strong uncertainty about causation that testimony admissible under Daubert will make apparent. Of course, one example does not establish the contention that this situation will increasingly be the norm. To support this claim, I have indicated the general characteristics that the example illustrates, characteristics which suggest that strong uncertainty about general causation is a recurrent feature of mass exposure litigation. My discussion sets aside a number of important issues pertaining to whether the use of expert witnesses provides juries with an accurate sense of the state of knowledge in the relevant field. The ways in which lawyers hire, prepare, examine, and cross-examine expert witnesses all arguably impede juries' understanding of the information expert evidence is supposed to help them comprehend. Even if we eliminated all the problems posed by these practices, the difficulty of recurrent strong uncertainty about causation would nonetheless persist as long as we employ admissibility standards that promote the accurate presentation of scientific knowledge. Suppose we became confident that juries were receiving scientific expert testimony undistorted by trial lawyers' tricks. Revised empiricism leads us to expect that in a significant number of cases even undistorted testimony would not provide a reasonable basis for concluding that it is more probable than not that a substance is safe or unsafe. This is because when strong uncertainty about causation exists, it is a product of science, not a product of how science is presented at trial. No matter how perfectly science is presented, the problem will remain.

_Evidence: With Thanks to the Reverend Bays_, 13 CARDozo L. REV. 303, 331 (1991) (suggesting that although a Bayesian approach to presenting DNA evidence might make some mathematical sense, it would not necessarily promote the jury's understanding of the role and relevance of DNA testing in criminal identification).

166. Samuel Gross has offered an account of why expert evidence "is frequently misleading, unintelligible or unreliable . . . ." Gross, _supra_ note 164, at 1131. Gross explains that the scope of permissible expert testimony, the expert's interest in pleasing the lawyer who has hired her, and the opportunity to shop for a confident, charismatic expert all contaminate the expert selection process. _Id._ at 1133. The importance of careful preparation of experts "pushes the expert to identify with the lawyers on her side and to become a partisan member of the litigation team." _Id._ at 1139. On direct examination, lawyers have an incentive to encourage experts "to compromise accuracy to achieve clarity, and to favor simple assertions over complex explanations." _Id._ at 1164. Finally, the broad scope of permissible questioning of experts during cross-examination allows the lawyer to confuse finders of fact by "pick[ing] and choos[ing] whatever articles and books she wants from the entire library of a profession, show[ing] them to the witness[,] and read[ing] selections or summariz[ing] their conclusions for the jury—but never ask[ing] the expert for comments or opinions." _Id._ at 1170.

167. In fact, the esophageal disease hypothetical is an example of a case in which undistorted scientific information fails to provide the basis for a conclusion one way or the other as to the toxicity of the substance in question.
V. Information About Causation and the Heart of Tort Law

Strong uncertainty about general causation strikes at the heart of the tort system. To appreciate the threat, we need to clarify the relationship between causation and the legal doctrine of tort law and the relationships between that doctrine and tort law’s objectives.

A. Tort Goals, Tort Doctrine, and Information About Causation

Tort law as we know it attempts to achieve three goals. First, it seeks to allocate resources to those who have been injured by unduly risky conduct or products. Second, it aims to deter excessively risky conduct and the manufacture of excessively risky products. Third, it tries to expressively yoke victims of overly risky activity with their injurers by requiring injurers to compensate those they have harmed.

These three goals are related to one another. Tort law accomplishes its deterrent effect by imposing liability on those who pose excessive risk.
to others and injure them; it accomplishes its allocative goal by shifting the resources of excessive-risk-creators to their victims; it achieves its expressive goal by requiring a payment of damages from tortfeasor to victim. Nonetheless, the goals are conceptually and practically distinct. Resources for victims of unduly risky conduct or products could come from a variety of sources, not just the party who created the risk. Fines and jail sentences could be used to deter inordinate risk-taking. Victims and injurers could be yoked together by requiring formal public apologies from excessive-risk-takers to those they have harmed. Contemporary tort law, however, rejects these alternative means to its ends, relying instead primarily on two liability regimes, negligence and strict products liability, to determine when a defendant should pay monetary damages to a plaintiff.

Understanding the relationship between causation and the traditional fundamental goals of the tort system requires an exact understanding of the role of information about causation within the law of negligence and strict products liability. First, consider an action for negligence. The plaintiff bears the burden of establishing that the defendant breached the duty of care, that the breach was the cause-in-fact and proximate cause of her injury, and that the plaintiff incurred damages as a result of the injury. Information about causation is important to two of these elements: cause-in-fact and breach.

The connection between information about causation and cause-in-fact is obvious. In order to establish that the injury would not have happened but for the defendant’s conduct, the plaintiff must have information about the causal powers of the defendant’s conduct. The connection between information about causation and breach is more subtle. One of the ways tort law allows a plaintiff to establish that the defendant has breached the duty of care is to allow the plaintiff to show that the defendant’s conduct was inefficiently risky—that the costs of the harms risked by the conduct, discounted by the likelihood of the harms occurring, exceeded the costs of taking precautions against these harms. Information about causation is critical to arguments based on the putative inefficiency of the defendant’s conduct. To establish inefficiency, the plaintiff must produce evidence of the harms risked by the defendant’s conduct. This requires information about the causal powers of that conduct, so that the plaintiff can establish what the consequences of the conduct could have been and how likely the

---

171. United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947). The plaintiff may also show breach in certain cases by arguing that the defendant’s conduct violated custom among those similarly situated, Keeton et al., supra note 170, § 33, or by arguing that the defendant’s conduct violated a criminal statute designed for the protection of those in the plaintiff’s position, id. § 36. Information about causation is irrelevant to arguments based on custom or statutes.
various consequences were. Without this information, the plaintiff cannot perform the calculus of risk.

In a strict products liability action, the plaintiff bears the burden of showing that the defendant's product was defective so as to be unreasonably dangerous and was a cause-in-fact of plaintiff's injury. As with a negligence claim, the relationship between information about causation and cause-in-fact is obvious. The relationship between this information and defect is more subtle.

In mass exposure litigation, plaintiffs typically argue that an entire product line is defective by virtue of its design (as opposed to arguing that a flaw in construction rendered one specific unit of the product unreasonably dangerous). Most jurisdictions recognize three types of design defect claims. First, a product may be defective because as designed, it fails to perform in accordance with ordinary consumer expectations. Second, a product may be defective because the risks created by its design outweigh the product's utility. Third, a failure to provide an adequate warning of the dangers associated with the product may be classified as a defect in its design.

All three approaches require information about causation.

173. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (1965) ("Defective condition. The rule stated in this Section applies . . . where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer . . . ."); id. § 402A cmt. i ("Unreasonably dangerous . . . . The article . . . must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it . . . .").

Some states apply a modified risk-utility analysis. See, e.g., Dart v. Wiebe Mfg., Inc., 709 P.2d 876, 880 (Ariz. 1985) (applying the risk-utility test only in situations in which the consumer-expectation test fails to provide a clear answer); Lamkin v. Towner, 563 N.E.2d 449, 458 (Ill. 1990) (requiring the plaintiff to present evidence of a safer alternative design); Morningstar v. Black & Decker Mfg. Co., 253 S.E.2d 666, 682-83 (W. Va. 1979) (adopting "[t]he standard of reasonable safeness and limiting the role of risk-utility analysis to "setting the general contours of relevant expert testimony concerning the defectiveness of the product").

175. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965) ("Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning . . . . as to its use."). Many courts have held that for the plaintiff to establish inadequate warning as a design defect, he must prove that the defendant-manufacturer knew or should have known of the risk or hazard about which it failed to warn, incorporating a negligence inquiry into the design defect theory. See, e.g., Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1083 (5th Cir. 1973) (applying Texas law), cert. denied, 419 U.S. 869 (1974). But see Beshada v. Johns-Manville Prods. Corp., 447 A.2d 539, 546 (N.J. 1982) (holding that a manufacturer's inability to know of dangers associated with exposure to asbestos does not constitute a defense to a strict products liability action). Beshada's holding has since been limited to the specific facts of that case. Feldman v. Lederle Labs., 479 A.2d 374, 387-88 (N.J. 1984).
To show that a product by design failed to perform as an ordinary consumer would have expected, we have to know how the product actually performed. We need to know what its causal effects on the consumer were before we can decide whether these outcomes conflict with ordinary consumer expectations. Likewise, making a risk-utility assessment requires sufficient information about the causal effects of a product's design to show whether the positive effects or the negative effects dominate. Note that the information required here resembles the information necessary to establish breach in a negligence action by using the calculus of risk. Finally, information about causation is relevant to determining the adequacy of a warning. Before we can decide whether a manufacturer provided adequate warning of a danger allegedly associated with its product, we need to know whether the product causes that problem, and this requires information about the product's causal powers.

To understand the relationship between tort doctrine involving causation and tort goals, we need to appreciate how determinations of cause-in-fact, breach, and design defect serve the fundamental objectives of tort. I will consider each doctrinal element's function in turn.

Establishing that the defendant's conduct or product was the cause-in-fact of the plaintiff's injury serves all three of the fundamental goals of tort law. To allocate resources to those who have been harmed by undue risk-taking, we need to know how an injured person received his injuries. This is a necessary step in establishing that his injury actually arose from an unduly risky activity. To effectively deter overly risky activity, tort liability must give people incentive to refrain from causing injury by such activity. By premising liability on a showing of causation, tort law motivates those people who are in a position to avoid the imposition of harm to do so. Finally, causation defines the relationship between an injurer and her victim: the victim is specifically the injurer's victim, rather than just any victim, precisely because the injurer caused that specific victim's harm.

Establishing breach by a calculus of risk serves two of tort law's goals. Tort's allocative goal is a restricted one, limited to those injured as a result of someone else's excessively risky activity. In a negligence

In addition to its role in a design defect case, adequacy of warning may be an issue in a negligence claim. In this posture, the question of adequacy pertains to the issue of breach. For the relationship between information about causation and breach, see supra text accompanying note 171.

176. This will be true regardless of which party bears the burden of proof on the risk-utility question. In some jurisdictions, a plaintiff alleging design defect who establishes cause-in-fact thereby shifts to the defendant the burden of demonstrating the safety of the product according to a risk-utility test. Barker, 573 P.2d at 455.

action, breach is the measure of undue riskiness. Determining that the plaintiff's injuries resulted from the defendant's breach ensures that the plaintiff merits aid. Tort's deterrence goal is also limited: tort seeks to deter only inordinately risky conduct, not all risky conduct. Demonstrating breach through the calculus of risk respects this limitation. By showing that the risks of the defendant's conduct outweighed its benefits, the plaintiff proves that the defendant's behavior created an excessive risk of harm, not just some risk of harm.

In a strict products liability action, demonstrating that a product is defective so as to be unreasonably dangerous serves the allocative and deterrence functions of tort law. Tort law does not attempt to shift resources to every person injured by a product. The goal is to shift resources to those injured by products that pose excessive risk, judged either by a consumer expectations test or by a risk-utility analysis. Likewise, tort law does not attempt to deter the manufacture of all products or all products somewhat likely to cause injury. Tort aims to deter production of products that are excessively likely to cause undesirable harm. Tort law provides correct incentives by allowing manufacturers to escape liability if they can show that their design satisfies ordinary consumer expectations, is appropriately risky, or properly advertises its risks.

The more perfectly legal factfinders ascertain cause-in-fact, breach, and design defect, the more likely it is that the current tort system will meet all of its objectives. But of course legal factfinders cannot and do not achieve perfection in these determinations. There are many reasons for this. The one I will concentrate upon is strong uncertainty about general causation, which I will argue is more problematic than other types of uncertainty sometimes encountered in mass exposure litigation.

B. The Impact of Different Kinds of Uncertainty About Causation

So far in this Article, I have been discussing strong uncertainty about general causation. When faced with this type of uncertainty, it is not possible to conclude that it is more likely than not that a substance is harmful to humans, nor is it possible to conclude that it is more likely than not that the substance is safe. Strong uncertainty about general causation is more threatening to the traditional objectives of tort law than either identity uncertainty about specific causation or probabilistic uncertainty about specific causation, two other types of uncertainty about causation sometimes encountered in mass exposure litigation.

Identity uncertainty about specific causation arises in cases involving multiple defendants where each defendant has produced a substance that has harmed people, but it is unclear which producer has caused whose
Courts have devised a variety of solutions to this problem, most of which focus on allocating liability among all the possible tortfeasors, exempting only those who can establish by a preponderance of the evidence that they did not cause the plaintiff's injury. Probabilistic uncertainty about specific causation arises in cases in which it is known that a substance causes a particular injury in a certain percentage of cases of that injury, but it is not possible to distinguish the cases caused by the substance from those caused by other factors. Courts have not modified traditional doctrine to address this type of uncertainty, although scholars have recommended proportional liability as a solution. Defendant-manufacturers would be required to compensate injured parties exposed to demonstrably toxic products in proportion to the established likelihood that the substance caused the plaintiffs' injuries.

Both market-share and proportional liability depend upon the existence of reliable, meaningful information about the toxicity of a litigated substance. Market-share liability assumes that the plaintiff has carried the burden of proof on the question of whether her injury was caused by the substance even though she has not met the burden of showing which particular defendant produced the particular batch to which she was exposed. Proportional liability assumes that even if the plaintiff cannot meet the traditional burden of proving that the defendant's conduct or product was more than fifty percent likely to have caused her injury, she can establish, with significant certainty, a specific probability that the defendant caused her injury. For example, she can provide convincing evidence of a forty-percent chance that the defendant's product injured her.

Premised on some significant degree of certainty about the causal powers of a litigated substance, market-share and proportional-liability schemes are able to further the traditional goals of tort, if not to accomplish them fully. Market-share liability requires excessive-risk-creators to compensate those who have been injured by the relevant kind of overly risky activity. This satisfies tort's allocative goal by shifting

---

178. This is the case, for example, in DES litigation, in which plaintiffs could not identify which of approximately 200 DES manufacturers made the specific dose that harmed them. See Sindell v. Abbott Labs., 607 P.2d 924, 926-28, 931, 936-38 (Cal.) (concluding that the plaintiff could maintain a cause of action against five DES manufacturers who produced a substantial percentage of the DES marketed despite the fact that the plaintiff could not prove that any of the defendants produced the specific dose taken by the plaintiff's mother), cert. denied, 449 U.S. 912 (1980).

179. See id. at 937 (creating a market-share theory of recovery); Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069, 1078 (N.Y.) (adopting the market-share theory in another DES case), cert. denied, 493 U.S. 944 (1989).


181. E.g., id. at 866, 859-66 ("[T]he proportionality rule is ideally suited to the task of resolving the problem of causal indeterminacy in mass exposure cases.").
resources to those injured by such activity. It also deters the production of excessively toxic substances by making manufacturers internalize costs associated with toxic products. Finally, market-share liability yokes together injurers with victims of their type of injurious activity even though the match is not based on a specific causal connection between the party who actually inflicted the injury and the party who suffered it. This expresses, to some degree, the connection between excessive risk creation, injury, and reparation.

Proportional liability approaches tort law's deterrence goal more nearly than it approaches the allocative and expressive goals. Ideally, a liability scheme forces defendants to internalize all the costs of their activities by requiring them to pay the total damages they inflicted. Rather than cover any one injured person's total losses, however, defendants under a proportional-liability scheme would pay the proportion of damages that corresponds to the probability that their conduct or product caused the plaintiffs' harms. If all those injured and exposed to the defendant's product or conduct were to seek recovery, the defendant's total liability would reflect the injury costs it had inflicted. This would deter defendants from imposing excessive injury costs.

Proportional liability would also mean, however, that some plaintiffs who had not in fact been injured by inordinately risky conduct or products would receive tort awards. In those cases, injurers would not be linked with the victims of (the relevant) injurious activity. Such outcomes would fail to serve the allocative and expressive goals of tort. Without proportional liability, though, these goals would be served even less. Under proportional liability, some plaintiffs who have indeed been injured by excessive-risk-creators receive resources from the relevant parties.

In the face of identity uncertainty about specific causation or probabilistic uncertainty about specific causation, relatively minor modifications of traditional tort rules permit significant accomplishment of tort law's goals. Strong uncertainty about general causation is another matter. Market-share and proportional-liability schemes approximate the outcomes that the traditional tort system would yield if there were fuller information about specific causation. Thus, they approximate the allocative outcomes, deterrence, and expressive connection between injurer and victim traditionally sought in tort. In contrast, strong uncertainty about general causation makes it impossible to approximate the results the system would reach with fuller information, and therefore makes it impossible to accomplish tort law's goals reliably.

When mass exposure litigation results in strong uncertainty about causation, it is impossible to tell whether any plaintiff was injured as a result of excessively risky conduct or an unduly risky product. Reaching a meaningful judgment on this question requires meaningful information about the causal history of a plaintiff's injuries. If the scientific evidence
warrants neither a conclusion that it is more likely than not that a substance causes harm nor a conclusion that it is more likely than not that the substance does not cause harm, a verdict in favor of a plaintiff or a group of plaintiffs is not based on a meaningful determination of the causal history of the plaintiffs' harms. The same point holds true for a verdict in favor of the defendant: In the face of strong uncertainty about general causation, a defendant's victory will not be based on a meaningful determination that the defendant did not cause the plaintiffs' harms.

Traditional rules regarding the burden of proof reflect a willingness to err on the side of failing to allocate resources to those who have been injured by inordinately risky conduct or products. If a plaintiff cannot show that it is more likely than not that a defendant's product or conduct causes harm to humans and caused the plaintiff's harm in particular, a verdict goes to the defendant. When there is recurrent strong uncertainty about general causation, this procedural mechanism has a dramatically pernicious effect on deterrence as well as on allocative outcomes.

Recurrent strong uncertainty about general causation prevents the law from regularly imposing liability in mass exposure cases when the defendant's action or product may in fact have created an excessive risk of undesirable harm. Whether she brings suit in negligence or strict products liability, if the plaintiff cannot meet the burden of proof on cause-in-fact, her action will fail. Strong uncertainty about general causation will prevent the plaintiff from meeting the burden. In such cases, a defendant will avoid liability even if her conduct or product poses excessive risk. Under current rules of procedure, even a perfectly functioning tort system will not reliably promote optimal levels of safety: it will underdeter excessively risky behavior. In fact, placing the burden of proof on the plaintiff creates a perverse incentive for actors to foster strong uncertainty about general causation, so as to escape liability whatever the actual causal powers of their conduct or product. In other words, the current system, rather than motivating actors to acquire sufficient information so as to align their estimations of risk with the actual causal impact their products or conduct will have, motivates actors to acquire only enough information about the causal powers of their products or conduct to be able to demonstrate strong uncertainty in the event of litigation.

Because recurrent strong uncertainty about general causation repeatedly interferes heavily with identifying both victims and creators of excessive risk, it will, of course, interfere heavily with pairing the two. This defeats the expressive goal of tort law.

C. The Scientific Attitude Toward Uncertainty

For those who favor the law's adopting a scientific approach to selecting information for factfinders to consider, it might seem appealing
for the law to adopt a scientific attitude toward uncertainty about causation. Since science and law gather information for different ultimate purposes, however, it does not make sense for the two fields to respond identically to uncertainty about matters of fact.

Law and science both seek correct factual information, but the two enterprises have different interests in this information. At one level, science pursues correct information simply to achieve a better understanding of the natural world. At another level, science seeks information in order to predict—and, ultimately, to control—what happens in that world. Regardless of which end—understanding or control—motivates a scientist, the appropriate response to uncertainty is to delay reaching a final conclusion until further research settles the issue. Likewise, it makes sense to revisit a previously settled issue if further data or more sophisticated theory casts doubt on the old conclusion. For science, these responses make sense because closure at the expense of correctness has no value to science. Understanding the natural world or predicting its behavior reliably requires factually correct conclusions, but conclusiveness in and of itself has no independent importance.

In law, the situation is different. Law pursues correct information in order to settle disputes promptly, decisively, and justly. Each of these goals is sometimes best served by deciding upon a final result in the face of uncertainty about seemingly pivotal matters of fact. Waiting for further research can easily be counterproductive to law’s ultimate purposes. This is especially true in large-scale, high-stakes litigation such as mass exposure lawsuits. Defendants in these cases typically face the prospect of hundreds, or even thousands, of lawsuits and potentially bankrupting liability exposure. Often, plaintiffs face debilitating long-term illnesses

182. The Federal Rules of Evidence reflect this orientation toward information: “These rules shall be construed to secure fairness in administration, elimination of unjustifiable expense and delay, and promotion of growth and development of the law of evidence to the end that the truth may be ascertained and proceedings justly determined.” FED. R. EVID. 102.

183. As Hart and McNaughton point out:

The law does not require absolute assurance of the perfect correctness of particular decisions. While it is of course important that the court be right in its determinations of fact, it is also important that the court decide the case when the parties ask for the decision and on the basis of the evidence presented by the parties. A decision must be made now, one way or the other. To require certainty or even near-certainty in such a context would be impractical and undesirable. The law thus compromises.

Henry M. Hart & John T. McNaughton, Evidence and Inference in the Law, DAEDALUS, Fall 1958, at 40, 45.

184. The Agent Orange litigation, for example, consolidated into a class action more than 600 separate actions originally filed by more than 15,000 named individuals. Peter H. Schuck, Agent Orange on Trial 4 (1986). Four hundred additional cases were brought by plaintiffs who “opted-out” of the class action. Id. In the Dalkon Shield case, 3.6 million women used the Dalkon Shield intrauterine device. Richard B. Sobol, Bending the Law 11 (1991). After resolving 7,700 cases at a cost of $260 million, id. at 23, the manufacturer of the Dalkon Shield, A.H. Robins Company, Inc., filed for bankruptcy in federal court. Id. at 47.
without easily available financial resources. Delaying already protracted litigation to await further scientific research would take a heavy toll on both groups. Mass exposure defendants would find it even more difficult to keep their business affairs in good order if it took longer than it already does to put a price tag on liability exposure. Even worthy plaintiffs would probably have a difficult time finding legal representation if payment of plaintiffs' attorneys' contingency fees could be delayed indefinitely while the courts awaited scientific research. Indefinitely staying results in mass exposure litigation harms societal interests as well as the litigants'. Postponing a final outcome ties up the courts, attorneys, and parties involved, making it difficult—if not impossible—for them to move on and allocate their resources elsewhere. In law, in contrast to science, closure and finality have value in their own right.

VI. Conclusion

In *Daubert v. Merrell Dow*, the Court adopted admissibility standards that reflect a contemporary philosophical understanding of science as a
dynamic field that achieves definite conclusions slowly and without dogmatic finality. In typical mass exposure cases, scientific research has only reached tentative, often contradictory conclusions about causation. The immaturity of scientific research, combined with the dynamic nature of science, means that at the time of mass exposure litigation, a reasonable factfinder will often be left in a state of strong uncertainty about general causation: \textit{i.e.}, the factfinder will be unable to conclude that it is more likely than not that a litigated substance is either safe or unsafe. In these circumstances, whichever party bears the burden of proof on the question of causation will lose not because the factfinder has good reason to conclude that the litigated substance does or does not cause harm, but because of a procedural default rule whose operation is not governed by the truth about causation. The current tort system, however, cannot operate effectively without substantively reliable information about the actual causal powers of allegedly harmful substances. The real difficulty presented by mass exposure litigation is recurrent strong uncertainty about causation, a substantive problem that cannot be redressed by revising admissibility standards or other procedural measures.

Because science cannot eliminate the problem of recurrent strong uncertainty about general causation in mass exposure litigation, and because science cannot tell law how to solve the problem, scholars, courts, and policymakers will have to look elsewhere for solutions. Before concluding my discussion, I sketch some possible adjustments and alternatives to the current tort system in order to identify some of the basic issues we would need to resolve before we could decide how the legal system should respond to strong recurrent uncertainty about causation.

The achievement of traditional tort goals depends heavily on reliable information about causation. Implicit in the traditional approach is the idea that the plaintiff’s failure to meet the burden of proof on causation generally arises from the fact that the defendant’s conduct or product did not cause the plaintiff’s harm. I have argued that in cases of strong uncertainty about general causation, this correlation breaks down. In a significant number of cases, scientific information about causation, considered in full, will leave the reasonable factfinder strongly uncertain about causation. But strong uncertainty does not necessarily correlate to safety. In at least some cases of strong uncertainty at the time of litigation, it will later be shown that the conduct or product at issue is in fact harmful to human beings.

We need to mute the impact of strong uncertainty about causation in order to minimize its interference with traditional tort goals. Alternatively, we could rethink our goals, reformulating them so that certainty about causation mattered less. I will survey three revisions of the current system, each of which would reduce the role of certainty about causation. The first
two suggestions are relatively minor modifications of the current system; they are both indirect methods for pursuing traditional tort goals that skirt the difficulties that strong uncertainty about causation creates for more direct pursuit of these goals. The third proposal, sketched in the most general terms, more drastically revises traditional goals. I present all three alternatives to the current tort system quickly and generally. Before any alternative could be selected for implementation, the details and effects of each one would have to be considered much more closely. I offer these lightly sketched alternatives to illustrate the ways in which redressing the problem of recurrent strong uncertainty about causation pushes us to reconsider traditional tort goals and how to achieve them.

One way to mute the impact of recurrent strong uncertainty about causation would be to shift the burden of proof on cause-in-fact and on breach or defect whenever the plaintiff could establish strong uncertainty about general causation. Another option would be to split damages in half—requiring the defendant to pay fifty percent of the plaintiff’s losses—in any case in which the plaintiff could establish strong uncertainty about causation, and the defendant could not eliminate it. Either of these changes to current rules would increase the incentive for the makers of potentially toxic substances to investigate the substances’ causal powers more carefully before distributing them widely.

Recall that repeatedly absolving defendants of liability in the face of strong uncertainty encourages defendants to market their products before they have extensive information about the causal powers of their goods. If strong uncertainty about general causation were an irremediable problem, shifting the burden of proof or splitting damages would simply invert the troublesome results produced by the current rules. Instead of erring on the side of failing to allocate resources to those who have in fact been injured by excessively risky behavior, we would err on the side of allocating resources to those whose injuries have some other causal history. Instead of sometimes mistakenly failing to require payment from defendants who have indeed taken undue risks, we would sometimes mistakenly require payment from defendants who have taken appropriate risks. And, instead of failing in some instances to yoke excessive-risk-creators with victims of their activities, we would sometimes wrongly yoke plaintiffs together with defendants whose activities have no causal connection to the plaintiffs’ injuries. These outcomes would be as damaging to the achievement of tort goals as current results are.

Strong uncertainty about general causation is not irremediable, however. It is a problem in mass exposure litigation because of the timing of such suits: they are put in motion and require resolution before there is sufficient scientific data to determine reliably the causal powers of the substances in question. If this timing problem could be eliminated or
mitigated, so too would be the frequency of strong uncertainty about general causation in mass exposure cases. For reasons I have already given, it does not make sense to solve the timing problem by staying the cases.\textsuperscript{187} It might, however, be possible to solve it by ensuring that there is more information available at the initiation of litigation. If manufacturers who could not eliminate strong uncertainty about the causal powers of their products were held liable for injuries to members of the exposed population, they would have an incentive to gather more extensive information about general causation in advance of large-scale production and marketing.\textsuperscript{188}

Fuller investigation into the causal properties of their products before production and marketing has costs, however. As the silicone breast implant example demonstrates, it can take a long time to accumulate significantly determinative scientific data, especially in mass exposure cases. Motivating manufacturers to complete the process prior to production and marketing will delay the availability of innovative, potentially beneficial products. In some cases, it might not be worthwhile for a manufacturer to research the causal powers of such products because the possible fruits of marketing them lie too far in the future.

Worries about inhibiting innovation make splitting damages a more attractive alternative than simply shifting the burden of proof on breach or defect and cause-in-fact. By ameliorating the costs of being unable to overcome strong uncertainty about causation, this proposal tempers the incentive to always invest in extensive pre-marketing research. Choosing between the alternatives of shifting the burden of proof and splitting the damages would require investigation into the empirical effects of each and a policy decision as to the relative merits of ensuring safety and dampening innovation.

Because they would promote the acquisition of information about causation, these modifications of current rules would indirectly foster tort law's traditional deterrence goal—even though in some cases a defendant who had in fact taken only appropriate risks, but was unable to establish this, would end up paying half or all of a plaintiff's damages. Nonetheless, shifting the burden and splitting the damages are ways to actually decrease the instances of strong uncertainty by changing the incentives created by the present system. Systematically fuller information about causation would promote allocation of resources to those injured by overly risky activity and more often yoke them with those who have engaged in excessively risky injury-causing activity.

\textsuperscript{187} See supra text accompanying notes 182-86.

\textsuperscript{188} More information might preempt litigation altogether. If manufacturers had more information about all of the causal consequences of their products, they would be more likely to take appropriate risks in marketing them.
A more drastic alternative to the current tort system's handling of mass exposure cases would replace the system altogether, substituting for it an administrative scheme that would allocate compensation on some principle other than information about the causal genesis of injury (such as need) and would regulate pre-market scientific research into the causal powers of substances without presupposing the availability of a tort remedy should the product later prove excessively risky. By detaching the allocative function from the deterrence function, this sort of administrative scheme drops tort's expressive goal of yoking undue-risk-takers who cause injury with their victims. Under such a plan, we would not require knowledge of the causal connections between risk-takers and injury victims in order to link them together. In addition, by premising resource allocation on some basis other than the causal history of a person's injuries, such a scheme would not necessitate information about causation to perform the allocative function. The deterrence mechanism in such a system would, however, still call for information about causation, because information about causation would be necessary in order to decide whether a product posed sufficiently low risks to qualify for distribution. The practical and political obstacles to this sort of program are daunting. As a response to recurrent strong uncertainty about causation, however, an administrative scheme holds some attractiveness because by abandoning tort's expressive goal and transforming its allocative one, this kind of program minimizes the significance of certainty about causation.

In muting the role of certainty about causation, each alternative to the traditional tort system relaxes the aspiration to one or more of tort law's traditional goals. Shifting the burden of proof to the defendant or splitting damages in cases of strong uncertainty means that some defendants who have not in fact created undue risks may incur all or some of the costs of injuries that they have not caused. Likewise, some plaintiffs who have not been the victims of overly risky activity may nonetheless receive money for their injuries. Finally, when defendants compensate plaintiffs whom they have not in fact injured, there is no expressive yoking of an excessively risky actor with his victim. The regulatory-administrative scheme that I sketched would eliminate the expressive function of the current tort system entirely. It would also transform the basis for allocating resources to injured people.

To decide whether any of these alternatives are acceptable or desirable, we would have to settle certain basic questions. Should we accomplish our goals with privatized mechanisms, such as tort liability, or through governmental intervention, such as administrative regulation, or a combination of the two approaches?\textsuperscript{189} Does it make sense to continue to

\textsuperscript{189} The debate over administrative versus judicial risk regulation has already begun. Peter Huber and Kip Viscusi champion the abilities of regulatory agencies in this area. W. KIP VISCUSI,
premise allocation on the causal history of injury rather than some other criterion, such as the injured person's needs? What is the proper relationship between risk and innovation? How much should we encourage or discourage the marketing of products prior to extensive scientific investigation of their causal powers? What is the social significance and value of yoking together injurers and victims? How might this be done other than through tort awards? Should a solution to the problem of recurrent strong uncertainty about causation extend to all injuries and activities or remain restricted to mass exposure episodes?

If the foregoing issues sound familiar, it is not surprising. Recurrent strong uncertainty about causation strikes at the heart of tort law as we know it, preventing the achievement of traditional goals and the vindication of the commitments they reflect. Fully understood, the problem of recurrent strong uncertainty quite naturally provokes us to revisit the most fundamental questions in tort.


190. Deciding who is entitled to resources under what circumstances is an old and vexed issue. Proponents of tort reform have been too quick to assume the existence of social consensus on this issue. See, e.g., Viscusi, supra note 189, at 172 (simply presuming that "[w]hen compensation fails to provide deterrence . . . [t]he appropriate level of compensation should not hinge on how the victim contracted the disease or whether the illness is job-related or product-related" and that "the compensation decision should depend instead on the effects of the disease on the victim's well-being and the consequent need for income support"). Viscusi's assumptions seem ill-founded in light of our long tradition of treating injury victims differently depending upon the causal origins of their problems rather than on the basis of need.

191. Deciding the importance of linking injurers and victims financially would help us decide how willing we should be to achieve our allocative goals through other means, such as first-party insurance or broad-based social insurance. Commentators such as Viscusi who argue that we should replace mass toxic tort litigation with a comprehensive social insurance program and a unified regulatory regime are too quick to assume that we are prepared to surrender entirely the expressive goal of linking injurers and victims. See Viscusi, supra note 189, at 169-74. Assessing the importance of yoking together injurers and victims will probably call for a consideration of our reasons for doing so, which will in turn require us to consider whether these reasons derive from a commitment to corrective justice, however it is understood, or from some other source. See supra note 169.

192. In this Article, I have concentrated on strong uncertainty about general causation in mass exposure litigation. The same problem arises in other tort contexts, especially medical malpractice cases in which the causal effects of a certain treatment may be strongly uncertain. Steps taken to respond to the problem of strong uncertainty about general causation might at least be appropriately applied in other tort settings in which the problem appears.