A Decade of Daubert

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A DECADE OF DAUBERT

DAVID G. OWEN

INTRODUCTION

Products liability litigation, involving the inner workings of science and technology, often resolves into a "battle of the experts." Proof of defectiveness and causation often requires engineers, toxicologists, epidemiologists, and other technical experts to explain the relevant science and engineering of product safety and accidents to a lay jury and the court. Understanding the various aspects of the design, manufacture, and labeling of products normally involves a host of complex, technical considerations requiring specialized expertise. Thus, mechanical, chemical, and materials engineers, chemists, physicists, pharmacologists, epidemiologists, and other technical specialists are often necessary to provide the fact finder with a comprehensive understanding of the manufacturing of a product, how it operates, whether and how it may have malfunctioned or otherwise caused an accident, and how a different design could have avoided similar accidents.

As products liability law spread its tentacles over the nation during the last third of the twentieth century, the expert witness business was born, grew up, and flourished. Tormented by a mounting plague of supposed "experts" testifying to "junk science" in courtrooms across the nation, manufacturers increasingly complained about the unfairness and illogic of basing outcomes in major products liability litigation on such "experts."
slender, defective reeds. In 1993, the United States Supreme Court joined issue with the problem in Daubert v. Merrell Dow Pharmaceuticals, Inc.\(^3\)

A decade now has passed, and it is time for a review of the use and abuse of expert testimony in products liability litigation.

I. SIGNIFICANCE OF EXPERT TESTIMONY

Expert testimony has special significance in products liability litigation for several reasons. Most fundamentally, judges and juries in most products liability cases use this testimony as the primary tool in deciding whether a particular product was defective and whether that defect caused the plaintiff’s injury. Some products, and the causes of some product failures, are quite simple to understand, such as the explosion of a thermos bottle\(^4\) or the presence of a cockroach in a sandwich.\(^5\) In such cases, expert testimony is unnecessary for there is little “beyond the ken” of the judge or jury.\(^6\) But the mechanisms of most product failures are more complex. In such cases, judges and juries generally are dependent on the information and opinions provided by scientific and technical specialists on the complex issues that typically lie at the heart of a products liability case. In this respect, judges and juries, who impliedly are incapable of understanding the technical aspects of such a case, are at the mercy of the experts. In addition, the law of evidence gives experts especially wide latitude to offer opinions not available to ordinary witnesses.\(^7\) For these reasons, expert testimony can be particularly powerful guidance, and it has a particular power to mislead.\(^8\) While the rules governing

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6. Virgil, 484 A.2d at 656 (“The general rule is well established that expert testimony is only required when the subject of the inference is so particularly related to some science or profession that it is beyond the ken of the average layman.”); see Faryniarz v. Nike, Inc., No. 00 Civ. 2623(NRB), 2002 WL 530997, at *2 (S.D.N.Y. Apr. 8, 2002) (finding that expert testimony was unnecessary for jury to find running shoes were defectively designed because of excessively long laces that could get caught on pull-tab).
8. See Daubert, 509 U.S. at 595 (“Judge Weinstein has explained: ‘Expert evidence can be both powerful and misleading because of the difficulty in evaluating it.’” (citation omitted)); Bert Black et al., Science and the Law in the Wake of Daubert: A New Search for Scientific Knowledge, 72 TEX. L. REV. 715, 789 (1994) (“[M]ost commentators believe ostensibly scientific testimony may sway a jury even when as science it is palpably wrong. Science can be greatly distorted by the pressures of litigation, but once it is admitted into evidence, it has an imprimatur of legitimacy and validity, and cross-examination often will not expose its flaws.”); see also Adina Schwartz, A “Dogma of Empiricism” Revisited: Daubert v. Merrell Dow Pharmaceuticals, Inc. and the Need to Resurrect the Philosophical Insight of Frye v. United States, 10 HARV. J. L. & TECH. 149, 196-98 (1997).
the admissibility of expert testimony on science and technology are treated extensively elsewhere, the topic is so centrally important to products liability litigation that it deserves special treatment in this context.

Expert testimony is often necessary to establish defectiveness in manufacture, design, and warnings and instructions. As mentioned earlier, juries normally need the guidance of expert testimony to understand the technical aspects of both defectiveness and causation. Without such testimony, juries would be left to surmise, conjecture, and speculation on these central elements of every case and cause. Thus, a products liability

case usually will fail without proof of defect and cause by expert testimony.\footnote{10}

Manufacturing defects are sometimes so self-evident that expert proof may not be required, but expert testimony ordinarily will be necessary to establish that an accident product deviated from the manufacturer's design specifications.\footnote{11} And while reliance on the malfunction doctrine can sometimes assist a plaintiff when the precise cause of a product failure cannot be shown,\footnote{12} expert proof is often necessary, even under this theory of recovery, to rule out other possible causes of the accident.

Simple warnings issues sometimes are entirely comprehensible by a jury and thus may not necessitate expert testimony.\footnote{14} But the science of how to communicate danger and safety information most effectively is evolving in sophistication such that expert testimony on warnings and instructions is often helpful, and sometimes mandatory, as in many cases involving the labeling of dangerous machinery,\footnote{15} pharmaceutical drugs,\footnote{16} and in other specialized labeling situations.\footnote{17}

\footnote{10. See, e.g., Cantrell v. Weber-Stephen Prod. Co., 2002 WL 1370671, at *2 (4th Cir. 2002) (applying Md. law and granting summary judgment for defendant where plaintiff failed to provide expert testimony on why gas grill exploded; without such testimony "[a] jury could only infer the presence of a defect in the grill by engaging in 'surmise, conjecture, or speculation'" (quoting Jensen v. Am. Motors Corp. 437 A.2d 242, 245 (Md. 1981))); Hochen v. Bobst Group, Inc., 290 F.3d 446, 450-51 (1st Cir. 2002) (applying Mass. law and affirming summary judgment against plaintiff who failed to designate expert under FED.R.Civ.P. 26(a)(2) in complex case involving allegedly defective design and manufacture of printing press); Moisenko v. Volkswagenwerk Aktiengesellschaft, 100 F. Supp. 2d 489, 492-93 (W.D. Mich. 2000) ("Without expert evidence comparing a striker plate with a flat-ending to one with a rolling-ball ending, Mr. Moisenko cannot meet the risk-utility test, and thus cannot establish a design defect. . . . As to the manufacturing defect claim, it is well-settled that such a claim cannot be proven without expert testimony." Defendant’s motion for summary judgment was granted.); Lessard v. Caterpillar, Inc., 737 N.Y.S.2d 191, 192 (N.Y. App. Div. 2002) ("The court properly granted defendant’s motion for a directed verdict, given the inability of plaintiff to establish a prima facie case of design defect in the absence of expert testimony."); Brooks v. Colonial Chevrolet-Buick, Inc., 579 So. 2d 1328, 1332 (Ala. 1991) ("Because of the complex and technical nature of the product and in order to present evidence from which a lay jury may reasonably infer that a defective condition of the product was the cause of the product’s failure and the cause of the resultant injury to the plaintiff, expert testimony is usually essential and, therefore, usually required."); see also MADDEN & OWEN, supra note 9, § 27.9 (discussing Weisgram v. Marley Co., 528 U.S. 440 (2000)).

\footnote{11. See MADDEN & OWEN, supra note 9, § 7.11.

\footnote{12. See id. 7.12.

\footnote{13. See id.


\footnote{15. For a description of a sophisticated system, see PRODUCT SAFETY SIGN AND LABEL SYSTEM (1993).


\footnote{17. See generally MADDEN & OWEN, supra note 9, at ch. 9; Ledford, supra note 9, at 465 (applying Daubert to warning-label testimony).}
Most jurisdictions define design defectiveness in terms of risk-utility analysis, an analytical approach that requires an evaluation of the feasibility, costs, and benefits of altering a design to avoid an injury.18 Such claims almost always require expert proof, sometimes on the mechanisms of how the accident occurred and almost always on how the accident feasibly could have been designed away.19 However, if design defectiveness is defined purely in consumer expectation terms,20 the appropriateness of expert testimony may depend upon the type of product whose design is under scrutiny. A jury might well need expert guidance on the safety expectations of users of industrial, professional, or other products designed for use by specialists in a field. But consumer goods, particularly simple ones, are another matter. It is difficult to see how the opinion of a technical or other expert on ordinary consumer expectations about the safety of a simple consumer product could assist a jury, which would seem to preclude expert testimony on defectiveness in such cases.21 Even design cases may be simple, however, in which case expert testimony is unnecessary.22

Regardless of the type of defect, expert testimony often is necessary to prove causation, the link that connects the product defect to the plaintiff’s harm.23 Causation is most typically in issue in toxic substance cases, where expert testimony on causation (and defectiveness) almost invariably is necessary.24 Even in cases involving durable goods, where proofs of defectiveness and causation are often linked together closely, expert testimony on how the defect caused the harm is usually necessary to the plaintiff’s case.25

18. See generally MADDEN & OWEN, supra note 9, at ch. 8.
19. See id.
20. Id.
21. Expert witnesses normally cannot assist the jury in determining consumer expectations. See, e.g., Soule v. Gen. Motors Corp., 882 P.2d 298, 308 (Cal. 1994) ("[W]here the minimum safety of a product is within the common knowledge of lay jurors, expert witnesses may not be used to demonstrate what an ordinary consumer would or should expect. Use of expert testimony for that purpose would invade the jury’s function . . . ."); Campbell v. Gen. Motors Corp., 649 P.2d 224, 233 (Cal. 1982) ("[O]ne can hardly imagine what credentials a witness must possess before he can be certified as an expert on the issue of ordinary consumer expectations." (quoting G. Schwartz, Foreword: Understanding Products Liability, 67 CAL. L. REV. 435, 480 (1979))).
23. See generally MADDEN & OWEN, supra note 9, at ch. 12.
To give but a few examples, judges and juries surely will need expert tutelage on defectiveness if the issue in dispute is whether the speed control mechanism for a paver should have been in the form of a lever rather than a rotary dial; whether a sport utility vehicle should have been equipped with a barrier between the front seats and cargo area, together with a warning, to make it safe for occupants in the rear; whether a forklift should have been equipped with a door or wire mesh; whether cigarettes could have been made safer; or whether a hay baler should have had a guard. Similarly, on causation, the fact finder will almost certainly need expert testimony if the parties disagree on whether a causal link exists between a plaintiff’s ingestion of Viagra and his heart attack; an allegedly defective product and a house fire that starts nearby; the absence of a kill switch on an outboard motor and injuries to the plaintiff’s hand; an anti-depressant drug taken by a teenager and his suicide; a spinal rod implanted in the plaintiff’s back to eliminate a painful condition and his quite similar post-operative pain; or exposure to various chemical substances and many illnesses and diseases.

In short, experts are crucial to both the prosecution and defense of a products liability case.

35. See Brooks v. Outboard Marine Corp., 234 F.3d 89, 92 (2d Cir. 2000).
II. QUALIFICATIONS AND SOURCES OF EXPERT WITNESSES

To serve as an expert witness, an individual must first be qualified—"by knowledge, skill, experience, training, or education"—to offer opinions on the particular specialized matter before the court. The bulk of experienced and otherwise qualified specialists in most fields of product design, manufacturing, and labeling are employed by private industry—by the very manufacturing enterprises who constitute the defendants in products liability litigation. Thus, because such persons are already in its employ, a manufacturer usually has little difficulty finding appropriate engineering and other experts to help defend a products liability case. Indeed, such experts may include the very persons who designed the accident product, advised on appropriate warnings, and designed and supervised the assembly process. Plaintiffs' lawyers, on the other hand, generally are limited to two principal resource pools for expert witness talent: universities and private consulting expert firms.

III. THE RISE OF THE "PROFESSIONAL" EXPERT WITNESS AND THE PROBLEM OF "JUNK SCIENCE"

As products liability litigation began to mushroom in the late 1960s and the 1970s, so too did the plaintiff's need for experts to battle a manufacturer's engineers and other experts over issues of product defectiveness and causation—in expert reports, depositions, and ultimately at trial. Straining the pool of then-existing technical talent, a surge in demand for expert testimony in the 1970s and 1980s spawned a whole new industry of "professional" expert engineers and other consulting specialists who mostly, but not exclusively, supported the plaintiff's bar. Many such

39. See FED. R. EVID. 702.
40. See, e.g., Goodwin v. MTD Prod., Inc., 232 F.3d 600 (7th Cir. 2000) (discussing a case involving a lawn mower that discharged a wing nut into plaintiff's eye; engineer was not qualified to give expert opinion on nature, scope, or cause of eye injury); Robertson v. Norton Co., 148 F.3d 905 (8th Cir. 1998) (discussing the explosion of a ceramic grinding wheel; ceramics engineer was not qualified to testify on adequacy of warnings); Polaino v. Bayer Corp., 122 F. Supp. 2d 63, 69 (D. Mass. 2000) (ruling that the chemist was not qualified to testify on defectiveness of x-ray chemical mixer); Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1310, 1315 (N.D. Okla. 2000) ("The simple possession of a medical degree is insufficient to qualify a physician to testify as to the advantages of a spinal fixation device, the medical causation of spine-related ailments, or the mechanical functioning of an orthopedic implantation device."); Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 833-35 (Wis. 2001) (ruling that a chemist not qualified to testify on whether latex gloves caused allergic reaction).
42. While manufacturers substantially rely on their own in-house technical experts, they frequently use outside consultants for accident reconstruction and the development of other proofs.
experts were of course entirely competent to testify on the issues they agreed to evaluate. But others advertised a willingness to testify, for a fee, on the defectiveness (and even the appropriateness of punitive damages) of just about anything, from toys to airplanes.44

The very idea of a professional expert witness is problematic. “Expertise” in any field requires substantial time to accumulate and to stay abreast of current developments—by reading, experimenting, writing, perhaps teaching, and otherwise pursuing knowledge in the specialized field of study. The problem is that much of a professional expert’s time is spent in courtrooms and preparing for trial rather than pursuing expertise. Moreover, because most professional experts are economically dependent on being retained by lawyers to testify that particular products were (or were not) defective and caused (or did not cause) particular injuries, they have a natural bias to arrive at conclusions that favor their employers. Without a steady moral compass—grounded in a personal reservoir of knowledge, judgment, and professional conviction—a professional witness will be tempted to tell the employing lawyer what the expert thinks the lawyer wants to hear, rather than what he or she needs to hear. Whether working for the plaintiff or defense, this temptation for professional witnesses to mold their findings and conclusions to make the case for their employer is persistent and strong; and it is insidious, in part because they may hide weaknesses in their testimony from their own employer.

The kind of twisted testimony45 that too easily results from a hired expert’s natural bias provides one explanation of why professional witnesses sometimes contradict themselves in different cases, a strategic Achilles heel which an opposing attorney may discover by diligent research. If the opposing attorney does not reveal such conflicting testimony until the trial, both the expert and the employing attorney will find themselves in the dreadful predicament of trying to explain the contradic-

43. See, e.g., Peter Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 COLO. L. REV. 277, 333 (1985) (“[A] Ph.D. can be found to swear to almost any ‘expert’ proposition, no matter how false or foolish.”); see generally Bernstein, supra note 24, at 119-23 (examining the seamy side of the expert witness business).


45. For one expert’s primer on how to mislead a jury, see Sanchez v. Black Bros. Co., 423 N.E.2d 1309, 1320 (Ill. App. Ct. 1981) (excerpting a speech given by defendant’s witness to engineering group on how to manipulate juries and obfuscate answers on cross examination).
tion on the spot. On occasion, professional witnesses knowingly provide false, perjurious testimony, which, if discovered, will likely devastate the party's entire case.46

The explosion of expert testimony in products liability litigation during the 1970s and 1980s, fueled by an expanding plaintiffs' bar fed by contingent fees, quite naturally led to a rather rapid increase of products liability lawsuits based on novel, untested, abstract, and occasionally quite fantastic theories of science and technology, propounded by "experts" who sometimes were dubiously qualified to testify on issues on which they claimed expertise. As products liability litigation during this period marched along, courts47 and commentators,48 always skeptical of this form of witness,49 increasingly decried a perceived growth in abuses of expert testimony—of "junk science" run amok.50

46. See, e.g., Harre v. A.H. Robins Co., 750 F.2d 1501 (11th Cir. 1985) (reversing and remanding judgment for defendant because verdict based in part on perjured testimony by defense expert); see also Jenkins v. Gen. Motors Corp., 446 F.2d 377, 399 (5th Cir. 1971) (holding that trial court properly excluded evidence that one of plaintiff's experts was under indictment for perjury); see generally Richmond, supra note 44, at 223.


49. See, e.g., Ferguson v. Hubbel, 97 N.Y. 507, 514 (N.Y. 1884) (stating that the expert witnesses' "opinions cannot fail generally to be warped by a desire to promote the cause in which they are enlisted"); Lee M. Friedman, Expert Testimony, Its Abuse and Reformation, 19 YALE L.J. 247, 249 (1910) (noting "a constant complaining and mistrust on the part of judges, juries and lawyers of the expert witness").

50. See Huber, Galileo's Revenge, supra note 48, at 3.

Junk science cuts across chemistry and pharmacology, medicine and engineering . . . . It is a catalog of every conceivable kind of error: data dredging, wishful thinking, truculent dogmatism, and, now and again, outright fraud.

On the legal side . . . [is] a speculative theory that expects lawyers, judges, and juries to search for causes at the far fringes of science and beyond. The legal establishment has adjusted rules of evidence accordingly, so that almost any self-styled scientist, no matter how strange or iconoclastic his views, will be welcome to testify in court. The same scientific questions are litigated again and again, in one courtroom after the next, so that error is almost inevitable.

Junk science is impelled through our courts by a mix of opportunity and incentive. "Let-it-all-in" legal theory creates the opportunity. The incentive is money: the prospect that the Midas-like touch of a credulous jury will now and again transform scientific dust into gold.

Id.; see generally Bert Black, A Unified Theory of Scientific Evidence, 56 FORDHAM L. REV. 595, 597-98 & nn. 1-3 (1988) (arguing that the problems historically posed by scientific evidence are becoming increasingly difficult because an "expert witness can be found to support almost any decision").
IV. EARLY LIMITATIONS ON EXPERT TESTIMONY

At early common law, the only real limitation on expert testimony was that the person proffered as an expert be qualified as an expert in the field. The courts generally allowed such experts to provide relevant testimony about technical matters as a matter of course: once a person was qualified as an expert, the judge simply admitted into evidence his or her relevant opinion testimony. This liberal approach to expert testimony reflected the thought that the market from which an expert made a living had reliably tested the quality of that expertise. While the marketplace test generally may have worked satisfactorily to permit expert determinations on whether a carriage maker or pharmacist acted with reasonable care in making a carriage or mixing a medicine, this test was unhelpful when applied to expert opinions about new science or technology, where an established market for such expertise did not yet exist.

This was the situation the Supreme Court faced in Frye v. United States, in which the defendant in a murder case offered the results of an early polygraph test to show his innocence. In passing on the merits of a new form of science or technology, ruled the Court, the test is whether it is “sufficiently established to have gained general acceptance in the particular field in which it belongs.” Shifting the fulcrum of decision from the expert to the expertise, the Frye “general acceptance” test tended to exclude testimony on cutting-edge science and technology since new ideas become accepted wisdom only over time. During the next half century, Frye’s general acceptance standard, although increasingly criti-

51. On early expert testimony, see John M. Chapin, Experts and Expert Testimony, 22 ALB. L.J. 365 (1880); Learned Hand, Historical and Practical Considerations Regarding Expert Testimony, 15 HARV. L. REV. 40 (1901); see also FAIGMAN ET AL., supra note 9; David L. Faigman et al., Check Your Crystal Ball at the Courthouse Door, Please: Exploring the Past, Understanding the Present, and Worrying About the Future of Scientific Evidence, 15 CARDOZO L. REV. 1799, 1803-09 (1994) (hereinafter Faigman et al., Crystal Ball) (concluding that a rigorous and thorough analysis of scientific data should be undertaken before admission into court); Stephan Landsman, Of Witches, Madmen, and Products Liability: An Historical Survey of the Use of Expert Testimony, 13 BEHAV. SCI. & L. 131, 133 (1995) (understanding that Daubert represents a step towards greater judicial control, yet raises questions about “the evenhandedness of heightened judicial scrutiny of proffered expert testimony”).
52. See FAIGMAN ET AL., supra note 9, at 3-5.
53. “The assurance of expertise was implied by the expert’s success in an occupation or profession that embraced that knowledge . . . . In effect, the marketplace determined whether valid knowledge existed by endowing it with commercial value.” Id. at 4.
54. 293 F. 1013 (D.C. Cir. 1923).
55. Frye, 293 F. at 1014.
56. See generally Faigman et al., Crystal Ball, supra note 51, at 1805-09.
cized,\textsuperscript{57} evolved into the prevailing test for admissibility of expert testimony.\textsuperscript{58}

As modern products liability and other technical litigation expanded in the late 1960s and early 1970s, coincident with the debate over the Federal Rules of Evidence then under consideration, the \textit{Frye} test suddenly became quite “trendy.”\textsuperscript{59} In 1975, the Federal Rules of Evidence were adopted, including Rule 702, which provided for the admission of scientific and technical evidence by a qualified expert if such testimony would “assist the trier of fact” (i.e., if it is helpful to the jury),\textsuperscript{60} and Rule 703, which allowed an expert to rely upon facts and data “reasonably relied upon by experts” in the field.\textsuperscript{61} Neither Rule 702 nor the Advisory Committee’s comment on it made any reference to the \textit{Frye} test, but most jurisdictions interpreted this rule to incorporate \textit{Frye’s} general acceptance standard.\textsuperscript{62}

During the 1980s and early 1990s, the logic and fairness of \textit{Frye’s} general acceptance test came under increasing scrutiny as courts increasingly debated whether and to what extent this test might be consistent with Rule 702.\textsuperscript{63} During this period, the courts struggled to find a balance between the need to open courtrooms to new science, on the one hand, with the problems from allowing experts to propound bad science, on the other. Increasingly, courts began to strike this balance by at least partially shifting the focus away from whether the science was “generally

\textsuperscript{57} Criticisms often centered on its conservatism and its vagueness. \textit{See, e.g.}, \textit{Faigman et al. supra} note 9, at 7-10 (examining criticisms of the \textit{Frye} test).


\textsuperscript{59} \textit{See} Harrison, \textit{supra} note 58, at 1034-35. But not all courts and commentators approved of the general acceptance test of admissibility. \textit{See} McCormick, \textit{supra} note 9, at 874-75 ("General scientific acceptance is a proper condition for taking judicial notice of scientific facts, but it is not a suitable criterion for the admissibility of scientific evidence.").

\textsuperscript{60} At the time, Federal Rule of Evidence 702 provided: "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." \textit{Fed. R. Evid. 702} (2000). Rule 702 was amended in 2000 to reflect the holding in \textit{Daubert}.

\textsuperscript{61} Federal Rule of Evidence 703, prior to the Dec. 1, 2000 amendments, provided: "The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible evidence." \textit{Fed. R. Evid. 703} (2000).

\textsuperscript{62} \textit{See} Faigman et al., \textit{Crystal Ball, supra} note 51, at 1803-09.

\textsuperscript{63} \textit{See generally} Harrison, \textit{supra} note 58, at 1057 (arguing that proper interpretation of Rules 702 and 703 of the Federal Rules of Evidence provides courts with adequate tools "to regulate the admissibility of novel scientific evidence," thus making the \textit{Frye} test unnecessary).
accepted," the Frye approach, to an evaluation of the methodology by which the expert reached his or her conclusion.64

V. DAUBERT AND ITS PROGENY

A. Daubert

In Daubert v. Merrell Dow Pharmaceuticals,65 after several years of avoiding the issue,66 the Supreme Court in 1993 finally decided to examine the admissibility of expert testimony on novel scientific theories and the relationship of the Frye test to Rule 702 of the Federal Rules of Evidence. Daubert involved the drug Bendectin, an anti-nausea medicine that, from 1956 until 1983, physicians widely prescribed to pregnant women for morning sickness.67 From the first Bendectin case filed in 1979, which claimed that the drug had caused the plaintiff's missing and malformed fingers, nearly 2000 similar cases eventually were filed claiming damages for birth defects from the drug.68 In Daubert, filed late in the life cycle of the litigation, the plaintiffs claimed that Benedictin administered to their mothers during pregnancy caused their birth defects.69 The defendant moved for summary judgment, arguing that no causal link existed between Bendectin and birth defects.70 In affidavits from its expert scientists, the defendant showed that none of the thirty-eight epidemiological studies of Bendectin published to date had found a

64. See, e.g., Christophersen v. Allied Signal Corp., 939 F.2d 1106, 1110 (5th Cir. 1991) (en banc) (stating that in order for an expert's scientific conclusions to be admissible, they must, inter alia, be based on "a well-founded methodology"); Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307, 310 (5th Cir. 1989) (stating that difficult questions such as whether Bendectin caused birth defects compel courts to "critically evaluate the reasoning process by which the experts connect data to their conclusions in order... to consistently and rationally resolve the disputes before them"), modified, 884 F.2d 166 (5th Cir. 1989); United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985); see generally Harrison, supra note 58, at 1057 (arguing that examining an expert's methodology would make the Frye test unnecessary).


66. See, for example, Justice White's dissents to the denial of certiorari in Mustafa v. United States, 479 U.S. 953, 953-54 (1986), and Christophersen v. Allied Signal Corp., 503 U.S. 912, 912 (1992). Prior to Daubert, the Frye test, which had been used almost exclusively in criminal cases, was increasingly subject to criticism. See Gross, supra note 9, at 242-46.

67. See Green, supra note 9, at 661 (indicating that Bendectin was prescribed during the 1960s and 1970s to upwards of 25% of all pregnant women in the U.S.). On the Bendectin litigation, see Michael D. Green, Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation (1996); Joseph Sanders, Bendectin on Trial: A Study of Mass Tort Litigation (1998); Joseph Sanders, From Science to Evidence: The Testimony on Causation in the Bendectin Cases, 46 STAN. L. REV. 1 (1993) [hereinafter Sanders, From Science to Evidence]; Joseph Sanders, The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts, 43 HASTINGS L.J. 301 (1992); Gross, supra note 9, at 243-44 (summarizing the Bendectin litigation).

68. See Sanders, From Science to Evidence, supra note 67, at 4.

69. See Daubert, 509 U.S. at 579.

70. Id.
causal connection between birth defects and the drug.\textsuperscript{71} In opposition, the plaintiffs offered affidavits from eight witnesses who concluded—on the basis of chemical structure analysis, in vitro (test tube) studies of animal cells, in vivo (live) animal studies, and a "reanalysis" of the previous epidemiological studies—that Bendectin could in fact cause birth defects.\textsuperscript{72} Concluding that the plaintiffs’ proffered expert evidence did not meet \textit{Frye}'s "general acceptance" standard of admissibility, the district court granted the defendant’s summary judgment motion, and the Ninth Circuit affirmed.\textsuperscript{73}

In the Supreme Court, the petitioning plaintiffs argued that the Federal Rules of Evidence had superseded the \textit{Frye} "general acceptance" standard.\textsuperscript{74} Vacating and remanding, the Supreme Court agreed that the Rules do not allow a court to use the degree of acceptance of a subject of scientific testimony as the sole determinant of admissibility.\textsuperscript{75} Because Rule 702 allows qualified experts to testify about "scientific . . . knowledge," the Court reasoned that a trial judge must determine that proposed expert testimony is both "scientific" and "knowledge"—that the subject of the testimony is "ground[ed] in the methods and procedures of science," that it is "derived by the scientific method."

An expert’s proposed testimony must be "supported by appropriate validation — i.e., 'good grounds.'"\textsuperscript{77} In short, expert testimony must be \textit{reliable}.\textsuperscript{78} In addition to requiring expert testimony be reliable, the Court further reasoned that Rule 702 requires that such testimony be \textit{relevant}, since the rule demands that expert scientific or technical testimony "assist the trier of fact to understand the evidence or to determine a fact in issue."\textsuperscript{79} This is the "helpfulness" requirement of Rule 702, requiring that expert testimony be sufficiently related to disputed facts to help the jury resolve facts or issues in dispute, a requirement that may be simply described as

\textsuperscript{71} There are four common types of scientific studies used to determine the toxicity of a substance:

[1] analyses of the chemical structure of the compound that focus on similarities between it and known toxins; [2] \textit{in vitro} tests that examine its effects on human or animal cells that are cultivated in the laboratory for this purpose; [3] \textit{in vivo} studies that test its effects on laboratory animals; and [4] \textit{epidemiological} studies that examine its effects on human beings. Gross, \textit{supra} note 66, at 238. Epidemiological studies on large populations of humans are widely considered the most informative measure of toxic consequences of the substance. \textit{Id.} at 238-39.

"There is general agreement that epidemiological studies are the best and most informative, since only they provide direct evidence on the occurrence of pathologies in people." \textit{Id.}

\textsuperscript{72} \textit{See Daubert v. Merrill Dow Pharm. Inc.}, 951 F.2d 1128 (9th Cir. 1991), affg 727 F. Supp. 570 (S.D. Cal. 1989).

\textsuperscript{73} \textit{See Daubert}, 509 U.S. at 579.

\textsuperscript{74} \textit{See Daubert}, 509 U.S. at 587.

\textsuperscript{75} \textit{See id. at} 587-89.

\textsuperscript{76} \textit{Id. at} 589-90.

\textsuperscript{77} \textit{Id. at} 590.

\textsuperscript{78} \textit{See id. at} 589-90.

\textsuperscript{79} \textit{Id. at} 591.
Thus, when a party proffers expert scientific testimony, the trial court must make a preliminary determination of both the (1) reliability (or validity), and (2) relevance (or fit) of the expert’s reasoning or methodology underlying the testimony proposed.81

Among the factors a court may usefully employ in assessing the validity of an expert’s proffered testimony on scientific evidence, the Court noted five:

(1) **Testability**: whether the theory or technique is testable and has been tested – its ability to withstand objective, verifiable challenge and scientific trial;82

(2) **Peer review**: whether it has been subjected to peer review and publication;

(3) **Error rate**: whether it has an acceptable known or potential rate of error;

(4) **Control standards**: whether its operation has been subjected to appropriate standards of control; and

(5) **General acceptance**: whether it is widely accepted in the relevant scientific community.83

These are Daubert’s now-familiar reliability factors. In determining the admissibility of expert testimony under Rule 702, the Court emphasized that the inquiry into pertinent reliability considerations should be flexible, and that the focus of inquiry “must be solely on principles and methodology, not on the conclusions that they generate.”84 Because the lower courts had based their decisions in this case almost exclusively on Frye’s general acceptance standard, rather than on the broader reliability and fit

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80. See id. at 591-92.
81. Id. at 592-93. Thus, “a trial judge must evaluate the proffered testimony to assure that it is at least minimally reliable; concerns about expert testimony cannot simply be referred to the jury as a question of weight.” Capra, supra note 9, at 701-02.
82. The Advisory Committee’s version of this factor is more prolix: “whether the expert’s technique or theory can be or has been tested – that is, whether the expert’s theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability.” CHRISTOPHER B. MUELLER & LAIRD C. KIRKPATRICK, EVIDENCE: PRACTICE UNDER THE RULES 152 (2d ed. Supp. 2002).
83. See id. at 593-94. Although the Court lumps factors (3) and (4) together, which has led most observers to a four-factor count, the separation of these two different considerations clarifies analysis. The five-factor list is adapted from Capra, supra note 9, at 702, which is the basis for the formulation in Fed. R. Evid. 702, advisory committee’s note (2000 amendment).
84. See Daubert, 509 U.S. at 593-95.
requirements of Federal Rule of Evidence 702, the Supreme Court remanded the judgment to the Court of Appeals. 85

B. Supreme Court Progeny

Since Daubert, the Supreme Court has revisited the expert testimony issue a number of times. In General Electric Co. v. Joiner, 86 a district court applied Daubert to exclude expert testimony that purported to link the plaintiff’s exposure to PCBs to his lung cancer, and the court of appeals reversed. 87 Reinstating the district court’s ruling, the Supreme Court emphasized that federal trial courts have wide discretion to exclude expert testimony, holding that such determinations are only subject to a permissive “abuse of discretion” standard of review. 88 The Court further noted that Daubert’s direction that courts focus on the expert’s methodology in no way precluded a trial judge from scrutinizing the quality of the expert’s conclusions. 89

Next came Kumho Tire Co. v. Carmichael, 90 a tire blowout case involving a worn tire containing at least two punctures that previously had been inadequately repaired. In a suit against the tire manufacturer, the plaintiffs claimed, on the basis of deposition testimony of an expert in tire failure analysis, that the cause of the blowout was a defect in the tire rather than abuse. 91 Although the expert’s testimony might have been viewed as “technical” rather than “scientific,” the trial court applied the gatekeeping principles of Daubert, closely scrutinizing the reliability of the expert’s hypotheses, methodology, and conclusions. 92 Concluding that they failed each of the Daubert factors, and that their reliability had not been established on any other ground, the district court excluded the expert’s testimony and granted the defendant’s motion for summary judgment. 93 The court of appeals reversed, ruling that Daubert applied

85. On remand, applying the Daubert analysis, the Ninth Circuit ruled again that the district court had properly excluded the plaintiffs’ expert testimony, concluding that the testimony of one of the plaintiffs’ experts was not reliable and that the testimony of the others was not relevant because they would only testify that Bendectin is “capable of causing” birth defects, not that the drug in fact (more likely than not) caused the plaintiffs’ birth defects. Daubert v. Merrell Dow Pharm. Inc., 43 F.3d 1311, 1321-22 (9th Cir. 1995).
87. See Joiner, 522 U.S. at 140-41.
88. Id. at 141.
89. The Court remarked: [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence, which is connected, to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion preferred. Id. at 146.
91. Kumho Tire, 526 U.S. at 142.
92. See id. at 145.
93. Id.
only to experts relying on "scientific" principles rather than on the kind of skill- or experience-based observation of the type relied upon by the plaintiff's expert.\footnote{Id.} Reversing the court of appeals, the Supreme Court held that Rule 702's broad reference to expert testimony on "scientific, technical, or other specialized knowledge" means that the Daubert gatekeeping principles apply to all expert testimony.\footnote{Id. at 147-49.} Further, the Court reaffirmed the flexibility of the reliability inquiry and noted that the trial court has wide latitude, subject only to review for abuse of discretion, to determine what reliability factors are appropriate to the particular expert testimony under examination.\footnote{Id. at 149-53.}

The final Supreme Court decision to date on expert testimony is \textit{Weisgram v. Marley Co.},\footnote{528 U.S. 440 (2000).} a wrongful death action against the manufacturer of a heater arising out of a house fire. On testimony by three experts that the heater was defective and that the defect caused the fire, the plaintiffs obtained a judgment on a jury verdict, over the defendant's objection that the testimony was unreliable and therefore inadmissible under Rule 702 and Daubert.\footnote{Weisgram, 528 U.S. at 455-56.} The court of appeals reversed, agreeing with the defendant that the plaintiffs' expert testimony offered mere speculation as to the heater's defectiveness, making it scientifically unsound.\footnote{Id.} Rather than remanding for a retrial, and reasoning that the plaintiffs had had a fair opportunity to prove their claim and so did not deserve a second chance, the court of appeals directed judgment for the defendant manufacturer.\footnote{Id. at 446.} The Supreme Court affirmed.\footnote{Id. at 455.} Rejecting an argument that a plaintiff might hold certain expert testimony in reserve to shore up the claim if the proffered expert testimony were to be found insufficient, the Court noted that Daubert put parties relying on expert evidence on notice of "the exacting standards of reliability" demanded of such evidence.\footnote{Id. at 455.} "It is implausible to suggest, post-Daubert, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail."\footnote{Id. at 455.} Reminding parties (usually plaintiffs) that they may well not get a second chance, \textit{Weisgram} underscores Daubert's basic message: parties bear responsibility for presenting expert testimony rigorously grounded in good science and technology and relevant to the particular issues in the case.
C. Amendment to Federal Rule of Evidence 702

In 2000,104 the Supreme Court approved certain amendments to the Federal Rules of Evidence on opinion evidence and expert testimony to conform them to the principles of Daubert and its progeny.105 In addition to making certain minor changes to Rules 701 and 703, the amendments added an important proviso to Rule 702 that permits expert testimony only if such testimony is grounded on “sufficient facts and data” and is the result of “reliable principles and methods” which are themselves reliably applied to the facts of the case.106 The Advisory Committee’s helpful Note to the 2000 amendment of Rule 702 observes that the amendment requires only that the data, principles, and methods used by an expert are reliable and reliably applied,107 and that the quality of expert testimony still largely remains tested by cross-examination and the other safeguards of the adversary system.108 Observing that “[a] review of the case law after Daubert shows that the rejection of expert testimony is the exception rather than the rule,”109 the Committee Note adds that the amendment “is not intended to provide an excuse for an automatic challenge to the testimony of every expert.”110

As for Daubert’s reliability factors, the Advisory Committee’s Note reiterates Daubert’s five-factor list set forth above and further enumerates several additional factors courts have found useful in varying contexts:

(1) Whether experts are “proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.”

(2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion.

(3) Whether the expert has adequately accounted for obvious alternative explanations.

104. The amendments were effective Dec. 1, 2000, a quarter century after the Rules were first adopted in 1975.
106. With the amended language italicized, Federal Rule of Evidence 702 now provides in full:

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, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVI. 702.
108. Id.
109. Id.
110. Id.
(4) Whether the expert "is being as careful as he would be in his regular professional work outside his paid litigation consulting."

(5) Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.\(^{111}\)

While recognizing the importance of these and the original \textit{Daubert} factors, the Advisory Committee observed that the amendment makes no attempt to "codify" the factors, which the Supreme Court has emphasized are not exclusive.\(^{112}\) Instead, the new standards added to Rule 702 are "broad enough to require consideration of any or all of the specific \textit{Daubert} factors where appropriate."\(^{113}\) In sum, the amendment (including the Committee Note) to Federal Rule of Evidence 702 does not provide a conclusive roadmap for each specific aspect of expert testimony, but it does provide helpful guidance on the fundamental \textit{Daubert} reliability principles.\(^{114}\)

\textbf{D. \textit{Daubert} in the Lower Federal Courts}

\textit{Daubert} has, as intended, forced courts to examine expert testimony more closely. Post-\textit{Daubert}, the federal district courts, exercising their newly appointed "gatekeeper" function, have scrutinized expert testimony more closely, often holding rigorous pre-trial "\textit{Daubert} hearings"—that are often outcome determinative—to determine the admissibility of proffered expert testimony.\(^{115}\) But heightened judicial scrutiny of expert testimony does not mean that a court will necessarily exclude a plaintiff's expert testimony, even if it is unusual: the circuit courts sometimes affirm plaintiff verdicts in novel contexts in which the traditional scientific indicia of defectiveness or causation is marginal at best,\(^{116}\) and they will reverse a district court for excluding a plaintiff's expert testi-

\begin{itemize}
\item \(^{111}\) Id. (internal citations omitted).
\item \(^{112}\) Id.
\item \(^{113}\) Id.
\item \(^{114}\) Id. Pointing to the Supreme Court's admonition that \textit{Daubert}'s reliability factors are not exclusive, the Advisory Committee's Note observes that the amendments do not attempt to "codify" the factors but instead set forth standards that are "broad enough to require consideration of any or all of the specific \textit{Daubert} factors where appropriate." Id.
\item \(^{115}\) See, e.g., Brasher v. Sandoz Pharm. Corp., 160 F. Supp. 2d 1291, 1295 n.12 (N.D. Ala. 2001); see also Rudlin, supra note 9, at 336. [T]he \textit{Daubert} hearing and ruling have effectively become virtually as a class certification hearing and ruling: once decided, a case either shrivels up and goes away, or becomes more dangerous to try. \textit{Daubert} hearings are often every bit as case dispositive, practically speaking, as a summary judgment hearing. Thus, practitioners whose cases rely in any material way on expert testimony must . . . be prepared for a full-blown "trial within a trial" that the \textit{Daubert} hearing often becomes.
\item \(^{116}\) See, e.g., Bonner v. ISP Tech., Inc., 259 F.3d 924, 927-28 (8th Cir. 2001) (affirming an award for an assembly line worker, who exposed to defendant's organic solvent, suffered psychological injuries, cognitive impairment, and Parkinsonian symptoms).\
\end{itemize}
mony with excessive zeal. But Daubert decisions frequently go the other way, excluding a plaintiff's expert testimony as unreliable or irrelevant. Thus, the lower federal courts have disallowed expert testimony on Daubert grounds because the expert proposed to testify on a novel causal theory, not generally accepted or subjected to peer review, that was developed only for the litigation; relied too heavily on the temporal proximity of harm to its alleged cause; failed sufficiently to inspect or test the accident product or a proposed alternative design; failed

117. See, e.g., Lauzon v. Senco Prod., Inc., 270 F.3d 681, 691 (8th Cir. 2001) (recognizing that only three published articles supported expert's theory that bottom-fire pneumatic nailers are defective, but ruling that limited peer review is not fatal because such nailers are new product); Smith v. Ford Motor Co., 215 F.3d 713, 720-21 (7th Cir. 2000) (rejecting expert testimony on single ground of lack of peer review is abuse of discretion; no single factor is conclusive in determining reliability of expert's methodology); Kennedy v. Collagen Corp., 161 F.3d 1226, 1230 (9th Cir. 1998) (ruling that the trial court failed properly to consider the reasoning and methodology of plaintiff's expert).

118. See, e.g., Daubert, 43 F.3d at 1313 (ruling, on remand, that testimony of plaintiff's experts, on link between Bendectin and birth defects, was not reliable or relevant); Grant v. Bristol-Myers Squibb, 97 F. Supp. 2d 986, 991, 992 (D. Ariz. 2000) (ruling that the conclusions of plaintiff's experts—that silicone breast implants cause various systemic diseases—was developed for the litigation, had not gained acceptance in the relevant scientific community, and that their scientific methods were not practiced by a recognized minority in the field); Nelson v. Am. Home Prod. Corp., 92 F. Supp. 2d 954, 972 (W.D. Mo. 2000) (ruling that none of plaintiff's experts had conducted independent research, outside context of litigation, on whether defendant's heart medication caused damage to optic nerve and vision).

119. See, e.g., Heller v. Shaw Indus., Inc., 167 F.3d 146 (3d Cir. 1999) (ruling causation testimony unreliable when symptoms did not appear for two weeks after carpet was installed and remained after it was removed); Polaino v. Bayer Corp., 122 F. Supp. 2d 63, 70 (D. Mass. 2000) (ruling that expert's hypothesis, resting on temporal proximity rather than scientific principles, was classic illustration of fallacy of post hoc ergo propter hoc); Wynacht v. Beckman Instruments, Inc., 113 F. Supp. 2d 1205, 1209 (E.D. Tenn. 2000) (finding that expert opinion on causation based solely on temporal relationship was unreliable, given complex nature of facts and expert's failure to identify biochemical, medical, or toxicological basis for opinion). But the immediacy of acute symptoms to exposure may buttress the reliability of an expert's causation hypothesis. See, e.g., Bonner, 259 F.3d at 931 (ruling strong temporal connection is sometimes powerful evidence of causation).

120. See, e.g., Dhillon v. Crown Controls Corp., 269 F.3d 865, 870 (7th Cir. 2001) ("hands-on testing is not an absolute prerequisite to the admission of expert testimony, but the theory here easily lends itself to testing and substantiation by this method, such that conclusions based only on personal opinion and experience do not suffice"); Pride v. BIC Corp., 218 F.3d 566 (6th Cir. 2000) (noticing that defendant's expert subjected cigarette lighter that allegedly malfunctioned to replicable laboratory tests, but plaintiff's experts did not); Brooks v. Outboard Marine Corp., 234 F.3d 89, 91, 92 (2d Cir. 2000) (ruling that plaintiff's expert failed to test his theory that lanyard-activated kill switch would have disengaged motor boat engine under circumstances of accident to user's hand: "The failure to test a theory of causation can justify a trial court's exclusion of the expert's testimony."); Shanks v. Home Depot, Inc., No. 1:00-CV-383, 2001 U.S. Dist. LEXIS 22468, at *7 (W.D. Mich. Dec. 2, 2001) (finding examination, but no testing, of ladder for load-bearing capacity); Booth v. Black & Decker, Inc., 166 F. Supp. 2d 215, 215 (E.D. Pa. 2001); Berry v. Crown Equip. Corp., 108 F. Supp. 2d 743, 754 (E.D. Mich. 2000) ("courts interpreting Daubert have considered testability of the expert's theory to be the most important of the four factors, and this is especially true in cases involving allegations of defect in product design"); Polaino, 122 F. Supp. 2d at 68-69; LaBelle v. Phillip Morris, Inc., No. 2-98-3235-23 (D.S.C. July 5, 2001), at *11-13 (regarding no testing of supposedly safer cigarette design). But see Travelers Prop. & Cas. Corp. v. Gen. Elec. Co.,
faithfully to reconstruct the circumstances of the accident, failed to provide a theory of causation supported by sufficient confirmatory studies; failed to conduct a differential diagnosis to rule out alternative potential causes, or applied such an approach improperly; failed to show the relevance ("fit") of accepted principles to the plaintiff's case; or otherwise failed to proffer reliable and relevant testimony—supported by reliable data, methods, or conclusions—that was likely to aid the trier of fact. Quite often, an expert's testimony will fail Daubert scrutiny for many of these reasons.

120 F. Supp. 2d 360, 366, 367 (D. Conn. 2001) (ruling that although theory was not tested, it was capable of being tested; testimony admitted).
121. See, e.g., J.B. Hunt Transp., Inc. v. Gen. Motors Corp., 243 F.3d 441, 444 (8th Cir. 2001); Brooks, 234 F.3d at 92.
122. See, e.g., Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 992 (8th Cir. 2001) (ruling that proposed expert testimony was insufficient to show that Parlodel can cause intracerebral hemorrhages); Turner v. Iowa Fire Equip. Co., 229 F.3d 1207, 1208 (8th Cir. 2000) (ruling that the expert's differential diagnosis identified condition, not the cause); Wynacht, 113 F. Supp. 2d at 1209 (ruling that the treating clinical physician failed to explain in a scientifically reliable manner how wastewater discharge from lab analyzer caused plaintiff's respiratory, neurological, digestive, cardiovascular, and urinary problems that followed the discharge).
123. See, e.g., Turner, 229 F.3d at 1208 (ruling that the expert made no attempt to exclude possible causes of respiratory problems, allegedly caused by accidental discharge of substance from fire suppression equipment, until only one remained); see also Schafersman v. Agland Coop, 631 N.W.2d 862 (Neb. 2001) (applying Frye test to facts, but adopting Daubert prospectively).
124. See, e.g., Glastetter, 252 F.3d at 989 (ruling that although differential diagnosis is presumptively admissible, experts lacked basis for "ruling in" Parlodel, drug for suppressing postpartum lactation, as cause of stroke); Alexander v. Smith & Nephew, 98 F. Supp. 2d 1310, 1316 (N.D. Okla. 2000) (ruling that expert's failure to explain why he eliminated other possible causes rendered methodology unreliable); see also Katherine R. Latimer, A Good Bedside Manner Wouldn't Be Enough, Either: Differential Diagnosis Under Daubert, 1 EXPERT EVID. REP., 33 (2001); Joseph Sanders & Julie Machal-Fulks, The Admissibility of Differential Diagnosis Testimony to Prove Causation in Toxic Tort Cases: The Interplay of Adjective and Substantive Law, 64 LAW & CONTEMP. PROBS. 107, 120-22 (2001).
125. See, e.g., Daubert, 43 F.3d at 1321-22 (affirming, on remand, summary judgment for defendant in Bendectin birth defect case because plaintiff's experts could not testify that relative risk was more than the 2.0 necessary to show probability of causal connection); Cipollone v. Yale Indus. Prod., Inc., 202 F.3d 376, 380 (1st Cir. 2000) (ruling that expert's testimony on dangerously narrow gap between fixed and moving handrail of loading dock lift was based on supposition that person's hand was widened by holding object, but plaintiff was holding nothing when accident occurred); Rapp v. Singh, 152 F. Supp. 2d 694, 705 (E.D. Pa. 2001) (recognizing that crashworthiness experts rigorously analyzed how plaintiff's car was propelled under defendant's tractor trailer, but data was insufficient on how absence of vertical attachment to bumper made design defective); Groome v. Matsushita Elec. Corp. of Am., No. 92-CV-3073, 2000 U.S. Dist. LEXIS 4082, at *4-5, *7-8 (E.D.N.Y. Mar. 30, 2000) (ruling that where plaintiff's expert had to loosen safety switches to get microwave to operate with door open, his testimony that "it would be a 'very easy mistake' to install them improperly" did not "fit" because there was no factual basis for his opinion).
126. See, e.g., J.B. Hunt Transp., Inc., 243 F.3d at 441 (excluding testimony on crash theory by accident reconstructionist, based on photographs alone and dubious testimony of expert "foamologist"); Mitchell v. Gencorp Inc., 165 F.3d 778, 779 (10th Cir. 1999) (ruling on chemicals that allegedly caused leukemia); Cacciola v. Selco Balers, Inc., 127 F. Supp. 2d 175, 181-83 (E.D.N.Y. 2001) (ruling that, having neither inspected machine itself nor interviewed injured worker, the engineer's deposition testimony that machine's safety interlock switch was too
It may well be that the experts in each case in which the testimony was excluded propounded bad science, or perhaps the plaintiffs' attorneys simply failed to adequately prepare their experts on the Daubert requirements before the trial, or perhaps they failed at trial (or at a Daubert hearing) to provide the court with a sufficient offer of proof. Yet, the cases show that Daubert provides federal trial judges with a powerful operating manual for excluding expert testimony that, in the court's sound discretion, fails to meet current criteria for "good science." There is indeed some logic to the view, suggested by the Supreme Court itself in Daubert, that its ruling is balanced in its effect—that, while closing the door to testimony based on unreliable theories and methodologies, it opens the door to expert testimony on cutting-edge science and technology. But the fact remains that only infrequently do courts invoke Daubert to exclude expert testimony proffered by defendants. Instead, courts almost always apply Daubert principles (often with good reason) to exclude a plaintiff's experts and, hence, to bar the plaintiff's claim.

accessible, based on photographs alone, "rests upon unsubstantiated generalizations, speculative hypotheses and subjective evaluation that are based neither upon any professional study or experience-based observation").

127. See, e.g., Oddi v. Ford Motor Co., 234 F.3d 136, 156-58 (3d Cir. 2000) (ruling that the "haphazard, intuitive inquiry" of plaintiff's expert engineer, who conducted no tests nor calculated forces involved in vehicle accident, failed each of eight reliability factors); Milanowicz v. Raymond Corp., 148 F. Supp. 2d 525, 537, 540 (D.N.J. 2001) (ruling that the testimony of consulting engineer on forklift truck design failed each of nine reliability indicia and required reconfiguration from Daubert for engineering cases).

128. See, e.g., Brooks, 234 F.3d at 90, 92 (ruling expert testimony that outboard motor, propeller which injured plaintiff's hand should have been equipped with kill switch inadmissible because plaintiff's expert had never seen the boat or motor, either in person or in photographs; did not know boat's configuration or dimensions; had not spoken to boys involved in accident nor otherwise knew precisely how accident happened; nor attempted to reconstruct the accident to test his theory that a lanyard-activated kill switch would have disengaged motor under circumstances of accident); Berry, 108 F. Supp. 2d at 754 (ruling that even if proffered expert witness had been qualified to testify on forklift design safety, his opinions were "quite simply unsupported by any reasonable measure of technical data or foundation and are wholly unreliable"); cf. Brasher, 160 F. Supp. 2d at 1295 n.12 (noting a busy trial court's natural temptation to apply Daubert "heavily-handedly" to reduce a heavy caseload).

129. See Daubert, 509 U.S. at 595-97.

130. See, e.g., Bonner, 259 F.3d at 928 (arguing that "[t]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victim's condition and the toxic substance, has not yet been completed" (quoting Turner, 229 F.3d at 1299)).


Booth v. Black & Decker, Inc.133 provides an example of a court applying Daubert to exclude a plaintiff's expert testimony. The case involved claims of defective manufacture and design against the manufacturer of a toaster oven for negligence, breach of warranty, and strict liability in tort for fire damage to the plaintiffs' house.134 Although the Fire Marshall determined that the fire was caused by a recently-repaired microwave that had been used shortly before the fire, the plaintiffs' expert,135 Thomas, determined that the fire originated in the defendant's toaster oven located in the same portion of the kitchen.136 The defendant moved for summary judgment, which hinged on the admissibility of plaintiffs' expert testimony that the toaster oven was defective and caused the fire.137

The court held a two-day Daubert hearing on Thomas' qualifications and the reliability of his opinion that the toaster oven was defective and caused the fire.138 The court first concluded that Thomas was qualified to offer expert testimony on the electrical aspects of consumer appliances, including toaster ovens, and that he was qualified to interpret the results of a scanning electron microscope examination he had conducted on the oven.139 On the issues of manufacturing defect and causation, Thomas hypothesized that while someone was operating the toaster oven, its power contacts spontaneously welded together, causing the toaster oven to overheat and catch fire.140 Attempting to confirm this hypothesis, Thomas testified that he used an electron microscope to examine the contacts, which showed indications of melting and scoring, suggesting to him that the surfaces had welded together.141 The toaster oven was defectively designed, in Thomas' view, for two reasons: (1) because it lacked a thermal cut-off device, to cut off power when the oven reached a certain temperature, to prevent it from overheating, and (2) because it contained an excessive amount of plastic with a low melting point.142

Applying the Third Circuit's version of the Daubert factors,143 the court ruled that the evidence failed to establish the reliability of Thomas'
methodology. Thomas' manufacturing defect theory was testable, but he had not attempted to get the power contacts of a similar toaster to weld together. While his microscopic investigation was a form of test, he failed to adequately explain why indications of melting and scoring mean that welding has occurred, nor did he offer any other basis for his conclusion other than his personal experience and "broad and circular assertions that such markings simply are what happens when welding occurs." Thomas asserted that his fire investigation methods were generally used by others in the field, but he failed to produce persuasive objective evidence to this effect. Prompted by defense counsel, Thomas claimed that he followed the fire investigation guidelines of the National Fire Protection Association, but he did not point to any specific procedures in the guidelines that he had followed. Nor did any credible evidence exist to establish that Thomas' examination method "was subject to peer review, had a known or potential rate of error, could be measured by existing standards, or was generally accepted." In short, because Thomas "did not take sufficient care in supporting the credibility or reliability of the methodology he applied, despite the best efforts of counsel to elicit it," his testimony that the toaster contained a manufacturing defect was inadmissible. Similarly, Thomas' design defectiveness theories, on which he offered no methodology whatsoever, were equally deficient: he neither sketched nor produced an example of the kind of thermal cut-off device he recommended, nor did he install one on an exemplar oven to test its ability to prevent overheating. While he claimed that Black and Decker used such a device on an oven sold in Canada, he failed to produce the Canadian model. As for his theory of excessive plastic materials, Thomas never explained how the plastic might have caused or affected the fire.

Thus, whether or not Thomas in fact conducted a reasonable investigation into the cause of the fire, he failed to provide the court with "enough basic, objective information" on the reliability of the investigation and his opinions based thereon.

Thomas performed no tests of his own to determine whether his hypotheses were indeed true; he merely examined the toaster oven and

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144. See Booth, 166 F. Supp. 2d at 219.
145. Id.
146. Id.
147. Id. at 220.
148. Id.
149. Id.
150. Id.
151. Id. at 221.
152. Id.
153. Id. at 219 n.4.
154. Id. at 221-22.
concluded it could have been safer. His testimony . . . seemed wholly based on his own training and experience, and he provided the Court with no objective anchor for his conclusions. 155

Based on a review of Thomas' expert reports, deposition testimony, and testimony during the Daubert hearing, the court found his causation inquiry to be "intuitive and haphazard, his methodology to be unreliable, and, consequently, his conclusions to be suspect." 156 Since the plaintiffs had failed to meet their burden of establishing the reliability of Thomas' testimony under the principles of Rule 702, Daubert, and Kumho Tire, Thomas' expert testimony on causation was inadmissible. 157 Because the plaintiffs had no other evidence to establish that a defect in the toaster oven probably caused the fire, the court granted summary judgment for the defendant. 158

But Daubert seeks to exclude only invalid or irrelevant evidence, and even a rigorous application of its principles does not compel the exclusion of expert testimony that is merely inconclusive or otherwise only marginally helpful to the trier of fact. Many product accidents leave few and ambiguous clues of accident causation, especially if the product is severely damaged in the accident or lost thereafter, 159 and the issue of design defectiveness is by nature vague and indeterminate. 160 In such cases, courts should allow plausible expert hypotheses, provided they are based on sound methodology and reasoning, that attempt to reconstruct the origins of the accident and how it might have been prevented.

Rudd v. General Motors Corp. 161 is an example of a case that allowed a plaintiff's expert testimony after rigorous Daubert scrutiny. The plaintiff was injured when a fan blade on his pickup truck broke lose and struck him while he stood in front of the truck's open hood twisting the distributor housing to adjust the engine's timing. 162 Plaintiff sued the vehicle manufacturer, claiming that the fan blade had been made of defective metal, a claim based largely on the testimony of his expert, Edmondson, a mechanical engineer with extensive experience in failure

155. Id. at 221.
156. Id.
157. Id. at 222.
158. Id. at 223. Nor would the malfunction theory help the plaintiffs, since even that theory required reasonable inferences that the particular product had malfunctioned and caused the harm. Because of the multiple possible causes of the fire in this case, expert testimony on causation was necessary on the malfunction theory, too. Id. at 220 n.5.
159. On the malfunction theory, see Madden & Owen, supra note 9, § 7.12.
160. On design defectiveness, see generally Madden & Owen, supra note 9, at ch. 8.
162. Rudd, 127 F. Supp. 2d at 1332, 1340.
analysis. GM moved for summary judgment, arguing that the plaintiff had offered no admissible evidence of a manufacturing defect.

Choosing not to hold a Daubert hearing, the court ruled on the admissibility of Edmondson’s testimony on the basis of his expert report and deposition testimony. Edmondson found no direct evidence of a physical flaw in the fan blade, but arrived at his conclusion circumstantially by excluding other possible explanations of how the fan blade might have broken. In particular, he first determined that the plaintiff’s use of the vehicle at the time the fan blade broke was entirely proper: the plaintiff’s technique in adjusting the timing, while running the engine at 1200 to 1500 rpms, was entirely normal and specifically recommended by GM’s tune-up manuals. Next, based on Edmondson’s visual examination, his “total indicator reading” measurements of the accident fan and fan assembly, and his background reading, he determined that prior to the accident the fan blade had not been bent, at the site of the fracture origin or elsewhere, and that no visible damage to the blade existed that might have caused the fatigue fracture and break. Had the fan blade been subjected to a sudden trauma during operation, Edmondson testified that it would have left physical indicia of the trauma, such as broken paint, scarring, or denting, none of which were visible. The absence of any indications that the fan had encountered abnormal forces during operation led him to conclude that a microscopic manufacturing defect, such as a scratch, grind mark, gas bubble, or an inclusion caused a metal-fatigue fracture. The court concluded that Edmondson’s systematic elimination of alternative causes led to circumstantial proof of defectiveness that was relevant to a jury’s determination of that issue.

Although the reliability of the Edmondson’s expert evidence was a closer question, the court concluded that it met each of the three specific reliability standards of new Rule 702—that it was based on (1) sufficient

163. Id. at 1332, 1338.
164. Id. at 1339.
165. Normally, the decision whether to hold a Daubert hearing is entirely discretionary with the trial court. There may be no need for such a hearing if the parties have developed an extensive evidentiary record, including expert reports, depositions, and the literature that supports the expert opinions, and assuming that the issues are well briefed. Id. at 1334 n.3 (citing authorities); see Nelson, 92 F. Supp. 2d at 967; Schafersman, 631 N.W.2d at 877. As with any discretionary matter, however, a trial court’s failure to hold a Daubert hearing in particular circumstances, whether or not requested by the losing party, may be an abuse of discretion, particularly if the admissibility issue turns on factual issues and will be determinative of summary judgment. See Padillas v. Stork-Gameco, Inc., 186 F.3d 412, 418 (3d Cir. 1999).
166. See Rudd, 127 F. Supp. 2d at 1340.
167. Id. at 1342.
168. Id.
169. Id. at 1340.
170. Id. at 1341.
171. Id.
172. See id. at 1342.
data, (2) reliable principles and methods, and (3) reliable application of the methods to the facts.\textsuperscript{173} First, the factual basis of Edmondson's testimony was sufficient—based on his visual inspection of the accident fan blade and other fans, his account of the use history of the truck and fan blade, his "total indicator reading" measurements, his reliance on two failure-analysis publications (which included a case study of a car fan fatigue fracture) and GM tune-up manuals, and his background and training analyzing metal fractures,\textsuperscript{174} including automotive fan fatigue fractures.\textsuperscript{175} Second, the court ascertained that Edmondson’s method for determining the cause of the fatigue fracture—by eliminating ("ruling out") other possible causes—was a well-established and reliable scientific method for determining causation.\textsuperscript{176} Moreover, because a specialty publication had employed the process-of-elimination method in a failure analysis model, which included a case history of a fatigue fracture in an automobile fan, this method further satisfied \textit{Daubert}'s reliability factors on publication and acceptance within a relevant community of experts.\textsuperscript{177} Third, and finally, the court found that Edmondson reliably applied this method to the accident fan—by determining that the fan’s history did not include improper operation and by closely inspecting the fan blade metal for physical indicia of other causes.\textsuperscript{178} Noting that Edmondson could not fairly be expected to assign a particular error rate to his techniques,\textsuperscript{179} the court concluded that his testimony was reliable, and hence admissible, "because he provide[d] a step-by-step and transparent account" of "reasoning processes and data sources" on which he relied, "the physical indicia he associate[d] with each possible alternative cause, and his reasons for excluding each of the alternative causes."	extsuperscript{180} By fully revealing the basis of his opinions, Edmondson’s testimony thus supplied the defendant with a fair basis to challenge his opinions by cross-examination.

\textsuperscript{173} Id.
\textsuperscript{174} The court quoted the Advisory Committee Note to Rule 702 to the effect that an expert’s \textit{experience} (alone or "in conjunction with other knowledge, skill, training or education") may provide a sufficient foundation for the expert’s testimony if the witness explains "how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." \textit{Id.} at 1336.
\textsuperscript{175} \textit{Id.} at 1342-43.
\textsuperscript{176} \textit{Id.} at 1343. In the medical context, experts quite often apply this well-accepted method for determining causation, called "differential diagnosis" (or "differential etiology"). \textit{See generally} Brew, \textit{supra} note 9, at 482-83 (stating that differential diagnosis, the process of "eliminating other possible causes, is an essential methodological component in establishing specific causation"); Sanders & Machial-Fulks, \textit{supra} note 124 (focusing on "one of the more difficult causal issues in torts: the proof of specific causation in toxic tort suits . . . through a process the courts have called differential diagnosis").
\textsuperscript{177} \textit{See Rudd}, 127 F. Supp. 2d at 1343.
\textsuperscript{178} \textit{Id.}
\textsuperscript{179} \textit{Id.}
\textsuperscript{180} \textit{Id.} at 1344.
and the presentation of contrary evidence, the basic tools of the adversary process.\footnote{Id.}

E. Daubert in the State Courts

Because \textit{Daubert} interprets Federal Rule of Evidence 702, it applies by its terms only to the federal courts. For this and other reasons, quite a few state courts, still trusting in \textit{Frye} and other conventional rules governing the admissibility of expert testimony, have refused to adopt the \textit{Daubert} principles.\footnote{As of 2002, roughly fifteen states still purport to follow \textit{Frye}. Recent reaffirmations of \textit{Frye} and rejections of \textit{Daubert} include: Logerquist v. McVey, 1 P.3d 113, 134 (Ariz. 2000) (en banc, 3-2 decision); Byrum v. Super. Ct., No. B153001, LEXIS 3809, at *6 (Cal. Ct. App. Feb. 20, 2002); Donaldson v. Cent. Ill. Pub. Serv. Co., 767 N.E.2d 314, 323 (Ill. 2002); Kuhn v. Sandoz Pharm. Corp., 14 P.3d 1170, 1178 (Kan. 2000); Kansas City Southern Ry. Co., Inc. v. Johnson, 798 So. 2d 374, 382 (Miss. 2001); Krause, Inc. v. Little, 34 P.3d 566, 569 (Nev. 2001); Blum v. Merrell Dow Pharm., Inc., 764 A.2d 1, 2 (Pa. 2000). \textit{See generally} Heather G. Hamilton, \textit{The Movement from Frye to Daubert: Where Do the States Stand?}, 38 JURIMETRICS J. 201, 208 (1998) (stating that "by 1992 after the \textit{Frye} heyday had passed states were poised for a new test," and as such, only four years later, "28 states either have adopted the \textit{Daubert} standard, explicitly assimilated it as similar to \textit{Daubert}'s, and since that time an increasing number of states have rejected \textit{Frye} and swung over to the \textit{Daubert} point of view.\footnote{As of 1998, Hamilton counted thirty-three states that had adopted \textit{Daubert}, to which tally at least two additional states must be added. \textit{See} People v. Shreck, 22 P.3d 68, 77 (Colo. 2001) (replacing \textit{Frye} test with \textit{Daubert} reliability standards); Schafersman v. Agland Coop, 631 N.W.2d 862, 867 (Neb. 2001) (same).} In addition, a large majority of states have adopted codes of evidence patterned on the Federal Rules of Evidence, including Rule 702 upon which \textit{Daubert} is based.\footnote{Hamilton reported that, as of 1998, only Connecticut, Massachusetts, New York, and Pennsylvania had not adopted Rule 702, and noted that Massachusetts had adopted \textit{Daubert} judicially. \textit{Hamilton, supra} note 182, at 209. Note, however, that few, if any, states have yet adopted the December 2000 amendment to Rule 702 that explicitly incorporates the \textit{Daubert} principles.} Moreover, to the extent that \textit{Daubert}'s precepts are grounded in reasoned principles of logic and fair play for adjudicating disputes involving principles of science and technology, those precepts have a certain logical and moral power that is difficult for state courts to ignore. For these reasons, a growing number of state courts, very possibly a majority, have now adopted the \textit{Daubert} principles of reliability and relevance for expert testimony.\footnote{The counts of states vary wildly. \textit{Compare} Hamilton, \textit{supra} note 182, at 209 (counting thirty-three states embracing \textit{Daubert} principles), \textit{with States Move to Daubert, supra} note 182, at}}
CONCLUSION: THE LEGACY OF DAUBERT

In Daubert and its progeny, the Supreme Court attempted to bridge the yawning gap between how reality is perceived and described, and how problems are resolved, in science and the law. In particular, the Court sought to improve the legitimacy of judicial determinations involving science and technology by forcing courts to rigorously scrutinize the foundations of an expert’s scientific or technological opinions. This is a messy task that requires both courts and lawyers to do the kind of rigorous science they may have entered law to avoid. By abandoning Frye’s “general acceptance” standard, which was based on the precept that courts should defer to scientific communities to decide for themselves whether a particular type of scientific approach should be recognized as useful, Daubert switched the basic responsibility for making such decisions to the courts, which on balance appears to make good sense. It is hard to gainsay the Court’s decision that trial judges should serve as “gatekeepers” for expert testimony, as preliminary decision-makers of whether a qualified expert witness has devoted as much rigor, and has applied the same exacting methodologies, to the matter before the court as the expert devotes to his or her own professional projects.

Daubert requires trial courts to look seriously at the quality of the science or technology of a witness proffered as an expert. Courts can no longer simply pass along to juries the principal task of determining the validity of expert testimony on difficult questions at the margin of established science. As door-closing rules governing the admissibility of expert testimony, the Daubert principles are capable of being applied oppressively to smother the judicial airing of legitimate disputes. Instead, the courts need to apply the principles even-handedly—excluding expert...
testimony insufficiently grounded in sound methodology, while allowing such testimony that reasonably if boldly reaches into uncharted waters of evolving knowledge. By requiring experts to provide reasoned bases for their opinions, and by requiring that such opinions be relevant to the legal issues in the case and grounded in reliable methodology, the reliability and relevancy principles of Daubert, used properly, provide a firm foundation for the fair and rational resolution of the scientific and technological issues which lie at the heart of products liability adjudication.

191. Moreover, trial judges must conduct their Daubert duties impartially and avoid giving an appearance that they disbelieve a party's expert witnesses. See, e.g., Price v. Blood Bank of Del., Inc., 790 A.2d 1203, 1210 (Del. 2002).