

## THE DRAINING OF *DAUBERT* AND THE RECIDIVISM OF JUNK SCIENCE IN FEDERAL AND STATE COURTS

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*This Article is dedicated to a great torts scholar and lifelong friend, the distinguished Dean of Hofstra University School of Law, Aaron Twerski. He has inspired generations of law students and also his friends to think and write about how to improve our system of justice.*

### I. INTRODUCTION

There is no more important issue in the law of torts than factual causation. If a defendant is held liable for something it did not do, then the justice system has failed. On the other hand, if a defendant is able to convince a jury that it did not cause an injury for which it was responsible, that is also a miscarriage of justice. Both failures of our

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justice system are more likely to arise when factual causation is entwined with scientific evidence.

In 1993, the Supreme Court of the United States addressed this issue head on by interpreting the impact of the Federal Rules of Evidence on scientific causation. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Supreme Court established a multi-factor-based approach to determining admissibility.<sup>1</sup> The test provided flexibility so as to separate sound science from fiction.<sup>2</sup> Of equal importance, the Supreme Court deputized trial court judges as “gatekeepers.”<sup>3</sup> This key role placed a serious and sound obligation on federal district court judges to protect lay jury fact finders against unreliable scientific expert testimony.

This Article begins with a brief review of the principles and policy underlying *Daubert* and its progeny. It then examines whether federal court judges have fulfilled their responsibility to serve as gatekeepers. We find that while most trial judges take their role as gatekeepers very seriously<sup>4</sup> and closely examine expert testimony to ensure its reliability and applicability, some have failed to follow both the letter and spirit of *Daubert*. This Article examines the subsequent impact of these rulings, finding that there is a roulette wheel randomness as to whether sound science will indeed prevail. Looking primarily to federal court opinions in civil litigation, the Article identifies five general areas of inconsistency in the application of expert testimony standards that have emerged in recent years.<sup>5</sup>

First among the five areas of identified inconsistency is that several courts continue to apply the broad relevance standard meant for lay testimony to expert evidence, rather than the closer “fit” required by the U.S. Supreme Court.

Second, some courts have misinterpreted their “flexibility” in

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1. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-94 (1993).

2. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (recognizing that while Rule 702 “was intended to liberalize the introduction of relevant expert evidence,” courts were charged with conducting a preliminary assessment as to the expert’s reasoning and methodology to assure its scientific validity and fit to the facts of the case).

3. *Daubert*, 509 U.S. at 597.

4. For example, many judges have participated in judicial education programs that are targeted to provide them with training in basic scientific methods so they can make admissibility determinations in cases involving complex scientific theories with greater confidence. *See, e.g.*, Tresa Baldas, *Judges Going to School for Training in Science*, NAT’L L.J., July 24, 2006, at 6 (discussing a new judicial scientific education program offered by the Advanced Science and Technology Adjudication Resource Center in Washington).

5. For the purpose of narrowing the field, this Article focuses primarily on tort law cases decided since 2000.

applying the *Daubert* factors to the point of abdication of their gatekeeper role. An example of this occurs when a court ignores a relevant *Daubert* factor, such as when it admits an expert's theory that has not been confirmed by an objective test, even when the expert could have easily done so. Another example involves the misuse of "differential diagnoses," a methodology of ruling out potential causes of an injury until only the most probable cause remains. Some courts have expanded this methodology beyond its reasonable degree of accuracy in the medical context. Other courts have left sound science even further behind by expanding "differential diagnoses" beyond the medical context into fields where it simply does not fit.

Third, some courts, misinterpreting language in *Daubert* and its progeny, limit *Daubert* gatekeeping to an expert's methodology and do not apply it to his or her conclusions. They admit highly speculative conclusions that are not supported by the expert's own methodology.

Fourth, courts differ on whether *Daubert* requires *in limine* pre-trial hearings as contrasted with making routine evidentiary rulings in the course of a trial. A closely related issue is whether a trial court has an obligation to provide a full record, including written findings of fact and conclusions of law, on its rulings on the admissibility or exclusion of expert evidence, for the purpose of appeal.

The next part of the Article finds that appellate courts differ on the applicable standard of review of a trial court's decisions to admit or not admit expert evidence. Some courts apply an "abuse of discretion" standard to the entire evidentiary ruling, while others apply a *de novo* standard to the trial court's application of the *Daubert* framework. In applying the abuse of discretion standard, some courts appear to take a much closer review than others.

The Article then examines the status of *Daubert*'s adoption in the states and explores dramatic differences in its application. The Article suggests that all state courts should adopt the federal gatekeeping procedure to ensure accuracy of results and consistency of verdicts, and also to eliminate incentives for major forum shopping between state and federal courts.

Finally, the Article examines a recent initiative of the American Law Institute ("ALI") that may unintentionally undermine *Daubert* standards, and compromise the serious gatekeeping role of judges.

The Article concludes that *Daubert* is more important today than it was twenty years ago at its inception. Judges of all philosophical views should stand fast as gatekeepers when ruling on the admission of expert evidence and protect against "junk science" in the courtroom.

## II. THE PRINCIPLES AND POLICY OF *DAUBERT* AND ITS PROGENY

### A. *Why Expert Testimony Requires Close Judicial Scrutiny*

Expert testimony, whether presented by plaintiffs or defendants, can strongly influence juries. An expert witness has extraordinary powers and privileges in court. Unlike lay witnesses, “an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.”<sup>6</sup> Experts are unique in that their testimony may be based on evidence that otherwise would not be admissible.<sup>7</sup> For example, experts can base their testimony on hearsay to justify their opinions, even if such underlying evidence is inadmissible.<sup>8</sup> Expert witnesses can testify on the ultimate issue in a case, even though a lay witness would be prohibited from doing so.<sup>9</sup>

The content of expert testimony is, by definition, outside the realm of an ordinary juror’s scope of knowledge.<sup>10</sup> The basic calipers that jurors use to evaluate testimony—their own life experience—are of little value when jurors evaluate whether an expert is telling the truth. As the Supreme Court recognized in *Daubert*: “Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it.”<sup>11</sup> It often addresses an “unfamiliar and esoteric field.”<sup>12</sup> Moreover, as one state high court recognized: “Evidence that purports to be based on science beyond the common knowledge of the average person that does not meet the judicial standard for scientific validity can mislead, confuse, and mystify the jury.”<sup>13</sup> In addition to overwhelming or misleading the jury, and regardless of whether such testimony is labeled scientific or technical, “[t]here are a score of other concerns associated with experts who lack a reliable basis for their opinion, ranging from their introducing evidence that is otherwise inadmissible to prolonging litigation and wasting time and resources.”<sup>14</sup>

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6. *Daubert*, 509 U.S. at 592.

7. See FED. R. EVID. 703.

8. See *Daubert*, 509 U.S. at 593; see also *Engebretsen v. Fairchild Aircraft Corp.*, 21 F.3d 721, 728-29 (6th Cir. 1994); *United States v. Sowards*, 339 F.2d 401, 402 (10th Cir. 1964).

9. See FED. R. EVID. 704(a).

10. See FED. R. EVID. 702.

11. *Daubert*, 509 U.S. at 595 (quoting Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)).

12. *Tabatchnick v. G. D. Searle & Co.*, 67 F.R.D. 49, 55 (D. N.J. 1975).

13. *State v. O’Key*, 899 P.2d 663, 678 n.20 (Or. 1995).

14. David L. Faigman et al., *How Good is Good Enough?: Expert Evidence Under Daubert and Kumho*, 50 CASE W. RES. L. REV. 645, 648 (2000).

From about 1923 until 1993, federal courts permitted parties to present expert testimony involving novel scientific theories if the underlying theory or basis of opinion was “generally accepted” as reliable within the expert’s particular field.<sup>15</sup> The “general acceptance” test, known as the “*Frye* standard,” while on its face seemingly restrictive, was liberally applied to favor admissibility of expert testimony. More importantly, judges did not engage in a thorough evaluation of the reliability of the proposed expert testimony. Simply stated, the *Frye* test looked at whether novel scientific evidence was generally accepted in the relevant scientific community.<sup>16</sup> If it was, then it could be admitted, so long as a proper foundation was shown and the evidence had minimal relevance to the case; if it was not, then it was inadmissible.<sup>17</sup> Courts generally took a “let the jury decide” approach, allowing trials to become a battle of purported experts without regard to the soundness of the evidence. Bad science presented as fact by shoddy experts resulted in the removal of beneficial products from the market and economic ruin for many companies.<sup>18</sup>

#### B. Rule 702, Daubert, and the Gatekeeping Role

In ruling that Congress’s adoption of the Federal Rules of Evidence in 1975 supplanted the test for admissibility of expert testimony then in effect in federal courts, the Supreme Court applied a major and helpful requirement in *Daubert*: Expert testimony must be subject to a strong and careful judicial gatekeeper function in order to protect a fundamental tenant of justice—finding the truth.

The Supreme Court instructed that when “[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.”<sup>19</sup> First, Rule 702 requires that the district court evaluate the qualifications of the witness to testify as an expert on the issue at hand.<sup>20</sup> Then, the Court tasked district courts with screening proffered

15. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

16. *Id.*

17. *See id.*

18. *See infra* Part II.C.

19. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993).

20. Rule 702 requires a witness to establish his or her expertise by reference to “knowledge, skill, experience, training, or education.” FED. R. EVID. 702. Even “[a] supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method . . .” *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999). *See also* *Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th

expert testimony to ensure that what is admitted “is not only relevant, but reliable.”<sup>21</sup> In determining reliability, the Court provided a nonexclusive list of key factors for courts to consider before admitting expert testimony, including (1) whether the theory or technique can be and has been tested, (2) whether it has been subjected to peer review and publication, (3) whether, in respect to a particular technique, there is a high “known or potential rate of error” and whether there are “standards controlling the technique’s operation”, and (4) whether the theory or technique enjoys general acceptance within the relevant scientific community.<sup>22</sup> It also required a determination as to whether the reasoning or methodology underlying the testimony is scientifically valid and properly applied to the facts of the case.<sup>23</sup>

Two subsequent Supreme Court decisions, *General Electric Co. v. Joiner*,<sup>24</sup> and *Kumho Tire Co. v. Carmichael*,<sup>25</sup> further clarified that *Daubert* requires a “fit” between the expert’s reasoning and conclusions, and applies to all technical or other specialized expert testimony, not just scientific evidence.<sup>26</sup> Together, this trio of cases stands for the fundamental principle that trial court judges must act as gatekeepers and carefully screen expert testimony to ensure its reliability. The United

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Cir. 2001) (“Though eminently qualified to testify as an expert hydrologist regarding matters of flood risk management, [the witness] sorely lacked the education, employment, or other practical personal experiences to testify as an expert specifically regarding safe warehousing practices.”); *cf.* *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) (“Rule 702 ‘contemplates a broad conception of expert qualifications.’”) (emphasis omitted) (quoting *Thomas v. Newton Int’l Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994)).

21. *Daubert*, 509 U.S. at 589.

22. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149-50 (citing *Daubert*, 509 U.S. at 592-94). The Rules Advisory Committee, in amending Rule 702 in 2000 to reflect *Daubert*, recognized several additional factors that courts might consider. Some courts, such as the Third Circuit, have taken this “*Daubert*-plus approach,” in which courts are encouraged to consider the factors included in *Daubert* as well as additional factors, if applicable, in each case. *See infra* notes 151-52 and accompanying text.

23. *Daubert*, 509 U.S. at 592-93.

24. 522 U.S. 136, 144-45 (1997) (finding the trial court did not err in excluding plaintiff’s expert testimony when the expert concluded that plaintiff’s cancer was caused by exposure to polychlorinated biphenyls because the expert relied on tests performed on infant lab mice that received massive, concentrated doses injected directly into their stomachs, and developed a different type of cancer than the plaintiff, while no adult mice developed cancer after similar injections).

25. 526 U.S. 137, 154-55 (1999) (finding trial court did not err in excluding expert from testifying when his opinion was based on visual and tactile examination of supposedly faulty tires, others did not use this method in the industry, and the expert equivocated about the reliability of his own testing method).

26. *See also* *Weisgram v. Marley Co.*, 528 U.S. 440, 455-56 (2000) (holding that an appellate court may direct entry of judgment as a matter of law when it determines that evidence was erroneously admitted at trial and that the remaining properly admitted evidence is insufficient to constitute a submissible case).

States Court of Appeals for the Third Circuit summarized Rule 702 as “embod[ying] three distinct substantive restrictions on the admission of expert testimony: qualification, reliability, and fit.”<sup>27</sup>

Initially, commentators primarily viewed *Daubert* as liberalizing expert testimony standards by allowing trial courts to take a more “flexible” approach to determining admissibility than the bright-line general acceptance inquiry.<sup>28</sup> After all, courts were no longer constrained to waiting for a theory to gain “general acceptance” in the field, but could look to other factors. While such an interpretation of *Daubert* is technically correct, it misses the more significant new gatekeeping role that the Supreme Court mandated for trial court judges. In moving to a factor-based approach, the Court provided appropriate flexibility to allow courts to acknowledge new developments in science and technology that may not be universally accepted, but have an objective, proven, and sound foundation. To determine whether a theory that is not generally accepted in the scientific community is sound is one reason why the Court required district court judges to carefully and independently screen expert testimony. The Supreme Court was absolutely clear in *Daubert* that federal district court judges conduct a preliminary assessment “to consider whether the testimony has been subjected to the scientific method, ruling out any subjective belief or unsupported speculation.”<sup>29</sup> In sum, while *Daubert* does not require courts to apply a test of “scientific certainty” to the admission of expert evidence, it does require that such testimony rest upon “good grounds,

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27. *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3d Cir. 1994)). Effective December 1, 2000, the Federal Rules of Evidence were amended to effectively codify this trilogy of U.S. Supreme Court cases. See *Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 869 (7th Cir. 2001) (stating that Rule 702 was amended in 2000 to “affirm[] the trial court’s role as gatekeeper and provide[] some general standards that the trial court must use to assess the reliability and helpfulness of the proffered expert testimony”) (alteration in original) (quoting FED. R. EVID. 702, advisory committee’s note (2000 amendments)).

28. See, e.g., Kaushal B. Majmudar, Note, *Daubert v. Merrell Dow: A Flexible Approach to the Admissibility of Novel Scientific Evidence*, 7 HARV. J.L. & TECH. 187, 188 (1993) (“This Note will argue that while *Daubert* is not a revolutionary decision, it marks a shift towards more flexible standards regarding the admissibility of scientific evidence.”). See also Judith A. Hasko, Note, *Daubert v. Merrell Dow Pharmaceuticals, Inc.: Flexible Judicial Screening of Scientific Expert Evidence Under Federal Rule of Evidence 702*, 1995 WIS. L. REV. 479, 479 (characterizing *Daubert* as “liberal” and *Frye* as “rigid”); J.E. Cullens, Jr., *A Review of Recent Daubert Decisions of Louisiana State Courts*, 52 LA. B.J. 352, 352 (2005) (“Although originally hailed as a triumph for plaintiffs’ attorneys attempting to use novel and untested scientific testimony to support their cases, trial judges—especially those sitting in federal courthouses—have typically used *Daubert* and its progeny to exclude rather than allow expert testimony at trial.”).

29. *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002) (citing *Porter v. Whitehall Labs. Inc.*, 9 F.3d 607, 614 (7th Cir. 1993)).

based on what is known.”<sup>30</sup>

The plaintiffs’ lawyers who lost the *Daubert* case argued that the judicial gatekeeper role is at odds with the jury system. It is not. Gatekeeping respects the role of judge and jury. It keeps our justice system functioning properly by shielding juries from misleading junk science. As the Second Circuit has recognized, the close evaluation of the fit between the scientific literature and the expert’s testimony required of district court judges by *Daubert* and its progeny do not “impinge upon the jury’s function. It is precisely such an undertaking that assures that an expert, when formulating an opinion for use in the courtroom, will employ the same level of intellectual rigor as would be expected in the scientific community.”<sup>31</sup>

### C. *The Public Policy Basis of Daubert*

It is not a coincidence that *Daubert* coincided with the emergence of toxic torts and the burgeoning use of experts in civil litigation.<sup>32</sup> Bad science presented as fact by experts can negatively impact the availability of beneficial products and services. For example, in early cases alleging that the morning sickness drug Bendectin caused birth defects, courts generally allowed both sides to present their evidence and let the jury decide the issue.<sup>33</sup> Despite overwhelming scientific evidence finding no link between the drug and birth defects, several juries in the

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30. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993); *see also* *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001) (“[N]either Rule 702 nor *Daubert* requires than an expert opinion resolve an ultimate issue of fact to a scientific absolute in order to be admissible.”); *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 390 (6th Cir. 2000) (finding that the district court “held the experts up to entirely too strict a standard” when it excluded their testimony because they could not determine the cause of death with certainty, but could only offer the probable cause); *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85-86 (1st Cir. 1998) (finding that the district court “set the bar too high” when it found that an expert’s technique, though it survived the rigors of testing, publication, peer review, and general acceptance within the scientific community, was unreliable due to a lack of precision). Some commentators have suggested that judges have occasionally “taken *Daubert* too far” by requiring a level of scientific certainty that is not attainable or requiring a “piece-by-piece” assessment of evidence rather than a holistic evaluation of the science. *See, e.g.*, Mark Hansen, *Science Experiment*, ABA J., Nov. 2005, at 10, 14 (quoting Georgetown University Law Center Professor Paul Rothstein).

31. *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 269 (2d Cir. 2002).

32. *See, e.g.*, Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 31 (1993) (citing studies that found a 1500 percent rise in the number of experts testifying in Cook County, Illinois between 1974 and 1989, and finding that experts testified in 86 percent of all cases, 95 percent of personal injury cases and 100 percent of product liability cases in a sample of California cases between 1985 and 1986).

33. *See, e.g.*, *Mekdeci v. Merrell Nat’l Labs.*, 711 F.2d 1510, 1510 (11th Cir. 1983) (upholding jury verdict).

mid-1980s, adrift in a sea of conflicting “expert” testimony, rendered multimillion-dollar awards after hearing expert evidence to the contrary.<sup>34</sup> These verdicts were ultimately reversed on appeal,<sup>35</sup> but not before the manufacturer removed Bendectin from the market in 1983, depriving women of the only Food and Drug Administration-approved medication that blunted the hard symptoms of morning sickness.<sup>36</sup> The *Daubert* case itself involved this very topic.<sup>37</sup> After *Daubert*, these Bendectin cases were thoroughly discredited.<sup>38</sup>

The Bendectin situation is not unique.<sup>39</sup> Silicone breast implant litigation forced Dow Corning to file Chapter 11 bankruptcy in 1995.<sup>40</sup> In those cases, some lower courts had abandoned their gatekeeping function. When scientists carefully examined the issue and acted as gatekeepers, no link was found between implants and autoimmune disorders, cancer, or any other serious disease.<sup>41</sup> Today, courts are

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34. See, e.g., *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990) (reversing a \$95 million verdict); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988) (affirming judgment for manufacturer notwithstanding a \$1.16 million verdict). See generally Sanders, *supra* note 32, at 4-12 (1993) (providing an overview of the Bendectin cases); Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System*, 88 GEO. L.J. 2167, 2171-72 (2000).

35. See, e.g., *Ealy*, 897 F.2d at 1160; see also Stewart, *supra* note 34, at 2171. Of the six cases examined by Joseph Sanders, five of the manufacturers eventually prevailed. See *Richardson*, 857 F.2d at 823; *In re Bendectin Litig.*, 857 F.2d 290, 290 (6th Cir. 1988); *Mekdeci*, 711 F.2d at 1510; *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 706 (Tex. 1997); *Hill v. Merrell Dow Pharm.*, No. C83-74TB (W.D. Wash. 1988) (decided without opinion). The verdict that remained intact and in favor of the plaintiffs was *Oxendine v. Merrell Dow Pharms., Inc.*, 506 A.2d 1100, 1113-15 (D.C. Cir. 1986). See Sanders, *supra* note 32, at 28-30 (recognizing that only one of six cases survived appellate review completely).

36. See Barbara J. Culliton, *Merrell Dow Stops Marketing Bendectin*, 221 SCI. 37, 37 (1983).

37. The trial court granted defendant’s motion for summary judgment because plaintiff’s expert theory was based on animal and test tube studies. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 582-83 (1993). No study supported plaintiff’s theory that Bendectin could cause malformations in human fetuses. *Id.* For these reasons, the trial court concluded that this theory did not meet the *Frye* general acceptance test. Plaintiffs appealed and the Ninth Circuit upheld the trial court’s ruling. The Supreme Court then set forth the *Daubert* factors and remanded the case for proceedings consistent with them. *Id.* at 597.

38. *Havner*, 953 S.W.2d at 708, 729 (extensively considering scientific methodology in a Bendectin case to find that the offered epidemiological studies failed to show a sufficiently increased risk and were not published or subject to peer review, and that offered animal studies did not support causation in humans).

39. PETER W. HUBER, *GALILEO’S REVENGE: JUNK SCIENCE IN THE COURTROOM 4* (1991) (stating that “junk science is not an altogether new phenomenon in the courtroom”).

40. James T. Rosenbaum, *Lessons from Litigation over Silicone Breast Implants: A Call for Activism by Scientists*, 276 SCI. 1524, 1524 (1997).

41. See MARCIA ANGELL, *SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 109-10* (1996) (authored by the executive editor of the *New England Journal of Medicine*).

applying *Daubert* to hold the line against unreliable testimony by experts hired by plaintiffs' lawyers who have attempted to attribute autism in children to thimerosal, a preservative used in life-saving vaccines, where all available peer-reviewed and generally accepted epidemiological studies contradict such a link.<sup>42</sup> Fortunately, judges have acted as gatekeepers and rejected such claims, preserving the availability of vaccines.

Whether courts exclude unreliable expert testimony impacts the outcome of such litigation as well as society as a whole.<sup>43</sup> Where there is no potentially broad harm to society, admitting unreliable expert testimony can unjustly harm a defendant where its product or conduct was not the cause of the plaintiff's injury. It undermines the ultimate function of courts—to seek the truth. It unnecessarily raises the cost and sometimes the availability of good products and services.

### III. THE SIGNIFICANT AND POSITIVE IMPACT OF *DAUBERT* IN THE COURTS

*Daubert* and its progeny “changed [the] deference-to-the-field approach . . . [and] brought [a] scientific culture to the courtroom.”<sup>44</sup> For example, in the first six years after *Daubert*, federal courts published 1065 opinions on expert admissibility, 871 of which involved civil cases, or over 36 times the number of rulings in civil cases under the *Frye* “general acceptance” test in the previous six-year period.<sup>45</sup>

A Federal Judicial Center survey of federal judges taken just prior to *Daubert* and again five years after *Daubert* found that “[j]udges were more likely to scrutinize expert testimony before trial and less likely to admit expert testimony” after *Daubert*.<sup>46</sup> Judges became less willing to

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42. See, e.g., *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 465, 473-75 (M.D.N.C. 2006) (granting summary judgment for the manufacturer defendant in case seeking to link thimerosal to autism where the plaintiff's expert's literature review did not meet the *Daubert* standard's requirements that expert testimony be derived by scientific method and relevant, that the expert doctor could not testify on general causation theory that autism could be caused by thimerosal, and that the proffered expert testimony on issue of specific causation, based on differential diagnosis, could not be admitted).

43. See Rosenbaum, *supra* note 40, at 1525 (discussing actions of some federal judges to exclude expert testimony that was not scientifically sound in the Bendectin and silicone breast implant litigation).

44. Faigman et al., *supra* note 14, at 655-56.

45. D. Michael Risinger, *Navigating Expert Reliability: Are Criminal Standards of Certainty Being Left on the Dock?*, 64 ALB. L. REV. 99, 104 (2000).

46. MOLLY TREADWAY JOHNSON ET AL., FED. JUDICIAL CTR., EXPERT TESTIMONY IN FEDERAL CIVIL TRIALS: A PRELIMINARY ANALYSIS I (2000).

invariably admit all proffered expert testimony.<sup>47</sup> According to the survey, 59% of federal judges admitted all proffered expert testimony in their most recent civil trial. This amount was down from 75% in response to the pre-*Daubert* survey question.<sup>48</sup> Generally, the testimony was excluded because it was not relevant.<sup>49</sup> Post-*Daubert*, judges became less likely to admit some types of expert testimony (65%) and more likely to hold pretrial hearings regarding admissibility of expert testimony (60%).<sup>50</sup>

A RAND Institute for Civil Justice study of federal district court decisions between 1980 (thirteen years prior to *Daubert*) and 1999 (six years after *Daubert*) produced similar results.<sup>51</sup> It found that “[s]tandards for reliability tightened in the years after the *Daubert* decision” and “the success rate for challenges rose.”<sup>52</sup> The proportion of evidence found unreliable after *Daubert* increased first in the physical or “hard” sciences, but there were later rises for health care and medicine, engineering and technology, social and behavioral sciences, and business, law, and public administration.<sup>53</sup> In one federal circuit, the exclusion rate for evidence based on physical science in product liability cases jumped from 53% during the two years before *Daubert* to 70% two years following *Daubert*.<sup>54</sup> Motions to dismiss on summary judgment were granted in 21% of challenges during the four years preceding *Daubert* compared to 48% in the two-year period beginning two years after *Daubert*, with 90% of the rulings against plaintiffs.<sup>55</sup> The study concluded: “[F]ollowing *Daubert*, judges scrutinized reliability more carefully and applied stricter standards in deciding whether to admit expert evidence. After *Daubert*, the proportion of challenged

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47. *Id.* at 4.

48. *Id.*

49. Judges most frequently excluded expert testimony because it was not relevant (47%), the witness was not qualified (42%), the proffered expert testimony would not help the trier of fact (40%), the facts or data upon which the expert testimony was based were not reliable (22%), the prejudicial nature of the testimony outweighed its probative value (21%), or the principles and methods underlying the expert’s testimony were not reliable (18%). *Id.* at 5.

50. *Id.* at 4.

51. LLOYD DIXON & BRIAN GILL, RAND INST. FOR CIV. JUST., CHANGES IN THE STANDARDS FOR ADMITTING EXPERT EVIDENCE IN FEDERAL CIVIL CASES SINCE THE *DAUBERT* DECISION 29 (2001), available at <http://www.rand.org/publications/MR/MR1439/MR1439.pdf>.

52. *Id.*

53. *See id.* at 33-35.

54. *Id.* at xvi.

55. *See id.* at 57, 62.

evidence in which reliability was discussed and the proportion of expert evidence found unreliable rose.”<sup>56</sup>

Distinguished law professor David Owen has also recognized that *Daubert* has successfully kept junk science out of federal product liability cases, where expert testimony is particularly important: “Post-*Daubert*, the federal district courts, exercising their newly appointed ‘gatekeeper’ function, have scrutinized expert testimony more closely, often holding rigorous pre-trial ‘*Daubert* hearings’—that are often outcome determinative—to determine the admissibility of proffered expert testimony.”<sup>57</sup>

*Daubert* has affected the admissibility of expert testimony in a wide range of areas. For example, prior to *Daubert*, courts increasingly allowed recovery for future lost profits based on expert testimony. A typical pre-*Daubert* case is *Perma Research & Development Co. v. Singer*, in which the Southern District of New York admitted a study prepared by a licensor projecting future profits at the time of entrance into a patent license contract.<sup>58</sup> Courts also permitted businesspeople in similar fields and certified public accountants to testify as experts in respect to future profits.<sup>59</sup> Such damages were traditionally considered too speculative to be recoverable.<sup>60</sup> Since *Daubert*, courts more often exclude such testimony. For example, *Parkway Garage Inc. v. City of Philadelphia*, a case decided soon after *Daubert*, involved damages where the city cancelled the lease of a parking garage. An expert was permitted to testify about the financial records of a parking garage, but any testimony about lost customers and their parking habits was excluded as too speculative and without basis in the expert’s field of economics.<sup>61</sup> Similarly, *Marcel v. Placid Oil Co.*,<sup>62</sup> *Henry v. Hess Oil Virgin Islands Corp.*,<sup>63</sup> and *Elcock v. Kmart Corp.*<sup>64</sup> provide three examples where courts adhering to *Daubert* principles excluded expert testimony on lost earnings in tort cases. In each case, the courts found

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56. *Id.* at 61.

57. David G. Owen, *A Decade of Daubert*, 80 DENVER UNIV. L. REV. 345, 362 (2002).

58. *Perma Research & Dev. Co. v. Singer*, 402 F. Supp. 881, 899-901 (S.D.N.Y. 1975), *aff’d*, 542 F.2d 111 (2d Cir. 1976).

59. *See, e.g.*, *Lee v. Joseph E. Seagram & Sons, Inc.*, 552 F.2d 447, 454-55 (2d Cir. 1977); *Harsha v. State Sav. Bank*, 346 N.W.2d 791, 798-99 (Iowa 1984).

60. *Harsha*, 346 N.W.2d at 797 (citing *Shinrone, Inc. v. Tasco, Inc.*, 283 N.W.2d 280, 286 (Iowa 1979)).

61. *Parkway Garage, Inc. v. City of Philadelphia*, No. 90-7752, 1994 WL 412430, at \*7-8 (E.D. Pa. Aug. 3, 1994).

62. *Marcel v. Placid Oil Co.*, 11 F.3d 563, 567-68 (5th Cir. 1994).

63. *Henry v. Hess Oil V.I. Corp.*, 163 F.R.D. 237, 246-48 (V.I. 1995).

64. *Elcock v. Kmart Corp.*, 233 F.3d 734, 754-56 (3d Cir. 2000).

that the experts' projections of future earnings failed to take into account the specific circumstances of the plaintiff. While expert testimony on future profits or earnings may sometimes be admitted under *Daubert*, "the key difference is the need for the expert to use methods that have a basis in her proffered field of expertise,"<sup>65</sup> an increased emphasis that the testimony "fit" the individual case, and the use of the scientific method to evaluate such evidence.<sup>66</sup>

In addition, *Daubert* has affected the admissibility of the testimony of economists on damages for lost enjoyment or value of life, sometimes referred to as "hedonic damages."<sup>67</sup> Prior to *Daubert*, some courts allowed such testimony with little or no review of the soundness of the approach.<sup>68</sup> Today, courts are increasingly willing to exclude testimony that applies statistics regarding the amount consumers are willing to pay for safety devices, compensation levels in risky jobs, or the government's willingness to impose safety regulations to suggest to a jury an expert opinion on the monetary value a person would purportedly pay to avoid death.<sup>69</sup> As one commentator recognized: "We may be on the way to a kind of judicial notice of the unreliability of [expert testimony on hedonic damages]."<sup>70</sup> One trial court judge ruled that "any attempted *Daubert/Kumho* analysis of [such a theory] is undertaken only at the risk of according it undue dignity. . . . Merely to pose the question of whether [the proposed expert's] proffered approach

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65. Shubha Ghosh, *Fragmenting Knowledge, Misconstruing Rule 702: How Lower Courts Have Resolved the Problem of Technical and Other Specialized Knowledge in Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 1 CHI.-KENT J. INTELL. PROP. 1, 43 (1999), <http://jip.kentlaw.edu/art/volume1/1-1-1.htm>.

66. *Id.* at 45, 46.

67. For a general discussion of hedonic damages and the admissibility of expert testimony quantifying such damages, see generally Victor E. Schwartz & Cary Silverman, *Hedonic Damages: The Bubbling Cauldron*, 69 BROOK. L. REV. 1037 (2004).

68. Ghosh, *supra* note 65, at 48-49. For example, in *Sherrod v. Berry*, a federal court permitted such testimony. 629 F. Supp. 159 (N.D. Ill. 1985). The court applied no particular standard and did not even evaluate the "general acceptance" of the proposed theory, most likely because the testimony was not scientific, but economic. With little analysis, the court found that the expert's method of valuing life was not speculative, but was admissible because it was "relevant and material and would aid the jury in determining the proper amount of damages in the event it found in favor of the plaintiff." *Id.* at 162.

69. See, e.g., *Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1246 (10th Cir. 2000) (allowing testimony about hedonic damages, "excluding the quantification which has troubled both courts and academics, but allowing an explanation adequate to insure the jury did not ignore a component of damages allowable under state law").

70. G. Michael Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 CREIGHTON L. REV. 939, 1015 (1996).

to hedonic damages demonstrates 'intellectual rigor' is to answer the question."<sup>71</sup>

Post-*Daubert*, courts are also less likely to admit testimony simply because the expert has testified before many other courts. For example, a Louisiana appellate court reversed a trial court admitting expert testimony because the trial court simply asserted that the expert had "been qualified by courts across the land," and thus the court did "not presume that all of them were incorrect."<sup>72</sup> Instead, the appellate court took a closer look at the witness's credentials and found he had no engineering degree, no employees, no facilities or equipment, and he had a poor educational background in engineering with employment experience that had nothing to do with auto design.<sup>73</sup>

Law professor David E. Bernstein recognized a strengthening of expert testimony standards in several areas soon after *Daubert*.<sup>74</sup> For instance, before *Daubert*, courts frequently admitted expert testimony based on "*post hoc* clinical evidence," meaning that experts could testify that a substance caused an injury simply because the plaintiff was exposed to the substance just prior to the injury.<sup>75</sup> An expert, for example, might testify that an infant developed a brain tumor as a result of a measles vaccination simply because the tumor developed soon after the vaccination. This is an example of the *post hoc ergo propter hoc* fallacy that is exposed as specious in first-year torts casebooks.<sup>76</sup> Since *Daubert*, *post hoc* evidence is frequently excluded.<sup>77</sup>

Professor Bernstein also found that courts more often require physicians testifying on the most likely cause of a patient's injury to eliminate other possible causes of the condition. He further found that courts more aggressively demanded that physicians consider the dosage of a substance to which a patient was exposed when giving an opinion on causation; and that courts require physicians to have expertise on the subject in the case; they no longer permitted a doctor to testify on any

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71. *Anderson v. Hale*, No. CIV-02-0113-F, 2002 WL 32026151, at \*7 (W.D. Okla. Nov. 4, 2002) (citation omitted).

72. *Mistich v. Volkswagen of Germany, Inc.*, 650 So. 2d. 385, 392 (La. Ct. App. 1995) (quoting an unreported decision).

73. *Id.* at 391-92.

74. David E. Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 15 CARDOZO L. REV. 2139, 2147 (1994).

75. *Id.*

76. See VICTOR E. SCHWARTZ ET AL., PROSSER, WADE & SCHWARTZ'S TORTS 267-68 (11th ed. 2005) (examining *Kramer Serv., Inc. v. Wilkins*, 186 So. 625 (Miss. 1939)).

77. Bernstein, *supra* note 74, at 2149.

medical issue.<sup>78</sup> Post-*Daubert* decisions have more consistently excluded physician testimony when offered outside his or her area of expertise.<sup>79</sup>

#### IV. THE DRAINING OF *DAUBERT*

Although *Daubert* has generally strengthened standards for the admissibility of expert testimony, some courts have deviated from the words or spirit of the Supreme Court's decision. An analysis of primarily federal appellate cases decided over the past five years reveals at least five areas of inconsistency: relevance, flexibility of *Daubert*'s application, application (or lack thereof) of the expert's methodology, the necessity of pre-trial *Daubert* hearings, and appellate standards of review.

##### A. *Relevance, Reliability, and Analytical Gaps*

The first of these areas of inconsistency involves a foundational issue of the law of evidence—relevance. The Federal Rules were set up to tilt toward admissibility of ordinary evidence. Federal Rules of Evidence 401 and 402 allow for broad admissibility of evidence so long as it is “relevant,” meaning that it has “any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.”<sup>80</sup> As the Supreme Court has recognized, “[t]he Rule’s basic standard of relevance thus is a liberal one.”<sup>81</sup>

When the admissibility of evidence offered by those presented as experts is at issue, the Federal Rules and the Supreme Court have recognized that additional safeguards are warranted and a higher level of relevance is required. In *Daubert*, the Court observed that while Rules 401 and 402 provide the “baseline” for admissibility, when expert testimony is offered, the more precise and rigorous requirements of

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78. *Id.* at 2159-63. For example, in the pre-*Daubert* case *Smith v. Ortho Pharm. Corp.*, the court found that a medical doctor who did not specialize in genetics, epidemiology, or teratology was qualified to testify on whether spermicide caused a child's birth defects, though it ultimately found the proffered evidence inadmissible. 770 F. Supp. 1561, 1567-68, 1581 (N.D. Ga. 1991).

79. *See, e.g.,* *Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 615 (7th Cir. 1993); *see also* *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 969-70 (10th Cir. 2001) (holding that the district court did not abuse its discretion when it excluded the testimony of a physician who specialized in oncology where the issue—intramedullary nailings and whether manufacturer warnings were adequate—was completely unrelated, and noting that “merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue”).

80. FED. R. EVID. 401, 402.

81. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993).

Rule 702 speak to the issue.<sup>82</sup> In effect, Rule 702's requirement that "scientific, technical, or other specialized knowledge . . . assist the trier of fact to understand the evidence or to determine a fact in issue"<sup>83</sup> trumps the otherwise liberal relevancy requirements of the Federal Rules. "Relevant," in the context of expert testimony, means a "valid scientific connection to the pertinent inquiry,"<sup>84</sup> a heightened level of relevance characterized by the Court in *Daubert* as one of "fit."<sup>85</sup> The Court further explained this "fit" requirement in *Joiner*:

[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 . . . 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 proffered.<sup>86</sup>

This is a higher standard of relevance than the "more or less probable" approach of Federal Rules of Evidence 401 and 402 that govern relevance generally. It provides that experts may not offer opinions that do not "fit" the particular facts of the case.<sup>87</sup> The higher standard recognizes that a district court has a special duty to examine proffered expert testimony, testimony that by definition is outside the realm of an ordinary juror's scope of knowledge, to ensure it is based on reliable, scientific principles.<sup>88</sup> In sum, the "sevens" are different than the "fours."<sup>89</sup> Moreover, an expert's methodology must not only be reliable, but when applied to the facts of a case, the conclusion should not require "too great an analytical gap."<sup>90</sup>

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82. *Id.* at 587-88.

83. FED. R. EVID. 702.

84. *Daubert*, 509 U.S. at 591-92.

85. *Id.* at 591 (adopting the standard applied by Judge Becker in *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)).

86. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

87. In *Kumho Tire*, the Supreme Court emphasized that a court must focus on the "reasonableness of using such an approach, along with [the expert's] particular method of analyzing the data thereby obtained, to draw a conclusion regarding the particular matter to which the expert testimony was directly relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 154 (1999).

88. In 2000, the Supreme Court again recognized that, "[s]ince *Daubert*, . . . parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet." *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000).

89. *Daubert*, 509 U.S. at 591 (finding that, in cases involving expert testimony, Rule 702 "goes primarily to relevance").

90. *See Joiner*, 522 U.S. at 146.

Despite the Supreme Court's instructions, some courts apply the broad relevancy standard of Rule 401 to determine the admissibility of expert testimony. For example, the Second Circuit has repeatedly looked to Rule 401 to determine the relevancy of expert testimony and disregarded the notion of "fit."<sup>91</sup> In a recent case, the Tenth Circuit looked only to whether there was "a logical relationship between the evidence proffered and the material issue that the evidence is supposed to support,"<sup>92</sup> rather than at the presence of the closer "fit" mandated by the Supreme Court. The difference between the fours and the sevens is significant because, under Rules 401 and 402, evidence need only pass a bare "some relation to an issue" threshold, while under Rule 702, the evidence must correspond to the facts of the case. These decisions have drained *Daubert* of its fundamental purpose: to assist juries in evaluating the credibility of reliable expert evidence.

Most federal courts have taken an approach that better protects against unreliable expert testimony, requiring a higher standard described as a "special relevance requirement"<sup>93</sup> or "higher than bare relevance,"<sup>94</sup> and have contrasted the "liberal admission of evidence"<sup>95</sup> standard reflected in Rules 401 and 402 with Rule 702's "more stringent standards of reliability and relevance."<sup>96</sup> They have found that "[e]ven a theory that might meet certain *Daubert* factors, such as peer review and publication, testing, known or potential error rate, and general

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91. See, e.g., *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265-66 (2d Cir. 2002) ("In fulfilling this gatekeeping role, the trial court should look to the standards of Rule 401 in analyzing whether proffered expert testimony is relevant, i.e., whether it 'has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.'") (citation omitted) (quoting *Campbell v. Metro. Prop. & Cas. Ins. Co.*, 239 F.3d 179, 184 (2d Cir. 2001) (quoting Rule 401's definition of relevance and not discussing "fit")); *Zuchowicz v. United States*, 140 F.3d 381, 387 (2d Cir. 1998) (holding, without discussing "fit," that, so long as an expert's opinion is based on reliable methodology, it should be admitted). In addition, the Fifth Circuit has occasionally gone down this erroneous path. See *Mathis v. Exxon Corp.*, 302 F.3d 448, 460 (5th Cir. 2002) (using Rule 401 to define relevancy under Rule 702). *But cf.* *Bocanegra v. Vicmar Servs., Inc.*, 320 F.3d 581, 584 (5th Cir. 2003) (articulating the heightened Rule 702 relevance requirement).

92. *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1234 (10th Cir. 2004) (admitting expert testimony based on products that had a different design from the water heater at issue without requiring the experts to account for those differences or to validate their theory).

93. *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) ("To be admissible, expert testimony must be relevant not only in the sense that all evidence must be relevant, but also in the incremental sense that the expert's proposed opinion, if admitted, would likely assist the trier of fact to understand or determine a fact in issue.") (citation omitted).

94. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994).

95. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1310 (11th Cir. 1999).

96. *Id.*; see also *McDowell v. Brown*, 392 F.3d 1283, 1295 (11th Cir. 2004).

acceptance, should not be admitted if it does not apply to the specific facts of the case.”<sup>97</sup>

Experienced litigators, such as Richard O. Faulk and Robert M. Hoffman, have observed that the heightened relevance analysis is becoming increasingly significant in some trial courts, and could potentially eclipse the *Daubert* factors.<sup>98</sup> They find that courts have “insist[ed] that the reasoning process be explained to ensure that the methodology and the facts and data upon which [they rely] are capable of producing an ultimate opinion that is relevant to the case.”<sup>99</sup> They recognize that there are actually two types of “analytical gaps” that can preclude admission of expert testimony.<sup>100</sup> The first type of analytical gap occurs when the data or assumptions relied upon by the expert do not fit the actual facts of the case.<sup>101</sup> This is primarily an issue of relevance. The second type of analytical gap occurs when the expert does not faithfully apply his or her methodology to the facts to reach the ultimate conclusion.<sup>102</sup> This is primarily an issue of reliability, and goes to the importance of a judge’s examination of an expert’s conclusions, not just his or her methodology. Both a relevance fit and reliability fit are important inquiries under *Daubert*.

#### 1. The Relevance Fit—Making Certain Expert Theories Are Consistent with the Facts of the Case and Theory of Liability

A number of courts, applying Rule 702, have properly precluded experts from testifying when their theory might be of interest to a jury (and admissible under the fourth), but could be misleading and prejudicial because it does not closely fit the facts. For example, a Rhode Island

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97. *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056, 1057 (8th Cir. 2000) (holding, in an antitrust case, that economist’s testimony was properly excluded because his model of the market did not reflect facts in evidence); *see also* *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 250 (6th Cir. 2001) (“This question of relevance, described as ‘fit,’ is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.”) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993)).

98. *See* Richard O. Faulk & Robert M. Hoffman, *Beyond Daubert and Robertson: Avoiding and Exploiting “Analytical Gaps” in Expert Testimony*, 33 *ADVOC.* 71, 71 (2005). They suggest that this may be the case because trial court judges may find it less challenging to determine whether an expert’s observations and methodology fit the facts of the case and supports his or her conclusions than attempting to apply each of the *Daubert* factors to different disciplines and factual scenarios. *See id.*

99. *Id.* at 74.

100. *See id.* at 74-75 (citing Kimberly S. Keller, *Bridging the Analytical Gap: The Gammill Alternative to Overcoming Robinson and Havner Challenges to Expert Testimony*, 33 *ST. MARY’S L.J.* 277, 312 (2002)).

101. *Id.*

102. *Id.*

woman was injured when she was struck by her rolling car after parking on a sloping driveway without setting the parking brake.<sup>103</sup> She claimed that her Mercedes was defective because it did not include a “park ignition interlock,” which would have prevented her from removing the key from the ignition until she engaged the parking brake,<sup>104</sup> and sought to introduce a mechanic to testify as an expert on product design.<sup>105</sup> In addition to finding the proffered witness unqualified to testify on automobile design, the appellate court found that the expert’s “false park detent theory” was unreliable, largely based on the lack of even an attempt to apply the theory to the circumstances in the case.<sup>106</sup> As the appellate court recognized:

[The proffered expert] examined the vehicle away from the site of the accident. He did not, in any way, attempt to replicate the known facts surrounding the injury-producing event, but rather, tested his theory by raising a wheel of the vehicle as it sat in [an automobile repair shop]. On the record before us, it appears that [the proffered expert] did little more than come to the unremarkable conclusion that the vehicle’s wheels would not turn when the gear selector level was in latched park, but that they would turn when the lever was in any other position.<sup>107</sup>

*Kempner Mobile Electronics, Inc. v. Southwestern Bell Mobile Systems* is another example of a case where an expert’s testimony on damages was at odds with the case’s theory of liability.<sup>108</sup> Kempner, a cellular phone sales agent, sued its exclusive service provider, Cingular, claiming that it would have entered an agreement to sell products for Nextel, rather than Cingular, had it know of Cingular’s alleged misrepresentations.<sup>109</sup> After a jury finding of liability, however, the expert sought to testify as to Kempner’s damages based on simultaneous sale of both Nextel and Cingular products.<sup>110</sup> Citing Rule 702, not Rule 401, the Seventh Circuit concluded that the district court properly

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103. *Bogosian v. Mercedes-Benz of N. Am., Inc.*, 104 F.3d 472, 474-75 (1st Cir. 1997).

104. *Id.* at 475.

105. *See id.*

106. *See id.* at 479-80.

107. *Id.* at 479.

108. *See Kempner Mobile Elecs., Inc., v. Sw. Bell Mobile Sys.*, 428 F.3d 706, 712 (7th Cir. 2005).

109. *Id.*

110. *See id.*

excluded the evidence as “irrelevant and inapplicable to its theory of liability.”<sup>111</sup>

*McDowell v. Brown*<sup>112</sup> shows how expert testimony can involve an impermissible leap from the theory to the facts of the case. The plaintiff, a prison inmate, complained to guards of back pain. They did not transport him to an off-site medical treatment facility until several hours later, and he then underwent surgery for an epidural abscess. Despite surgery and treatment, he was rendered a paraplegic. The plaintiff sued the facility, arguing that the delay in treatment caused his paralysis. He attempted to bolster this theory with the testimony of two expert witnesses, who cited a study analyzing treatment delays of forty-eight hours, not the four hours the plaintiff waited.<sup>113</sup> For this reason, the trial court found, and the Eleventh Circuit affirmed, that there was too large an analytical gap between the study relied upon by the experts and the conclusion they reached in the plaintiff’s case.<sup>114</sup>

There are many other examples of courts properly excluding testimony where an expert’s theory did not follow the facts in evidence or the plaintiff’s theory of liability.<sup>115</sup> Focusing on the specific rules of evidence in the 701 series of cases is appropriate in terms of proper statutory construction, as the specific trumps the general, sound public policy, and the Supreme Court’s ruling in *Daubert* itself.

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111. See *id.* at 713; see also *Masters v. Hesston Corp.*, 291 F.3d 985, 991-93 (7th Cir. 2002) (finding that the expert was well-qualified and his testimony in a product defect case was based on accepted engineering principles, but was not properly applied to the particular design at issue).

112. 392 F.3d 1283 (11th Cir. 2004).

113. *Id.* at 1299-1300.

114. *Id.* at 1299-1302.

115. See, e.g., *J.B. Hunt Transp., Inc. v. Gen. Motors Corp.*, 243 F.3d 441, 444-45 (8th Cir. 2001). In *J.B. Hunt*, the Eighth Circuit ruled that the district court properly excluded the testimony of an accident reconstructionist where his theory was based on three collisions with the plaintiff’s car, where eye-witness testimony established that the plaintiff’s vehicle only twice collided with one of the three vehicles involved. The circuit court also upheld the district court’s decision to exclude the testimony of a second purported expert, a “foamologist,” which was built upon the three-car collision theory proffered by the first expert. See also *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1138-39 (9th Cir. 2002) (reversing and remanding on grounds that the district court failed to consider whether plaintiff’s expert demonstrated that released radiation could cause the plaintiff’s ailment); *Children’s Broad. Corp. v. Walt Disney Corp.*, 245 F.3d 1008, 1018-19 (8th Cir. 2001) (ruling that the district court acted within its discretion when it ordered a new trial because, among other flaws, the plaintiff’s expert testified on damages based on the original counts in the complaint, while only three counts had survived summary judgment).

## 2. The Reliability Fit—Requiring Conclusion to Flow from Methodology

Perhaps misled by unclear language in *Daubert*, some courts have declined to act as gatekeepers with respect to an expert's conclusions as contrasted with his or her reasoning, methodology, or premises. The fact that these courts have taken the wrong path may stem from a statement in *Daubert* that: "The focus [of the admissibility inquiry], of course, must be solely on principles and methodology, not on the conclusions that they generate."<sup>116</sup> Some courts have interpreted this language to mean that they must focus their reliability analysis exclusively on an expert's methodology,<sup>117</sup> while permitting conclusions (which may lack reliability) to dodge the gatekeeping function. Other courts have properly recognized the potential for a "methodology-conclusion gap,"<sup>118</sup> and held that district court judges should examine an expert's ultimate conclusion "to determine whether they could reliably follow from the facts known to the expert and the methodology used."<sup>119</sup>

As discussed earlier, *Joiner* clarified that "conclusions and methodology are not entirely distinct from one another."<sup>120</sup> When experts' conclusions do not follow from the science, data, or other facts supporting their theories, there is "simply too great an analytical gap" to

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116. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993).

117. *See, e.g., TFWS, Inc. v. Schaefer*, 325 F.3d 234, 240 (4th Cir. 2003) (stating that, "[i]n applying *Daubert*, a court evaluates the methodology or reasoning that the preferred scientific or technical expert uses to reach his conclusion; the court does not evaluate the conclusion itself," and upholding admission of expert testimony to establish that Maryland liquor prices were higher than the rest of the country even though the expert's analysis was limited on sales in metropolitan areas); *Smith v. BMW N. Am., Inc.*, 308 F.3d 913, 919 n.9 (8th Cir. 2002) ("Under *Daubert*, a court should review only the methodology of the expert, not his or her conclusion."); *Campbell v. Metro. Prop. & Cas. Ins. Co.*, 239 F.3d 179, 186 (2d Cir. 2001) (finding that a district court must focus "solely on . . . methodology, not on the conclusions they generate" in ruling that expert testimony was admissible despite gaps or inconsistencies between the reasoning and conclusion) (quoting *Daubert*, 509 U.S. at 595).

118. *See Faulk & Hoffman, supra* note 98, at 75.

119. *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) ("[T]rial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable."); *see also Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 254 (6th Cir. 2001) (finding that although there are commonly observed symptoms of PCB exposure documented in scientific literature, an expert's conclusion that PCB exposure caused the kinds of symptoms experienced by the plaintiffs in the case at issue was not reliable); *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 279 (5th Cir. 1998) (en banc) (noting that "[s]everal post-*Daubert* cases have cautioned about leaping from an accepted scientific premise to an unsupported one," and finding no scientific support for the expert's conclusion that exposure to any irritant at unknown levels triggers the asthmatic-type condition experienced by the plaintiff).

120. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

admit the testimony.<sup>121</sup> The Court further instructed that “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”<sup>122</sup>

As a matter of basic logic in the search for the truth, *Daubert* principles must be applied to both an expert’s methodology and to his or her conclusions. Experts, unlike lay witnesses, are permitted to reach conclusions on the ultimate issue in the case.<sup>123</sup> For that very reason, it is particularly important to ensure their conclusions flow from their methodology before they are permitted to testify. To paraphrase Justice Cardozo, conclusions in the air, so to speak, will not do.<sup>124</sup>

As the Third Circuit recognized in *Heller v. Shaw Industries, Inc.*:

[T]he reliability analysis applies to all aspects of an expert’s testimony: the methodology, the facts underlying the expert’s opinion, the link between the facts and the conclusion, *et alia*.

....

[R]eliable methods for making a diagnosis cannot sanitize an otherwise untrustworthy conclusion.

....

... While the district court may not reject an expert’s conclusion simply because the court finds it wanting, it is surely within the court’s province to ensure that the conclusion, particularly a medical expert’s ultimate conclusion on causation, “fits” with the data alleged to support it.<sup>125</sup>

When a court looks to the data underlying expert opinion but neglects to evaluate its relation to the expert’s conclusion, as the Michigan Supreme Court has recognized, “ostensibly legitimate data may serve as a Trojan horse that facilitates the surreptitious advance of junk science and spurious, unreliable opinions.”<sup>126</sup>

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121. *Id.*

122. *Id.*

123. FED. R. EVID. 704(a) (stating that opinion testimony is not objectionable simply because it embraces an ultimate issue to be decided by the trier of fact).

124. See *Palsgraf v. Long Island R.R.*, 162 N.E. 99, 99 (N.Y. 1928).

125. *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155-58 (3d Cir. 1999). The court repeatedly emphasized that the experts’ conclusions failed to flow from their data and methodologies. See *id.* at 158-61.

126. *Gilbert v. DaimlerChrysler Corp.*, 685 N.W.2d 391, 409 (Mich. 2004).

A trial and retrial in *Amorgianos v. National Railroad Passenger Corp.*<sup>127</sup> illustrates the impact of a trial court's decision permitting an expert to testify about conclusions that did not properly flow from his or her methodology. In that case, the plaintiff claimed he inhaled toxic fumes while painting a bridge, which lead to neurological and cognitive conditions as well as various physical ailments.<sup>128</sup> The plaintiff called his treating physician to testify that he suffered from a persistent nervous system disorder that severely limited his strength, ability to walk, and arm movement.<sup>129</sup> The physician concluded that the fumes caused the injury, largely based on the timing of his symptom's onset in relation to the paint job.<sup>130</sup> The physician's diagnosis was directly refuted by a video showing the plaintiff walking without apparent difficulty, a medical report filed by the plaintiff after a car accident in which he denied the types of physical problems alleged in the lawsuit, and an independent medical examiner who found no abnormal condition.<sup>131</sup> In addition, the plaintiff complained of a lack of reflexes only in the left side of his body, when the condition diagnosed typically manifested itself in bilateral, symmetrical symptoms.<sup>132</sup>

In the first trial, the court admitted the expert testimony and the jury returned a \$3.3 million award that included lost earnings, pain and suffering, and loss of consortium.<sup>133</sup> Following the verdict, the district court judge found that the verdict was against the weight of the evidence and ordered a new trial.<sup>134</sup> The case was reassigned to another district court judge who granted the defendant's *Daubert* motion to exclude the expert testimony as unreliable and ultimately granted the defendant's motion for summary judgment due to the lack of evidence of general causation.<sup>135</sup> The district court found, and the Second Circuit affirmed, that the studies cited by the physician had too great an analytical gap to support her conclusion that the plaintiff's injury was caused from exposure to the paint fumes for three reasons: (1) they did not consider short-term effects of exposure; (2) they included individuals who were exposed to substances other than those to which the plaintiff was exposed; and (3) they all found symmetrical disabling effects, not an

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127. 303 F.3d 256 (2d Cir. 2002).

128. *Id.* at 260.

129. *Id.* at 262.

130. *Id.*

131. *Id.* at 263.

132. *Id.*

133. *Id.* at 260.

134. *Id.*

135. *Id.*

effect on one side of the body as the plaintiff complained.<sup>136</sup> The appellate court rejected the plaintiff's contention that the district court judge "traded a judicial robe for a white lab coat,"<sup>137</sup> stating that "when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony."<sup>138</sup> An expert's analysis must be reliable "at every step," including reaching a conclusion based on the facts and methodology.<sup>139</sup>

On the other hand, the Tenth Circuit permitted a Trojan horse to slip through the gate in *Bitler v. A.O. Smith Co.*<sup>140</sup> In that case, the question was whether a defect in a water heater's gas control mechanism caused a house fire.<sup>141</sup> The plaintiffs' experts based their analysis on research finding that *large* copper sulfide particles can cause leaks in water heaters without a mesh inlet screen.<sup>142</sup> The experts based their assessment on this data, but did not test their theory.<sup>143</sup> Nevertheless, the experts presented to the jury the conclusion that *tiny* particles mixed with grease could surpass the protective screen of the water heater at issue and cause an intermittent gas leak.<sup>144</sup> The defendants explained the logic gap by way of analogy, stating: "Sommer's theory is akin to concluding that because a large boulder, bounding down a hillside, may be capable of crushing a passing car, a small pebble could do so as well."<sup>145</sup>

As these cases show, the gatekeeper role is compromised when expert testimony is admitted because the methodology is apparently sound, but the conclusion is detached from the facts of the case or the expert's analysis.

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136. *Id.* at 270. The court excluded the testimony of an industrial hygienist's conclusions due to a similar lack of fit between the scientific literature and the facts of the case. *Id.*

137. *Id.* at 264.

138. *Id.* at 266.

139. *See id.* at 267.

140. *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227 (10th Cir. 2005), *cert. denied*, 126 S. Ct. 395 (2005).

141. *See id.* at 1231.

142. *See id.*

143. *Id.* at 1235.

144. *See id.* at 1231, 1238.

145. Petition for Writ of Certiorari at 11, *White-Rodgers v. Bitler*, 126 S. Ct. 395 (2005) (No. 04-1485).

B. “Flexibility” Does Not Mean “Abdication”

Courts have occasionally misinterpreted the nature and extent of their flexibility in applying the *Daubert* factors, sometimes to the point of abdication. Those courts unduly emphasize language in the Supreme Court’s opinion, which characterized the inquiry as “flexible,” stated that the trial court “may” consider the provided factors, and clarified that the factors were not intended as a “definitive checklist or test” for determining whether a theory or technique is reliable.<sup>146</sup> These qualifications, however, stemmed from the possibility that, in some circumstances, applying one or more of the other factors discussed by the Court might not be feasible or applicable in a particular case.<sup>147</sup>

As Justice Scalia, joined by Justices O’Connor and Thomas, cautioned at the time, “[T]he discretion it endorses—trial-court discretion in choosing the manner of testing expert reliability—is not discretion to abandon the gatekeeping function.”<sup>148</sup> In accord with this philosophy, the Fifth Circuit has warned that “*Kumho Tire*’s emphasis on the word ‘may’ should not be misunderstood to grant open season on the admission of expert testimony by permitting courts discretionarily to disavow the *Daubert* factors.”<sup>149</sup> The Seventh Circuit has similarly cautioned that while the *Daubert* factors are nonexclusive and flexible, “[i]t is incumbent upon the trial court to carefully consider these factors before admitting any expert scientific evidence.”<sup>150</sup>

Some courts have gone further. They not only look to the four factors articulated in *Daubert*, but also closely consider additional factors. The Third Circuit, for example, has adopted this “*Daubert-plus* approach.” It encourages trial courts to consider the factors discussed in *Daubert* as well as the method’s nonjudicial uses and the relationship of the technique to methods that have been established as reliable.<sup>151</sup> Some

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146. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-94 (1993).

147. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999) (“[W]hether *Daubert*’s specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine.”).

148. *Id.* at 158-59 (Scalia, J., concurring).

149. *Black v. Food Lion, Inc.*, 171 F.3d 308, 311 (5th Cir. 1999).

150. *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002); *see also Elsayed Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1066 (9th Cir. 2002) (vacating a district court’s admission of expert testimony when it found that the court “abdicated its gatekeeping role by failing to make any determination that [the expert’s] testimony was reliable”).

151. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 n.8 (3d Cir. 1994) (finding relevant factors to include “(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to

appellate courts have found it particularly appropriate for a district court determining reliability to consider whether the expert's opinions were formed for the purpose of testifying and funded by the attorneys litigating the case or whether they were developed naturally outside the context of litigation.<sup>152</sup>

Nevertheless, other courts continue to admit expert testimony without engaging in an adequate *Daubert* analysis of its reliability.<sup>153</sup> By overemphasizing the "flexible" approach language, they may admit expert testimony after closely relying on a single factor or permit admission even when one applicable factor, i.e., testing, is clearly not met. These courts, in a sense, view *Daubert* as liberalizing the admissibility of expert testimony (beyond general acceptance under *Frye*) to provide additional options to find that evidence is admissible without undertaking the corresponding thorough review of its reliability.

### 1. Testing a Readily Testable Theory

An example of such abrogation occurs when a court ignores a relevant *Daubert* factor, such as when it admits an expert's theory that is readily testable even though the expert did not attempt to prove its accuracy. Expert testimony must be "ground[ed] in the methods and procedures of science" to satisfy the standard of evidentiary reliability.<sup>154</sup> *Daubert* recognized that, first and foremost, what distinguishes theory or technique from admissible expert testimony is whether it can be and has been tested.<sup>155</sup> The Supreme Court emphasized the importance of testing as a "key" to determining admissibility of expert testimony.<sup>156</sup> Courts generally recognize the testing factor as "*Daubert's* most significant guidepost."<sup>157</sup>

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be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put"); see also *Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 534-35 (7th Cir. 2005) (quoting six additional factors discussed by the 2000 Advisory Committee's Notes to Rule 702).

152. *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1056 (9th Cir. 2003); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001).

153. See *infra* notes 285-90 and accompanying text.

154. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

155. See *id.* at 593. It may surprise some to learn that an originator of the scientific method was not a scientist, but none other than a lawyer. In 1620, Sir Francis Bacon, a barrister who rose to be Lord Chancellor of England under the reign of James I, published his seminal work, *Novum Organum*. Bacon believed that "investigating and discovering truth" about nature requires a repeating cycle of observation, hypothesis, experimental tests, and the need for independent verification. FRANCIS BACON, *NOVUM ORGANUM* (1620), reprinted in *ADVANCEMENT OF LEARNING AND NOVUM ORGANUM* 316-17, 332 (rev. ed., Willey Book Co. 1944) (1900).

156. *Daubert*, 509 U.S. at 593 ("Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what

Testing is not only important with respect to scientific evidence, it is important with respect to technical or other specialized knowledge as well. In *Kumho Tire*, the Court found that Rule 702 made “no relevant distinction between ‘scientific’ knowledge and ‘technical’ or ‘other specialized’ knowledge” and found that the district court’s gatekeeping obligation applied equally to all expert testimony.<sup>158</sup> As one of the nation’s leading authorities on scientific evidentiary issues, Professor Margaret Berger has recognized: “Although Rule 702 specifies that an expert may be qualified through experience, the Court’s emphasis in *Daubert* on ‘testability’ suggested that an expert should not be allowed to base a conclusion solely on experience if the conclusion can be easily tested.”<sup>159</sup>

An expert’s hypothesis, without testing, is rendered unsupported speculation. As a well-respected scientific research text states:

The most important feature of a hypothesis is that it is a mere trial idea, a tentative suggestion concerning the nature of things. Until it has been *tested*, it should not be confused with a *law*. Unfortunately, in many fields, especially on the borderlines of science, hypotheses are often accepted without adequate tests. Plausibility is not a substitute for evidence, however great may be the emotional wish to believe.<sup>160</sup>

In effect, without testing, the expert has thrown his or her hands in the air and exclaimed, “Gotcha!” after developing a reasonable theory to explain an event, but before verifying it. This is a common mistake that diligent federal judges can protect against by exercising their gatekeeping function.<sup>161</sup>

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distinguishes science from other fields of human inquiry.”) (emphasis added) (quoting Michael D. Green, *Legal Theory: Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 645 (1992)); see also *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc) (“[T]he party seeking to have the district court admit expert testimony must demonstrate that the expert’s findings and conclusions are based on the scientific method, and, therefore, are reliable. This requires some objective, independent validation of the expert’s methodology.”); *State v. O’Key*, 899 P.2d 663, 672 (Or. 1995) (en banc) (“The scientific method is a validation technique, consisting of the formulation of hypotheses, followed by observation or experimentation to test the hypotheses.”).

157. *Chapman v. Maytag Corp.*, 297 F.3d 682, 688 (7th Cir. 2002).

158. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

159. Margaret A. Berger, *The Supreme Court’s Trilogy on Admissibility of Expert Testimony*, in FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 15 (2d ed. 2000) [hereinafter REFERENCE MANUAL].

160. E. BRIGHT WILSON, JR., AN INTRODUCTION TO SCIENTIFIC RESEARCH 26 (1952).

161. As college students are instructed in introductory level courses: “The most fundamental error is to mistake the hypothesis for an explanation of a phenomenon, without performing experimental tests. Sometimes ‘common sense’ and ‘logic’ tempt us into believing that no test is needed. There are numerous examples of this, dating from the Greek philosophers to the present

As gatekeepers, judges have an obligation to keep theories out of the courtroom unless and until the expert's hypothesis is tested. Reliable expert testimony should not require a leap of faith. For instance, when a light bulb will not turn on, there are at least three likely potential causes: the bulb could be burned out, the bulb could be loose in the socket, or the circuit breaker could have triggered. Rather than postulate on the most likely cause of the problem based on a cursory visual examination, statistics on bulb lifetimes, and potential electrical current problems, an "expert" ought to shake the bulb, attempt to tighten it, and reset the circuit breaker.

As the authors of the treatise *Modern Scientific Evidence: The Law and Science of Expert Testimony* have observed: "[M]any courts are willing to reject testimony when it is clear that the expert could create better evidence. . . . Simply put, courts are beginning to wonder, if these theories and opinions are testable, why haven't they been tested?"<sup>162</sup>

Testing is particularly important in product liability cases in which the relative safety of an alternative design is at issue. As the Seventh Circuit, which considers testing "crucial" in such cases, has explained:

In alternative design cases, we have consistently recognized the importance of testing the alternative design. In deciding whether an alternative design is appropriate, an expert needs to look at a number of considerations: "the degree to which the alternative design is compatible with existing systems . . . ; the relative efficiency of the two designs; the short- and long-term maintenance costs associated with the alternative design; the ability of the purchaser to service and to maintain the alternative designs; the relative cost of installing two designs; and the effect, if any, that the alternative design would have on the price of the machine." Many of these considerations are product- and manufacturer-specific and cannot be reliably determined without testing.<sup>163</sup>

For that reason, the Seventh Circuit found that the district court properly excluded the testimony of two expert witnesses who would have testified that the plaintiff would not have been injured if the forklift in which he was riding included a rear door rather than an open back.<sup>164</sup>

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day." Frank Wolfs, Laboratory Experiments 1996-1997, Appendix E: Introduction to the Scientific Method, [http://teacher.nsr.rochester.edu/phy\\_labs/AppendixE/AppendixE.html](http://teacher.nsr.rochester.edu/phy_labs/AppendixE/AppendixE.html) (last visited Nov. 12, 2006).

162. Faigman et al., *supra* note 14, at 666.

163. *Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 870 (7th Cir. 2001) (citation omitted) (quoting *Cummins v. Lyle Indus.*, 93 F.3d 362, 369 (7th Cir. 1996)).

164. *Id.* at 869-71.

The experts had not performed any tests of their hypothetical models to determine whether the alternative design would be economically feasible and would actually be as safe as, or safer than, the doorless model.<sup>165</sup> The court noted that, in some situations, evidence suggested that the presence of a rear door could exacerbate the injuries of the operator by not allowing a quick escape from a tipping vehicle.<sup>166</sup>

Another example is *Zaremba v. General Motors Corp.*, which involved the collision of a Pontiac Trans Am, driven by a drunk driver speeding at nearly one hundred miles per hour, into a curb at a fork in the road.<sup>167</sup> The crash killed the driver and severely injured the backseat passenger, while the front seat passenger survived with minor injuries.<sup>168</sup> The passengers were not wearing seatbelts. The plaintiffs sued the manufacturer claiming that the vehicle's "T-top" design was defective. Plaintiffs sought to call two expert witnesses: an engineer to testify on a safer alternative design and a medical doctor to testify that the plaintiffs' injuries would not have been so severe had the manufacturer adopted the alternative design.<sup>169</sup> The district court found that the engineer's testimony was inadmissible because, among other reasons, he had not examined or tested the Trans Am, had not created a drawing or prototype of his alternative design, and had not tested his alternative design.<sup>170</sup> Without the testimony of the engineer, the district court found, the doctor was "on even shakier ground" in testifying as to how the plaintiffs might have fared in the theoretical car.<sup>171</sup> The Second Circuit agreed, finding that "[n]umerous courts have excluded expert testimony

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165. *Id.* at 869-70.

166. *Id.* at 871. In another forklift accident case one year earlier, the question was whether the vehicle's design should have included wire mesh guarding in the front of the operator's compartment to protect the occupant from harm. *See Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 535 (7th Cir. 2000). In that case, the Seventh Circuit affirmed a district court's decision to exclude expert testimony where the expert had not tested the proposed design or made any attempt to show its economic feasibility. *Id.* at 536-39. The Eighth Circuit has also excluded expert testimony in forklift product liability cases where the expert had never designed a forklift or similar machine; never tested his proposed protective device; and never examined another vehicle with such a design, as well as where the expert had never designed the recommended safety device. *See Anderson v. Raymond Corp.*, 340 F.3d 520, 523 (8th Cir. 2003); *Dancy v. Hyster Co.*, 127 F.3d 649, 652 (8th Cir. 1997).

167. 360 F.3d 355 (2d Cir. 2004).

168. *Id.* at 356.

169. *Id.* at 357.

170. *Id.*

171. *Id.* (quoting the unreported district court decision).

regarding a safer alternative design where the expert failed to create drawings or models or administer tests.”<sup>172</sup>

The lack of testing can exclude a defendant’s expert witness just as well as expert testimony offered in support of a plaintiff. For instance, in *Black v. M & W Gear Co.*, the plaintiff claimed that her husband would have survived the rollover of his riding lawnmower if it had included a four-post rollover mechanism.<sup>173</sup> The defendant offered an expert witness to testify that a rollover system would not have resulted in a different outcome. The trial court excluded defendant’s expert from testifying because he had not conducted any tests supporting his conclusion. Additionally, his testimony revealed that he was mistaken about the type of rollover bar that was central to the plaintiff’s claim.<sup>174</sup> The Tenth Circuit affirmed, finding that the trial court appropriately concluded that the defendant’s expert testimony was “without any basis whatsoever.”<sup>175</sup>

The testing method itself must be reliable. Courts should reject “haphazard” tests conducted solely for the purpose of litigation.<sup>176</sup> For example, in a recent product liability case, the plaintiff claimed that a defect in a machine used to cut flooring failed to properly shut off, resulting in an injury to his leg.<sup>177</sup> The plaintiff’s expert witness conducted and videotaped two tests spanning about twenty minutes in support of the plaintiff’s allegations.<sup>178</sup> The first test involved observing the machine when strapped between two desk chairs in the plaintiff’s counsel’s conference room.<sup>179</sup> The second test involved observing the

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172. *Id.* at 358-59 (citing *Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 536-38 (7th Cir. 2000); *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 992 (5th Cir. 1997); *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996); *Brooks v. Outbound Marine Corp.*, 234 F.3d 89, 92 (2d Cir. 2000)). The “testing” factor of *Daubert* may not always require experts to develop a prototype of the proposed alternative design in order for their opinions to be admitted. *See, e.g.*, *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1012 (8th Cir. 2005). When such testing is not practically or economically feasible, an expert must, at a minimum, prepare drawings or models of the purported safer design or show how the proposed safety-enhancing component could be incorporated into the existing design and demonstrate how the proposed device would function. *See id.* (holding that district court properly excluded expert testimony of mechanical engineering professor on proposed incorporation of safety trip cord or braking device into industrial sander where expert did not show how such devices would be incorporated into the machine and work to protect the operator).

173. 269 F.3d 1220, 1226 (10th Cir. 2001).

174. *Id.* at 1236-37.

175. *Id.* at 1237.

176. *See Pullins v. Stihl Inc.*, No. 03-5343, 2006 WL 1390586, at \*3, \*5 (E.D. Pa. May 19, 2006).

177. *Id.* at \*1.

178. *See id.* at \*3.

179. *Id.*

machine when placed on a cord in the expert's driveway.<sup>180</sup> The expert could not remember what model machine the plaintiff used or explain various aspects of his own testing methods.<sup>181</sup> The district court ruled that the methods the expert used to reach his conclusions "can only be described as exactly the kind of 'junk science' that *Daubert* sought to purge from the federal courts."<sup>182</sup> The court, acting as a gatekeeper, excluded the expert's testimony as well as that of a second expert who primarily based his conclusions on the same unreliable tests.<sup>183</sup>

Not all courts place an appropriate emphasis on testing. For example, in a case against Maytag alleging that a defect in a kitchen range caused a man's electrocution, the district court admitted the testimony of an expert who represented to the court that he was "currently designing a testing procedure which when completed will conclusively prove [his] theory to be true."<sup>184</sup> In reversing the judgment in that case, the Seventh Circuit wisely emphasized that "the absence of any testing indicates that [the expert's] proffered opinions cannot fairly be characterized as scientific knowledge" and amount to "nothing more than unverified statements unsupported by scientific methodology."<sup>185</sup>

Another example of a district court admitting expert testimony without testing, only to be reversed by the circuit court, is *Weisgram v. Marley Co.*<sup>186</sup> In *Weisgram*, the plaintiff alleged that a defect in a baseboard heater caused a fire that destroyed a home and killed one of its occupants. The Eighth Circuit found that the district court committed prejudicial error in admitting the testimony of three expert witnesses: a fire captain, a master electrician, and a metallurgist.<sup>187</sup> While the Eighth Circuit's decided that the fire captain's theory as to how the fire spread was based on unsupported speculation that went beyond his expertise,<sup>188</sup> its decision with regard to the other two witnesses was based in large

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180. *Id.*

181. *Id.* at \*3 & n.3.

182. *Id.* at \*3.

183. *See id.* at \*4-5.

184. *Chapman v. Maytag Corp.*, 297 F.3d 682, 686 (7th Cir. 2002).

185. *Id.* at 688. *See infra* note 290 for further discussion of this case. *See also* *Clark v. Takata Corp.*, 192 F.3d 750, 757-59 (7th Cir. 1999) (holding, in a case involving whether a lap belt, fastened properly, would have protected a passenger from spinal injury resulting from a rollover, that the district court properly excluded the plaintiff's expert's opinion where he did no testing based on the passenger's height or weight, the force of impact, or the strength or flexion of the particular lap belt to support his "bottom line" conclusion that the passenger would not have suffered serious injury).

186. 169 F.3d 514 (8th Cir. 1999).

187. *See id.* at 520-21.

188. *Id.* at 518-19.

part on the experts' failures to test their theories. For example, the appellate court found that the master electrician "did no testing to bolster this . . . theory of fire cause and origin."<sup>189</sup> The court found that the absence of such testing rendered his testimony "rank speculation" and "nothing more than pure conjecture" as to whether the manufacturer's baseboard heater was defective and caused a fire.<sup>190</sup> Likewise, the metallurgist testified that the heater failed to shut off, but he "performed no tests to determine whether it was even theoretically possible that the contacts could get sufficiently hot to weld [leading the heater to not shut down] during the operation of the heater" and also performed no tests to determine why the backup system did not sense the temperature and shut the heater down.<sup>191</sup>

Some courts have strayed from the sound basics of the *Daubert* decision and admitted expert testimony based on cursory visual inspections when testing or other "better evidence" could verify or support their theory.<sup>192</sup> For example, the Tenth Circuit, when faced with a case with facts similar to *Weisgram*, did not require the experts to test their theory. *Bitler v. A.O. Smith Corp.* involved plaintiffs who were injured by a gas explosion in their home.<sup>193</sup> Investigators discovered two potential causes for the explosion: a leaking "T-connector" on the bedroom heater, and a leaking gas control valve on the water heater, manufactured by the defendant. The plaintiffs maintained that the water heater leak caused the explosion. Their theory was that copper sulfide particles became lodged in the water heater's safety valve, preventing an adequate seal, and allowing the gas to leak.<sup>194</sup> Plaintiffs' experts "observed the physical evidence at the scene and deduced the likely cause of the explosion,"<sup>195</sup> but did not conduct any objective testing to confirm their theory. The defendants challenged that theory, pointing out that no particles large enough to obstruct the valve were found at the site. Unlike the Eighth Circuit, the Tenth Circuit dismissed *Daubert's*

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189. *Id.* at 519-20.

190. *Id.* at 520.

191. *Id.* at 521. The U.S. Supreme Court affirmed, after finding that the expert testimony was improperly admitted and there was insufficient evidence to show causation, that the Eighth Circuit was within its discretion to direct judgment for the defendant, rather than remand for a new trial. See *Weisgram v. Marley Co.*, 528 U.S. 440, 456 (2000).

192. See, e.g., *Correa v. Cruisers*, 298 F.3d 13, 26 (1st Cir. 2002) (permitting a mechanic to testify that a boat had a bad fuel system when he conducted only a cursory visual inspection that revealed a "fouled up" spark plug and excessive smoke, but did not use any instruments or gauges).

193. 400 F.3d 1227, 1227 (10th Cir. 2005). See *supra* notes 140-45 and accompanying text for more discussion of this case.

194. *Id.* at 1231.

195. *Id.* at 1235.

“testing” requirement and found that plaintiffs’ experts were not required to test their theory because the science involved was not “novel”<sup>196</sup> or otherwise disputed.<sup>197</sup> Curiously, the same court that had indicated that testing was essential in *Black v. M & W Gear Co.*,<sup>198</sup> concluded in *Bitler* that *Daubert* does not require scientific testing in every case to establish reliability.<sup>199</sup> It found that the district court acted within its discretion when it permitted the expert testimony without requiring objective testing.<sup>200</sup> The *Bitler* decision is a particularly egregious example of the draining of *Daubert*, as the expert could have easily and inexpensively tested his theory. One could reasonably conclude that the expert’s failure to conduct such a test was predicated on his belief that a test would not support his conclusion.

2. A “Differential Diagnosis” Should Not Mean Guesswork and is Not a Substitute for Sound Science

Another example of the draining of *Daubert* occurs with respect to the admissibility of “differential diagnoses.” Physicians traditionally use this process to determine “which of two or more *diseases* with similar symptoms and signs the patient is suffering from, by means of comparing the various competing diagnostic hypotheses with the clinical findings.”<sup>201</sup> Environmental and occupational health physicians, however, occasionally use the term “differential diagnosis” to include the process of determining whether an environmental or occupational exposure *caused* the patient’s disease.<sup>202</sup> It is this latter definition focusing on external causation that is often used in litigation. For example, the Fourth Circuit has explained differential diagnosis as a process used by doctors to diagnose a patient by listing several possible causes of the patient’s symptoms, then, through the process of elimination, striking unlikely causes until isolating the most probable

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196. *Id.* at 1235-36.

197. *Id.* The court distinguished these facts from those in another Tenth Circuit Case, *Truck Insurance Exchange v. MagneTek, Inc.*, 360 F.3d 1211 (10th Cir. 2004), where the plaintiff offered an unproven theory that wood could ignite at lower temperatures than science had previously acknowledged. *Bitler*, 400 F.3d at 1235-36 (citing *Truck Ins. Exch.*, 360 F.3d at 1211-13).

198. *See supra* notes 173-75 and accompanying text.

199. *Bitler*, 400 F.3d at 1236.

200. *Id.*

201. Mary Sue Henifin et al., *Reference Guide on Medical Testimony*, in REFERENCE MANUAL, *supra* note 159, at 481 (emphasis added); *see also id.* at 443.

202. *Id.* at 443; *see also* *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000) (distinguishing between the traditional use of differential diagnosis to determine the patient’s *condition* from its use in litigation to determine the *cause* of that condition).

one.<sup>203</sup> A number of courts have accepted the use of differential diagnoses in order to determine causation in the medical context.<sup>204</sup> There are indications that its use is expanding into other areas as well.

a. Differential Diagnosis in the Medical Context

Unless courts properly fulfill their gatekeeper role, expert witnesses can cross what is sometimes a fine line between differential diagnosis and pure guesswork.<sup>205</sup> In such an analysis, courts must ensure that an expert's initial decision to "rule in" a particular source as a potential cause of the plaintiff's injury has a sound scientific basis.<sup>206</sup> For instance, in ruling in potential causes for the purpose of a differential diagnosis, it is improper to include alternatives that contradict established epidemiological studies. Those studies are properly understood by both scientists and judges as the "best evidence of general causation."<sup>207</sup> The court must then review the expert's reasoning to

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203. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999).

204. *See, e.g., Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003) (recognizing differences in usage of the term "differential diagnosis" to identify a patient's disease or the cause of that disease, and finding that "[d]ifferential diagnosis is a common scientific technique, and federal courts, generally speaking, have recognized that a properly conducted differential diagnosis is admissible under *Daubert*"); *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1211-12 (10th Cir. 2002) (stating that differential diagnosis is admissible in some cases, so long as it is reliable); *Glatstetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (finding that a differential diagnosis is "presumptively admissible," and citing *Turner*, 229 F.3d at 1208 (recognizing that "[m]ost circuits have held that a reliable differential diagnosis satisfies *Daubert* and provides a valid foundation for admitting an expert opinion," but excluding such testimony where the differential diagnosis identified the plaintiff's condition, not the cause of that condition)); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758 (3d Cir. 1994) ("[D]ifferential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results . . .").

205. There may be cases where district courts have been too harsh in their assessment of differential diagnosis techniques, considering them guesswork even when supported by scientific evidence. For example, in *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248 (1st Cir. 1998), the district court did not permit the defendant's experts to testify that the product user's chlamydia provided an alternative cause of the her pelvic inflammatory disease ("PID") although scientific studies supported chlamydia as one of the most common causes for the plaintiff's type of PID. *See id.* at 252. The district court based its decision in part on the prejudicial effect of introducing "sexual innuendo" into the trial and in part on the court's skepticism of differential diagnosis. *See id.* at 251. The First Circuit reversed and found that the district court had improperly precluded the Dalkon Shield Claimants Trust from offering a valid defense. *See id.* at 253.

206. *See, e.g., McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1252-53 (11th Cir. 2005) (holding that expert inappropriately "ruled in" the herbal weight-loss supplement Metabolife as the cause of plaintiffs' ailments, despite the lack of scientific evidence establishing such a connection).

207. *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882, 885-86 (10th Cir. 2005) (finding that district court properly excluded expert who would testify that silicone breast implants are responsible for systemic autoimmune disease when such testimony was "flatly contradictory" to all epidemiological studies on the issue); *see also Raynor v. Merrell Pharms., Inc.*, 104 F.3d 1371,

ensure that he or she has good grounds for ruling out each cause as less probable than the remaining causes. Finally, the court should require the expert to adequately address and rule out other plausible alternative causes raised by the opposing party or, at least, offer an explanation as to why he or she has concluded that they were not the sole cause.<sup>208</sup> Some courts have admitted differential diagnoses that do not meet these standards. Many of these cases overemphasize temporal relationships, rather than focusing on causation established through the scientific method.<sup>209</sup> These courts have fallen for one of the oldest myths, the *post hoc ergo propter hoc* fallacy.<sup>210</sup> This fallacy says that because one event follows another, the second event was therefore caused by the first event.<sup>211</sup> Reduced to its basic form, it can be used to prove that washing one's car can cause it to rain.

Moreover, it is inappropriate to permit a treating physician who was primarily concerned with establishing his patient's condition to utilize an incomplete differential diagnosis to speculate about its causation.<sup>212</sup> Such expert testimony has the propensity to mislead the jury because a physician may be well within his expertise to diagnose a patient's condition, but may not have a sound basis for giving an opinion about how a plaintiff contracted the disease. Differential diagnoses of this type are likely to come "more as an afterthought, in an ad hoc manner" and may fail to systematically consider and rule out alternative potential causes.<sup>213</sup>

There are many examples of trial courts properly serving as gatekeepers to distinguish between a differential diagnosis based on sound science and guesswork in the medical context. For example, in a case involving whether use of the diabetes medication Rezulin led to the plaintiff's liver failure, the trial court found, and the Second Circuit

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1374-75 (D.C. Cir. 1997) (providing that expert theories drawn from in vitro and animal studies had been disproven by established epidemiology); *Meister v. Med. Eng'g Corp.*, 267 F.3d 1123, 1127-32 (D.C. Cir. 2001) (excluding plaintiff's expert testimony that implants caused plaintiff's scleroderma when experts failed to show that her ailment can be caused by silicone implants).

208. See *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999).

209. See *McClain*, 401 F.3d at 1243 (reversing a trial court admission of expert testimony where the experts' conclusion that the herbal weight-loss supplement Metabolife caused the plaintiffs' health problems was supported only by the temporal relationship between the two, and warning that "[d]rawing such a conclusion from temporal relationships leads to the blunder of the *post hoc ergo propter hoc* fallacy," which "literally means 'after this, because of this.'" (citing BLACK'S LAW DICTIONARY 1186 (7th ed. 1999))).

210. See SCHWARTZ ET AL., *supra* note 76, at 268.

211. See *id.*

212. See *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000).

213. See *id.*

affirmed, that the expert failed to offer any medical studies or other evidence tying the drug to the plaintiff's condition.<sup>214</sup> In another case, the Second Circuit found that the trial court properly excluded an expert's concededly "controversial" theory that the plaintiff's exposure to fuels containing benzene and polycyclic aromatic hydrocarbons ("PAHs") while working on a ship caused his cancer because it was not "grounded in reliable scientific methods, as required by *Daubert*."<sup>215</sup> The district court ruled that the expert "was ready to form a conclusion first, without any basis, and then try to justify it [later]."<sup>216</sup> Moreover, the expert failed to rule out the seaman's heavy drinking and smoking over two decades as probable alternative causes, both of which studies established as major risk factors for cancer.<sup>217</sup> Likewise, the Eighth Circuit affirmed a trial court's exclusion of expert testimony seeking to draw a link between Parlodel, a medication taken to suppress postpartum lactation, and stroke.<sup>218</sup> The expert relied primarily on case reports, which the court viewed as "simply a doctor's account of a particular patient's reaction to a drug or other stimulus,"<sup>219</sup> noting that such reports do not consider alternative causes of the condition,<sup>220</sup> contain little analysis, often omit relevant facts, and show little more than a temporal association which does not substitute for scientifically valid proof of causation.<sup>221</sup> Most recently, a district court found "irregularities" in an

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214. See *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) ("Where an expert employs differential diagnosis to 'rule out other potential causes' for the injury at issue, he must also 'rule in the suspected cause' and do so using 'scientifically valid methodology.'") (quoting *Cavallo v. Star Enter.*, 892 F. Supp. 756, 771 (E.D. Va. 1995), *aff'd on this ground, rev'd on other grounds*, 100 F.3d 1150 (4th Cir. 1996)).

215. *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 37-38, 50 (2d Cir. 2004), *cert. denied*, 126 S. Ct. 355 (2005).

216. *Id.* at 38.

217. *Id.* at 50.

218. See *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 988-92 (8th Cir. 2001) (per curiam).

219. *Id.* at 989.

220. For example, the Eighth Circuit noted that the plaintiff had occasionally suffered from migraines prior to the stroke, was overweight, and smoked heavily for several years. See *id.* at 987.

221. See *id.* at 989-90. The court also recognized the "critical" difference between a regulation and litigation. See *id.* at 991. In response to the plaintiff's argument that the FDA's revocation of Parlodel's indication for suppressing lactation, the Eighth Circuit recognized that the FDA decision was based on a balancing of the drug's limited beneficial use against the possible harm to women already susceptible to disease. "The methodology employed by a government agency 'results from the preventative perspective that the agencies adopt in order to reduce public exposure to harmful substances,'" which requires a lesser showing of harm than the preponderance of evidence standard used to assess tort liability. *Id.* (quoting *Hollander v. Sandoz Pharms. Corp.*, 95 F. Supp. 1230, 1234 n.9 (W.D. Okla. 2000)). Thus, the Eighth Circuit found that an FDA decision to rescind a drug application is unreliable proof of medical causation. *Id.* For additional decisions recognizing the difference between preventative government agency standards and actions and reliable evidence of

expert's differential diagnosis associating thimerosal, a preservative included in RhoGAM (a drug given to pregnant women that significantly decreases the risk of Hemolytic Disease of the Newborn as well as childhood vaccines) with the development of autism.<sup>222</sup> In addition to various other problems with the expert's qualifications and methodology, his differential diagnosis failed to consider and rule out a potential genetic cause of the condition.<sup>223</sup>

In some cases, appellate courts have had to intervene to keep out questionable differential diagnoses. For example, one plaintiff claimed that her slip and fall on a film of mayonnaise resulted in fibromyalgia syndrome, a condition characterized by complaints of generalized pain, chronic fatigue, and poor sleep, most common in women between the ages of thirty and fifty, and often associated with hormonal problems.<sup>224</sup> A magistrate permitted the expert to testify to drawing such a conclusion, despite a lack of underlying medical support.<sup>225</sup> The Fifth Circuit explained its reversal:

This analysis amounts to saying that because [the expert] thought she had eliminated other possible causes of fibromyalgia, even though she does not know the real "cause," it had to be the fall at Food Lion. This is not an exercise in scientific logic but in the fallacy of *post-hoc propter-hoc* reasoning, which is as unacceptable in science as in law. By the same "logic," [the expert] could have concluded that if [the plaintiff] had gone on a trip to Disney World and been jostled in a ride, that event could have contributed to the onset of fibromyalgia.<sup>226</sup>

Two Fourth Circuit cases show the roulette wheel that can characterize decisions admitting and excluding differential diagnoses. In *Westberry v. Gislaved Gummi AB*, the plaintiff claimed that his inhalation of talc in the workplace led to his sinus problems.<sup>227</sup> The employer contended that the plaintiff's expert could cite no

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causation for the purpose of tort liability, see *National Bank of Commerce v. Associated Milk Producers, Inc.*, 191 F.3d 858, 860-61 (8th Cir. 1999); *Mitchell v. Gencorp. Inc.*, 165 F.3d 778, 783 n.3 (10th Cir. 1999); *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp.2d 1347, 1366 (N.D. Ga. 2001), *aff'd, sub nom. Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002).

222. See *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 465, 477 (M.D.N.C. 2006).

223. See *id.* 477-78.

224. *Black v. Food Lion, Inc.*, 171 F.3d 308, 309 (5th Cir. 1999).

225. *Id.* at 313-14.

226. *Id.* Four years after the Fifth Circuit considered whether there was sufficient medical evidence to permit an expert to testify that trauma causes fibromyalgia syndrome and found that, although medical science had advanced in treating fibromyalgia, it had not sufficiently progressed on causation of the condition since its opinion in *Black* to permit admission. See *Vargas v. Lee*, 317 F.3d 498, 501 (5th Cir. 2003).

227. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999).

epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data supporting such a link.<sup>228</sup> Instead, the defendant claimed that the expert relied on a flawed differential diagnosis, in that he could not “rule in” talc as a possible cause of the disease and his assessment was largely based on the temporal relationship between the exposure and onset of the disease.<sup>229</sup> The Fourth Circuit, however, upheld admission of the testimony—which allowed the jury to infer that the plaintiff’s level of exposure to talc was substantial enough to cause the irritation—despite a lack of measurement of the level of the plaintiff’s actual exposure.<sup>230</sup> While the court recognized that “the mere fact that two events correspond in time does not mean that the two necessarily are related in any causative fashion,” it found that a temporal relationship “can provide compelling evidence of causation” when there is additional evidence of causation, such as an established scientific connection between the exposure and illness, or improvement of the condition when the exposure is removed but a worsening when it returns.<sup>231</sup> Finally, the court found that the expert had sufficiently considered and ruled out alternative causes suggested by the defendant, such as water skiing and a cold in close temporal proximity to onset of the illness.<sup>232</sup>

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228. *Id.* at 262.

229. *See id.* at 262-63.

230. *Id.* at 264.

231. *See id.* at 264-65. This ruling can be compared to *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 277-79 (5th Cir. 1998), in which the Fifth Circuit upheld the district court’s exclusion of expert testimony that the plaintiff’s brief inhalation of chemicals during cleanup of a spill resulted in an asthmatic-type condition, reactive airways dysfunctional syndrome (“RADS”). The court found that the expert’s conclusion was largely based on the temporal relationship between exposure and onset, but the expert failed to consider the level and duration of exposure, and there was no scientific evidence to support the theory that exposure to the chemical at issue could cause RADS at a nominal level. *See id.* “In absence of an established scientific connection between exposure and illness, or compelling circumstances . . . , the temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation.” *Id.* at 278. The court also noted that the expert failed to rule out other more probable causes of onset, such as the plaintiff’s twenty years of moderate to heavy smoking, recent recovery from pneumonia before contact with the chemicals, or suffering from a similar asthmatic condition in his youth. *See id.* at 279.

232. *Westberry*, 178 F.3d at 365-66. *See also* *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 246-50 (5th Cir. 2002) (reversing exclusion of expert’s testimony that plaintiff’s salmonella infection was caused by contaminated syringe where product included chicken parts and expert had ruled out alternative causes, although medical literature did not support connection or find similar cases, and other syringes in production lot were not contaminated); *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 261, 265, 267 (6th Cir. 2001) (reversing exclusion of expert testimony that railroad conductor and brakeman’s Carpal Tunnel Syndrome was a result of workplace activities based on differential diagnosis where plaintiff’s “work did not involve typical monotonous repetitive hand

Two years later, the Fourth Circuit applied the principles expressed in *Westberry* to exclude, rather than admit, expert testimony. In *Cooper v. Smith & Nephew, Inc.*, a plaintiff offered an expert to testify as to his “unconventional views” regarding the safety and efficacy of the use of pedicle screws in spinal surgery.<sup>233</sup> The case involved a system for stabilizing the spine by fusing two or more vertebrae together endorsed as safe by the Food and Drug Administration, although not explicitly approved for that purpose.<sup>234</sup> This system was used unsuccessfully on the plaintiff, who continued his twenty-five year, pack-a-day cigarette habit despite the warnings of his physicians as to the harmful effect of smoking on the potential for success of the surgery.<sup>235</sup> Even though this non-union was a well-known risk of spinal fusion, the expert sought to testify that the broken screw caused the non-union, not that the non-union caused the screw to break.<sup>236</sup> The expert’s testimony was based on his differential diagnosis.<sup>237</sup> The Fourth Circuit affirmed the district court’s exclusion of the expert testimony on the basis that he failed to consider and rule out smoking, which was established in the medical literature as leading to non-unions, as well as other potential causes of the non-union.<sup>238</sup>

b. Expanded Acceptance of Differential Diagnosis “Beyond the Medical Context”

While a sound differential diagnosis may be “generally accepted” in the medical context, a recent opinion allowed its use in a completely different field. In a case we have referred to where the Tenth Circuit refused to require an expert to test his theory, although it would be easy to do so, the court also permitted the plaintiffs’ experts to use the process of elimination to reach a conclusion that debris lodged in the valve of a water heater caused a gas leak.<sup>239</sup> Specifically, plaintiffs’ experts worked “backwards to the cause of a single explosion” by “eliminating possible

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activities which have been the subject of study” in the scientific literature, after expert ruled out plaintiffs’ outside-of-work activities as potential causes).

233. See *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 201 (4th Cir. 2001).

234. *Id.* at 197.

235. *Id.* at 197-98.

236. *Id.* at 201.

237. *Id.* at 200.

238. *Id.* at 202-03. The court also excluded the expert’s testimony because he had failed to conduct a physical examination of the plaintiff, a practice that was not consistent with the expert’s own diagnostic standards in his medical practice. See *id.* at 203.

239. See *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1237-38 (10th Cir. 2005).

causes as improbable until the most likely one [was] identified.”<sup>240</sup> The Tenth Circuit concluded that: “[I]n this circumstance [differential diagnosis] is a valid scientific technique to establish causation,”<sup>241</sup> but acknowledged that it was “not so clear” whether it is otherwise acceptable outside the medical context.<sup>242</sup> In sum, the *Bitler* court took a theory that has often been misapplied in the medical context and misapplied it in a new and totally different area of expert knowledge.

The Tenth Circuit’s decision in *Bitler* may provide ammunition for those who would like to abandon sound science and expand use of the process of elimination into other areas. In fact, *The Federal Litigator*, a West newsletter tracking civil procedure and evidentiary decisions, referred to *Bitler* in its “Litigation Tips” section, stating: “There is no reason why differential diagnosis-based expert testimony should not be similarly admissible as evidence of causation in the nonmedical context.”<sup>243</sup> A recent law review article has also highlighted the use of a differential diagnosis to determine the cause of a propane gas explosion, noting that a differential diagnosis “is not limited to medical diagnosis.”<sup>244</sup> Therefore, although the Tenth Circuit in *Bitler* at least qualified its holding to the facts before the court, it may have opened the door for differential diagnoses beyond the medical context.<sup>245</sup>

### 3. Undue Reliance on One Factor While Ignoring Others

In *Kuhmo Tire Co. v. Carmichael*, where the Supreme Court expanded *Daubert*’s principles based on science to almost all areas of expert evidence, Justices Scalia, O’Connor and Thomas filed a separate concurring opinion to make an additional important point.<sup>246</sup> First, they

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240. *Id.* at 1237.

241. *Id.* at 1236.

242. *Id.* at 1237. In *Stibbs v. Mapco, Inc.*, 945 F. Supp. 1220 (S.D. Iowa 1996), the court also admitted a differential diagnosis offered for the purpose of establishing the fact that there had been a propane explosion, and the circumstances surrounding the explosion. *Id.* at 1225-26. The court, however, found that the differential diagnosis was problematic as to the cause of the explosion because the expert’s conclusions were not supported by the facts. *Id.* at 1223-25.

243. Don Zupanec, *Expert Testimony—Differential Diagnosis—Nonmedical Context* F.R.E. 702, 20 FED. LITIG. 14, Feb. 2005, at 45.

244. Donald Patterson, *The When, If, and How of Challenging Expert Testimony in Federal Court*, 29 AM. J. TRIAL ADVOC. 167, 192 (2005).

245. See *Non-Medical Experts May Use “Differential Analysis” to Find Causation*, 2 ANDREWS EXPERT & SCI. EVID. LITIG. REP. 7, Dec. 2004 (discussing *Bitler* as authority for non-medical experts to use differential analysis). *But see* *Cooper Tire & Rubber Co. v. Mendez*, No. 04-1039, 2006 LEXIS 555, at \*28 (Tex. June 16, 2006) (rejecting the use of a differential diagnosis when “the universe of possible causes for the tire failure is simply too large and too uncertain to allow an expert to prove a manufacturing defect merely by the process of elimination”).

246. See *supra* note 148 and accompanying text.

reiterated their agreement with the majority that *Daubert* does not permit discretion to abandon the gatekeeping function.<sup>247</sup> Then, the concurring trio went one step further and concluded that *Daubert* is not discretion to “function inadequately.”<sup>248</sup> They explained that “in a particular case the failure to apply one or another of [the *Daubert* factors] may be unreasonable, and hence an abuse of discretion.”<sup>249</sup>

Despite this guidance, some courts have unduly relied on a single *Daubert* factor while ignoring others, or placed excessive emphasis on an expert’s credentials. For example, in a case in which a worker claimed that glue fumes in the workplace caused her throat polyps, the Second Circuit upheld a district court decision admitting the testimony of a consulting engineer and a physician based largely on their experience and credentials, despite their inability to pinpoint scientific support for such a link.<sup>250</sup> Instead, the court found that “[d]isputes as to the strength of [an expert’s] credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony,”<sup>251</sup> the classic leave-it-to-the-jury approach. Such a statement shows a fundamental misconception and abdication of the gatekeeper role. Credentials do not rule. Sounds science does, and it is the trial judge’s duty to act as a gatekeeper in evaluating whether the expert relied on reliable evidence.

The Ninth Circuit has diminished the importance of *Daubert* by requiring only “some kind of reliability determination” when considering non-scientific or non-technical expert testimony.<sup>252</sup> It found that the trial court met that standard when it considered only the “knowledge and experience” of the plaintiff’s expert insurance adjuster.<sup>253</sup> The court stopped short of categorically holding that *Daubert* only applies in scientific and technical cases, but nonetheless drained its meaning by permitting the trial court to apply only a few factors.<sup>254</sup>

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247. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 159 (1999) (Scalia, J., concurring).

248. *Id.*

249. *Id.*

250. *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1040-44 (2d Cir. 1995).

251. *Id.* at 1044.

252. *See Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004). This test originates from an earlier Ninth Circuit case, *Elsayed Mukhtar v. Cal. State Univ.*, 299 F.3d 1053 (9th Cir. 2002).

253. *Hangarter*, 373 F.3d at 1018.

254. *See id.*

A Ninth Circuit case that turned on whether a piece of imported fabric was hand- or power-loomed provides a final example.<sup>255</sup> Proper designation was important to the plaintiff, an importer, because power-loomed products are subject to a quota and a higher import duty rate and require a visa for entry.<sup>256</sup> The district court relied solely on customs standards distinguishing hand- from power-woven fabric, without determining their reliability.<sup>257</sup> The Federal Circuit reversed and remanded, finding that the trial court over-relied on the “generally accepted” customs standards, particularly since the importer-plaintiff raised legitimate concerns about their reliability.<sup>258</sup> If the district court had been faithful to *Daubert*, it would have required testing or other *Daubert* factors to establish a “more persuasive showing of reliability.”<sup>259</sup>

### C. Requiring “*Daubert* Hearings” and a Complete Record

Prior to *Daubert*, judges ordinarily made decisions on the admissibility of expert testimony during trial, in front of a jury, upon the objection of counsel. Since that time, most federal courts encourage litigants to request a pre-trial hearing on the admissibility of proposed expert testimony. Federal courts, however, appear to differ on the value they place on *Daubert* hearings. A related issue is whether district courts have an obligation to provide a full record, including written findings of fact and conclusions of law, on their rulings on the admissibility or exclusion of expert evidence for the purpose of appeal. These logical requirements do not necessarily favor either plaintiffs or defendants. As the cases below demonstrate, in some instances, courts have admitted or excluded expert testimony for either side without a formal *Daubert* hearing or a sufficient record.

#### 1. *Daubert* Hearings are a Necessary Aspect of the Gatekeeping Role

Pre-trial *Daubert* hearings provide an opportunity for a judge to closely review the relevance and reliability of the proposed expert testimony, as well as the expert’s credentials, and to make an informed decision as to its admissibility. The *Daubert* hearing alerts the trial judge

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255. See *Libas, Ltd. v. United States*, 193 F.3d 1361, 1366-67 (Fed. Cir. 1999).

256. *Id.* at 1363.

257. *Id.* at 1365-68.

258. *Id.* at 1368-69.

259. See *id.* at 1369.

to potential disputes concerning experts and requires the court to recognize its obligations under *Daubert* to closely examine both whether the proposed expert is qualified in the area in which he or she will testify and the relevance and reliability of the proposed expert's methodology and conclusions in advance of trial. Whether an expert should be permitted to testify is both a complex and vital issue. It is easily outcome determinative, but not so easily decided in the midst of an actual trial.

Scheduling the *Daubert* hearing at the outset of litigation reduces the risk of evidentiary ambush arising from the late disclosure or nondisclosure of experts. It also provides litigants with a preview of the strength of their opponents' cases, which may encourage settlement or support a motion to dismiss a weak case on summary judgment.

Despite the benefits of providing a pre-trial hearing, some appellate courts have sent mixed messages as to if and when such a hearing is required. Most courts find that if there is an extensive evidentiary record, a district court may opt to make a preliminary determination to admit or exclude expert testimony without a formal hearing.<sup>260</sup> Nevertheless, it is clear from the language of many of these decisions that appellate courts view *Daubert* hearings as a near-essential component to an admissibility determination and they strongly encourage, if not require, such hearings.

For example, the Eighth Circuit, while not necessarily requiring a pre-trial hearing,<sup>261</sup> has suggested that challenges to admissibility of expert testimony should be raised prior to trial, and "ideally," a *Daubert* hearing, if conducted, should occur well before the expert is scheduled to testify.<sup>262</sup> The Ninth Circuit has found that a district court "did not necessarily abuse its discretion" in refusing to hold a *Daubert* hearing, but it "encourage[d] the court to hold a [*Daubert*] hearing on remand to

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260. See, e.g., *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1138-39 (9th Cir. 2002) (finding that a district court is not required to hold a *Daubert* hearing so long as it has an adequate record before it, such as expert reports, deposition testimony, and affidavits); *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 249, 253-54 (6th Cir. 2001) (upholding a district court's decision to exclude the plaintiffs' expert testimony without holding a *Daubert* hearing in PCB exposure case where the parties had fully briefed the issue, there was an "extensive record," and the proposed experts failed to determine the actual level of the plaintiffs' exposure to PCBs, "utterly ignored" numerous other possible causes for their claimed injuries, and found no support for their theory of causation in the scientific literature); *Oddi v. Ford Motor Co.*, 234 F.3d 136, 153-55 (3d Cir. 2000) (finding that the district court acted within its discretion in excluding a plaintiff's expert witness from testifying on the crashworthiness of a truck despite its failure to hold a *Daubert* hearing where there was an extensive evidentiary record including a preliminary report, an amended report, an affidavit, and two depositions, and the plaintiff could not explain how he was prejudiced by the lack of a hearing).

261. See, e.g., *Anderson v. Raymond Corp.*, 340 F.3d 520, 523-24 (8th Cir. 2003).

262. See *In re Air Crash at Little Rock Ark.*, 291 F.3d 503, 514 (8th Cir. 2002).

provide plaintiffs with an opportunity to respond to the defendants' challenges, including an opportunity to question defendants' expert opinions, submitted in support of their *Daubert* motions."<sup>263</sup> Likewise, the Eleventh Circuit has recognized *Daubert* hearings as particularly "helpful in 'complicated cases involving multiple expert witnesses.'"<sup>264</sup>

In some instances, courts have properly found that failure to hold a *Daubert* hearing is reversible error. For example, the Third Circuit held that a district court erred by refusing the defendant's repeated request for a *Daubert* hearing concerning the admissibility of the testimony of the plaintiff's economic loss expert.<sup>265</sup> The Third Circuit found that the proposed expert had not fully explained his methodology and it was not possible for the opposing party to effectively analyze the expert's methods in the midst of a trial.<sup>266</sup> A *Daubert* hearing "would have permitted a fuller assessment of [the expert's] analytical processes and thus was a necessary predicate for a proper determination as to the reliability of [the expert's] methods."<sup>267</sup>

Other courts have dismissed the need for a *Daubert* hearing. In several cases, the Sixth Circuit has found that a district court is not required to hold a *Daubert* hearing and provide formal findings.<sup>268</sup> For example, in a case involving a rollover accident of a sports utility vehicle, the defendant, Ford Motor Company, requested a pre-trial hearing on the admissibility of the testimony of the plaintiffs' accident

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263. *In re Hanford Nuclear*, 292 F.3d at 1138-39 (emphasis added) (upholding exclusion of the testimony of an expert on behalf of thousands of plaintiffs who claimed that exposure to emissions from a nearby nuclear facility caused them various illnesses). *Cf. Hangartar v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004) (finding that the court's "probing" of the proposed experts' "knowledge and experience" sufficiently satisfied *Daubert*'s gatekeeping function, and that separate, pre-trial reliability hearings were not required, stating that "[n]owhere in *Daubert* . . . does the Supreme Court mandate the form that the inquiry into relevance and reliability must take") (quoting *United States v. Alatorre*, 222 F.3d 1098, 1102 (9th Cir. 2000)).

264. *United States v. Hansen*, 262 F.3d 1217, 1234 (11th Cir. 2001) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 564-65 n.21 (11th Cir. 1998)); *see also Cook v. Sheriff of Monroe County*, 402 F.3d 1092, 1114 (11th Cir. 2005) (finding no abuse of discretion when the judge did not hold a preliminary hearing to determine admissibility of plaintiff's lone expert witness, and stating that "because this is not a 'complicated case involving multiple expert witnesses' we cannot conclude that the district court abused its discretion by not holding a *Daubert* hearing").

265. *Elcock v. Kmart Corp.*, 233 F.3d 734, 744-45 (3d Cir. 2000).

266. *See id.* at 747.

267. *Id.* at 745 (citation omitted).

268. *See Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 249 (6th Cir. 2001); *Clay v. Ford Motor Co.*, 215 F.3d 663, 667 (6th Cir. 2000); *Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999) (holding, in a case where the expert's testimony conflicted with eye witness accounts, that "the trial court is not required to hold an actual hearing to comply with *Daubert*, [but] is required to make an initial assessment of the relevance and reliability of the expert testimony").

reconstruction expert.<sup>269</sup> The Sixth Circuit affirmed, even though it recognized that the district court judge never ruled on Ford's motion for a preliminary hearing, requiring Ford to raise continuing objections at trial.<sup>270</sup> Although the Sixth Circuit characterized whether the district court abused its discretion as "a close case," it concluded there was no error, as it found the expert's testimony "was relevant to the issues in this case."<sup>271</sup> The court's brief analysis, which, like the district court's, did not explicitly examine the testimony's satisfaction of any of the *Daubert* factors,<sup>272</sup> demonstrates the potential adverse result when there is no *Daubert* hearing and an apparently incomplete record.<sup>273</sup>

## 2. Written Findings of Fact and Conclusions of Law Are Essential to Appellate Review

Although appellate courts do not ordinarily reverse district courts for failure to hold *Daubert* hearings, they are more likely to do so when a district court does not provide written findings of fact and conclusions of law supporting its ruling on admissibility. Creation of a sufficiently developed record is an "absolute necessity" to appellate review.<sup>274</sup> As

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269. *Clay*, 215 F.3d at 666.

270. *See id.* at 666-67. The district court judge denied Ford's request for a hearing because the company waited to file it until one week before trial with "no good cause" shown for the delay. *Id.* The court determined the motion could have been made much sooner because it "was predicated on a ruling made almost three months earlier." *Id.* at 666.

271. *Id.* at 666-67.

272. *See id.* at 668-69.

273. The Sixth Circuit has also found that *Daubert* hearings are unnecessary where reliability is "taken for granted," where the expert's methods "are relatively uncontroversial" and not "original," and particularly when the expert provides a technical, experience-based assessment. *See Bureau v. State Farm Fire & Cas. Co.*, 129 F. App'x 972, 975-77 (6th Cir. 2005) (finding no error where the district court summarily denied a *Daubert* motion to exclude the testimony of the defendant's roofing expert who sought to testify that a poor roof and inadequate ventilation caused chronic moisture in the attic, based solely on a visual inspection of the roof, when the expert did not use any sophisticated equipment that would mislead the jury or lead the jury to give his testimony great weight, and finding that peer review or empirical analysis was unnecessary for this type of technical, experience-based assessment).

274. *Goebel v. Denver & Rio Grande W. R.R. Co. (Goebel I)*, 215 F.3d 1083, 1088 (10th Cir. 2000). The only exception to this requirement may be when there is no objection raised to the proffered expert testimony. *See, e.g., Hoult v. Hoult*, 57 F.3d 1, 4-5 (1st Cir. 1995) ("We think *Daubert* does instruct district courts to conduct a preliminary assessment of the reliability of expert testimony, even in the absence of an objection. We do not think, however, that district courts are required, *sua sponte*, to make explicit on-the-record rulings regarding the admissibility of expert testimony."); *United States v. Locascio*, 6 F.3d 924, 938-39 (2d Cir. 1993) (rejecting a *sua sponte* obligation to make a finding on admissibility with respect to all expert testimony).

the Seventh Circuit has recognized: “[T]he gatekeeper must do more than just make conclusory statements.”<sup>275</sup>

For example, the Tenth Circuit has properly instructed that a trial court “must adequately demonstrate by specific findings on the record that it has performed its duty as a gatekeeper,” because “[w]ithout specific findings or discussion on the record, it is impossible on appeal to determine whether the district court ‘carefully and meticulously review[ed] the proffered scientific evidence’ or simply made an off-the-cuff decision to admit [or exclude] the expert testimony.”<sup>276</sup> For purposes of appellate review, “a natural requirement of this function is the creation of ‘a sufficiently developed record in order to allow a determination of whether the district court properly applied the relevant law.’”<sup>277</sup> Indeed, without sufficient findings an appellate court is wholly unable to analyze what occurred below. Similarly, the Sixth Circuit has found that “[a] district court should not make a *Daubert* ruling prematurely, but should only do so when the record is complete enough to measure the proffered testimony against the proper standards of reliability and relevance.”<sup>278</sup> In that case, the court was unable to determine whether the district court erred in excluding two veterinarians from testifying on the cause of a champion pony’s death after surgery because the record lacked veterinary studies that verified or contradicted the experts’ contentions.<sup>279</sup>

These decisions show that regardless of whether a district court conducts a formal *Daubert* hearing, it must create a record when it makes decisions about the admissibility of expert testimony so that the decision is subject to effective appellate review.

*D. Appellate Review: Trial Court Discretion “Is Not Discretion to Abandon the Gatekeeping Function”*

Appellate courts vary both on the applicable standard of review and how they apply it. Some courts apply an “abuse of discretion” standard

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275. *Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 535 (7th Cir. 2005). See *infra* notes 287-90 and accompanying text for further discussion of this case.

276. *Goebel I*, 215 F.3d at 1088 (first alteration in original) (quoting *United States v. Call*, 129 F.3d 1402, 1405 (10th Cir. 1997)). On remand, the district court found in favor of the plaintiff, and on appeal the Tenth Circuit affirmed. See *Goebel v. Denver & Rio Grande W. R.R. Co. (Goebel II)*, 346 F.3d 987, 989, 1001 (10th Cir. 2003). *Goebel II* did not disturb *Goebel I*’s holding requiring specific findings and discussion on the record. See *id.* at 990.

277. *Goebel I*, 215 F.3d at 1088 (quoting *United States v. Nichols*, 169 F.3d 1255, 1262 (10th Cir. 1999)); *United States v. Lee*, 25 F.3d 997, 999 (11th Cir. 1994) (encouraging specific findings).

278. *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 393 (6th Cir. 2000).

279. See *id.*

to the entire evidentiary ruling, while others apply a *de novo* standard to the trial court's application of the *Daubert*-Rule 702 framework—a question of law—and an abuse of discretion standard to the application of that framework to a particular expert—a question of fact. Moreover, in applying the abuse of discretion standard, some courts appear to take a much closer review than others.

### 1. The Standard of Review

The Second, Fourth, Fifth, Eighth, and Ninth Circuits consistently apply an abuse of discretion standard to both the trial judge's determination of how to test an expert's reliability, as well as its application of that standard to the facts of the case.<sup>280</sup> Some of their decisions rely on *Joiner*, in which the Supreme Court reversed the Eleventh Circuit's application of “a particularly stringent standard of review,”<sup>281</sup> in favor of an abuse of discretion standard.<sup>282</sup> Other courts rely on language in *Kumho Tire* in which the Supreme Court stated that the district court's discretion “applies as much to the trial court's decisions about *how to determine reliability* as to its ultimate conclusion.”<sup>283</sup> In a concurring opinion, Justice Scalia clarified this point:

[T]rial-court discretion in choosing the manner of testing expert reliability [is] not discretion to abandon the gatekeeping function. I think it worth adding that it is not discretion to perform the function inadequately. Rather, it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky.<sup>284</sup>

Some circuits have adopted a two-step standard of review. They first apply *de novo* or “plenary” review to determine whether the trial court applied the proper legal standards for reviewing expert testimony. The appellate court then evaluates the trial court's determination of

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280. See, e.g., *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005) (citing *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 292, 296 (8th Cir. 1996)); *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001); *Black v. Food Lion, Inc.*, 171 F.3d 308, 310 (5th Cir. 1999).

281. See, e.g., *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (quoting *Joiner v. Gen. Elec. Co.*, 78 F.3d 524, 529 (11th Cir. 1996), *rev'd*, 522 U.S. 136 (1997)).

282. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“[W]e hold, therefore, that abuse of discretion is the proper standard by which to review a district court's decision to admit or exclude scientific evidence.”).

283. See, e.g., *Amorgianos*, 303 F.3d at 265 (quoting *Kumho Tire Co., Inc. v. Carmichael*, 526 U.S. 137, 152 (1999)); see also *Cooper*, 259 F.3d at 200 (same); *Black*, 171 F.3d at 310 (same).

284. *Kumho Tire*, 526 U.S. at 158-59 (Scalia, J., concurring).

whether specific proffered expert testimony is admissible based on an abuse of discretion review. The Tenth Circuit describes the two-step review process as follows:

[W]e review *de novo* the question of whether the district court performed its gatekeeper role and applied the proper legal standard in admitting an expert's testimony. We then review for abuse of discretion the trial court's actual application of the gatekeeper standard in deciding whether to admit or exclude an expert's testimony.<sup>285</sup>

This means that an appellate court first takes a fresh look at whether the trial court properly applied the *Daubert* framework in evaluating the proposed expert testimony, such as whether the testimony qualified as scientific or technical evidence, whether it merely focused on the expert's professional qualifications rather than the methodology used or conclusions reached, whether it conducted an adequate pre-trial hearing or other preliminary assessment, and whether it engaged in the type of thorough, independent review mandated by the Supreme Court. The appellate court would then review whether the trial court properly applied the *Daubert* factors to admit or exclude the specific expert evidence at issue under an abuse of discretion standard. The Third, Seventh, and Tenth Circuits consistently apply this dual standard of review to evidentiary rulings.<sup>286</sup>

For example, in *Fuesting v. Zimmer*, the Seventh Circuit applied *de novo* review to find that the district court did not complete an adequate *Daubert* analysis of expert testimony admitted in a product liability claim involving the sterilization technique used on a prosthetic knee.<sup>287</sup>

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285. *Goebel v. Denver & Rio Grande W. R.R. (Goebel II)*, 346 F.3d 987, 989-90 (10th Cir. 2003) (citation omitted). *See also* *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 883 (10th Cir. 2005) (reaffirming the *de novo* standard); *Fuesting v. Zimmer, Inc.*, 421 F.3d 528, 534 (7th Cir. 2005) ("We first undertake a *de novo* review of whether the district court properly followed the framework set forth in *Daubert*. Provided the district court adhered to *Daubert*'s parameters, we will not disturb the district court's findings unless they are manifestly erroneous." (citations omitted) (quoting *Bradley v. Brown*, 42 F.3d 434, 436 (7th Cir. 1994))).

286. *See, e.g., Norris*, 397 F.3d at 883; *Kempner Mobile Elecs., Inc. v. Sw. Bell Mobile Sys.*, 428 F.3d 706, 712 (7th Cir. 2005); *Montgomery County v. Microvote Corp.*, 320 F.3d 440, 445 (3d Cir. 2003). The Sixth Circuit has also applied the dual standard of review, though earlier opinions applied an abuse of discretion standard. *Compare Bureau v. State Farm Fire & Cas. Co.*, 129 F. App'x 972, 974-75 (6th Cir. 2005) (applying abuse of discretion review to the district court's weighing of the *Daubert* factors, but noting that "[t]he standard of review for whether the district court abdicated its *Daubert* gatekeeping role . . . is *de novo*"), with *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("[W]e must review [the] ruling that [the] proffered expert testimony was inadmissible, and, even in the context of summary judgment, we review that decision for abuse of discretion.").

287. *Fuesting*, 421 F.3d at 534-35.

The appellate court found that the trial court had closely analyzed the expert's credentials, but engaged in an incomplete and insufficient analysis of the *Daubert* factors.<sup>288</sup> "To satisfy its essential role," the Seventh Circuit stated, "the gatekeeper must do more than just make conclusory statements."<sup>289</sup> The Seventh Circuit then applied the relevant *Daubert* factors to find the testimony unreliable, as it was untested, unpublished, based on an inadequate methodology to support the expert's conclusion, formulated primarily for the purpose of litigation, and did not adequately consider the alternative sterilization techniques available at the time of the plaintiffs' surgery.<sup>290</sup>

## 2. Application of the Abuse of Discretion Standard

Circuit courts generally agree that a trial court abuses its discretion when it completely fails to perform a reliability analysis.<sup>291</sup> In evaluating whether a trial court has abused its discretion in admitting expert testimony, several appellate courts go further by applying abuse of discretion "with teeth," in which they closely examine the factors applied by the trial court to determine whether it omitted a key factor, improperly applied a factor, or inappropriately balanced the applied factors. Courts show practical wisdom when they observe that the abuse of discretion standard should not be applied to "render trial court decisions impervious to scrutiny."<sup>292</sup> An abuse of discretion occurs when a trial court commits a "meaningful error in judgment,"<sup>293</sup> such as when it ignores a material factor that deserves significant weight, improperly

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288. *See id.* at 535.

289. *Id.*

290. *See id.* at 535-37; *see also* *Chapman v. Maytag Corp.*, 297 F.3d 682, 686-87 (7th Cir. 2002) (applying *de novo* review in a product liability case in which the plaintiff's husband was electrocuted by current escaping from a kitchen range to reverse a district court's admission of the plaintiff's expert's novel, untested, and unsubstantiated "resistive short" theory where the "court conducted virtually no *Daubert* analysis"); *cf.* *Walker v. Soo Line R.R.*, 208 F.3d 581, 590 (7th Cir. 2000) (applying *de novo* review to find that the district court properly admitted expert testimony offered by the defendant where the plaintiff argued that the court conducted only a cursory *Daubert* hearing followed by an oral ruling).

291. *See, e.g.*, *Elsayed Mukhtar v. Cal. State Univ.*, 299 F.3d 1053, 1066 (9th Cir. 2002); *United States v. Velarde*, 214 F.3d 1204, 1208 (10th Cir. 2000). *But cf.* *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004) (excusing a district court that failed to apply *Daubert*, finding its factors inapplicable to the expert testimony at issue).

292. *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 83 (1st Cir. 1998).

293. *Id.* (quoting *Anderson v. Cryovac, Inc.*, 862 F.2d 910, 923 (1st Cir. 1988)).

relies upon a factor, or makes a serious mistake in weighing the factors.<sup>294</sup>

Unfortunately, other appellate courts drain the core thrust of the *Daubert* decision when they engage in a much more limited review of the trial court's ruling, or at least rhetorically appear to provide more substantial deference to trial courts in applying the abuse of discretion standard. For example, in a case in which the Sixth Circuit reversed a district court's exclusion of a differential diagnosis, the appellate court characterized the abuse of discretion standard as "highly deferential," only allowing an overturning of the decision if "arbitrary, unjustifiable or clearly unreasonable."<sup>295</sup> What signal does this send to trial courts that may disagree with *Daubert*'s gatekeeping role? The Eighth Circuit has reversed evidentiary rulings "[o]nly if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury."<sup>296</sup> The Ninth Circuit similarly has required a "definite and firm conviction that the district court committed a clear error of judgment" in admitting the expert testimony.<sup>297</sup> The Tenth Circuit has looked to whether the district court's decision was "whimsical or manifestly unreasonable."<sup>298</sup> Such approaches can lead appellate courts to affirm the admission of questionable expert testimony with little examination, communicating to trial courts that something just short of whimsical is acceptable.<sup>299</sup>

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294. *Id.* (citing *Foster v. Mydas Assocs., Inc.*, 943 F.2d 139, 143 (1st Cir. 1991)); *see also* *Kempner Mobile Elecs., Inc.*, 428 F.3d 706, 712 (7th Cir. 2005); *Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 869 (7th Cir. 2001).

295. *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 267 (6th Cir. 2000) (quoting *Plain Dealer Pub. Co. v. City of Lakewood*, 794 F.2d 1139, 1148 (6th Cir. 1986)).

296. *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)); *see also id.* at 932.

297. *See, e.g., Clausen v. M/V New Carissa*, 339 F.3d 1049, 1055 (9th Cir. 2003).

298. *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1223 (10th Cir. 2003) (quoting *Atl. Richfield Co. v. Farm Credit Bank of Wichita*, 226 F.3d 1138, 1163-64 (10th Cir. 2000)); *see also McKenzie v. Benton*, 388 F.3d 1342, 1351 (10th Cir. 2004) (granting "substantial deference to the district judge's application of *Daubert*," and accepting *Kumho*'s holding that trial judges must have "considerable leeway").

299. *See, e.g., Bonner*, 259 F.3d at 930-32 (affirming admission of medical testimony on the cause of the plaintiff's neurological condition where defendant argued that there was no epidemiological support for the expert's conclusion, that the expert did not determine the quantity of the chemical to which the plaintiff was exposed or the threshold level for harm, and that he had designed but not yet tested his theory, as well as affirming admission of testimony of a second medical expert whose opinion was developed for litigation).

V. THE PROBLEM OF STATE COURTS THAT DO NOT FOLLOW  
*DAUBERT'S* LETTER AND SPIRIT

Some state courts have followed the core, sound message of *Daubert*, and their judges serve as gatekeepers against unsound expert testimony. About half of the states have adopted the essential principles of *Daubert*, either expressly or by implication.<sup>300</sup> These courts can consider a wide range of factors to determine the reliability of expert testimony. Fourteen states, including some of the most populous ones, continue to apply the *Frye* “general acceptance test.”<sup>301</sup> The challenge of this eighty-year-old test is that it may exclude testimony about theories that are reliable and based on sound science, but have not yet gained general acceptance in the field, while allowing admission of theories that have arguably gained general acceptance, yet have not been subject to peer review or vigorous testing and may not fit the facts of the case. Other states have adopted their own standards, or hybrids of the two approaches, and conform to neither *Daubert* nor *Frye*.<sup>302</sup>

In some states, the standard for determining reliability appears very similar to the federal standard, but is interpreted and applied much less stringently. This is the case in New Jersey, where, as evidence professor David E. Bernstein, a leading expert in evidentiary law, has recognized, “despite the [New Jersey] test’s superficial similarity to *Daubert* and *Joiner*, the New Jersey courts are known to be quite liberal about

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300. See DEFENSE RESEARCH INST., *FRYE/DAUBERT: A STATE REFERENCE GUIDE* 3 (2005). Jurisdictions adopting the principles of *Daubert* include Alaska, Arkansas, Connecticut, Delaware, District of Columbia, Georgia, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Vermont, West Virginia, and Wyoming. See *id.* Some states may apply *Daubert* to certain types of expert testimony, such as those seeking to speak on novel scientific evidence, but not to other types of evidence. See, e.g., *State v. Bowman*, 89 P.3d 986, 993 (Mont. 2004).

301. Jurisdictions rejecting *Daubert* and continuing to follow the *Frye* general acceptance test include Arizona, California, Florida, Illinois, Kansas, Maryland, Minnesota, New York, North Dakota, Pennsylvania, and Washington. DEFENSE RESEARCH INST., *supra* note 300, at 3.

302. Eight states apply their own standard for determining the admissibility of scientific evidence, without expressly adopting or rejecting the principles of *Daubert* and its progeny, including Colorado, Hawaii, Idaho, Indiana, Iowa, Maine, Missouri, New Jersey, North Carolina, South Carolina, Utah, and Wisconsin. See *id.* at 4. Some of these courts view the *Daubert* analysis as “helpful,” but do not follow it in every case. See, e.g., *Sears Roebuck & Co. v. Manuilov*, 742 N.E.2d 453, 461 n.5 (Ind. 2001); *Leaf v. Goodyear Tire & Rubber Co.*, 590 N.W.2d 525, 532 (Iowa 1999). In addition, four states, Alabama, Nevada, Tennessee, and Virginia, have adopted a combination of the *Frye* and *Daubert* standards. See DEFENSE RESEARCH INST., *supra* note 300, at 3. Tennessee has not expressly adopted *Daubert*, but has adopted a nearly identical approach that could be considered even more stringent than *Daubert*. See *McDaniel v. CSX Transp., Inc.*, 955 S.W.2d 257, 265 (Tenn. 1997); DEFENSE RESEARCH INST., *supra* note 300, at 40.

admitting expert scientific testimony in civil cases.”<sup>303</sup> Indeed, the New Jersey Supreme Court has consistently reversed lower court rulings that have excluded expert testimony of questionable reliability after a thorough review.<sup>304</sup> The same may be said about Louisiana, a state that professes to follow *Daubert*, where, after closely examining state court decisions between 2002 and 2004, Louisiana attorney J.E. Cullens, Jr. concluded that “*Daubert* gatekeepers in Louisiana state courts seem more like friendly doormen . . . .”<sup>305</sup>

There remains a clear gap between evidentiary standards in federal court and state courts. This ignores the sound message of judges acting as gatekeepers and, perhaps worse, is a clarion call to forum shopping between federal and state courts. As Mr. Cullens recognized: “The *Daubert* gate is undeniably more open in state court: ask the doorman nicely to enter, and she should let you pass.”<sup>306</sup> In 2004, the Lawyers for Civil Justice (“LCJ”) conducted three separate surveys of state court experiences regarding the admissibility of expert evidence. The surveys included responses from approximately 800 attorneys in 49 states. In

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303. David E. Bernstein & Jeffrey D. Jackson, *The Daubert Trilogy in the States*, 44 JURIMETRICS 351, 363-64 (2004); see also DEFENSE RESEARCH INST., *supra* note 300, at 30 (“New Jersey courts are known to be quite liberal about admitting expert scientific testimony in civil matters.”).

304. See, e.g., *Clark v. Safety-Kleen Corp.*, 845 A.2d 587, 599-601 (N.J. 2004) (reversing exclusion of a research chemist’s testimony on medical causation that went beyond the chemical composition of the cleaner at issue, despite finding isolated statements problematic and noting that the expert’s opinion could have benefited from “more careful curbing”); *Lindquist v. City of Jersey City Fire Dep’t*, 814 A.2d 1069, 1074-75, 1078-79 (N.J. 2003) (reversing an intermediate appellate court’s ruling that the absence of studies demonstrating that firefighting can cause emphysema left the plaintiff’s expert without a credible foundation, and finding that New Jersey had adopted a broader, less restrictive standard for proving causation in toxic tort litigation); *Kemp ex rel. Wright v. State*, 809 A.2d 77, 81-82, 84-85, 89 (N.J. 2002) (reversing the exclusion of a medical expert’s opinion as unreliable when the trial and intermediate appellate courts had found an absence of medical studies or reports establishing a causal connection between rubella vaccination during pregnancy and congenital rubella syndrome (“CRS”), that the plaintiff could have been exposed to the virus in the wild, and that a Center for Disease Control study confirmed that vaccination does not cause CRS, and characterizing *Daubert* and New Jersey case law as “relax[ing] the standard for the admissibility of scientific evidence”); *Landrigan v. Celotex Corp.*, 605 A.2d 1079, 1088 (N.J. 1992) (reversing exclusion of two witness’s testimony: that of an epidemiologist, whose testimony was deemed inadmissible because, not being a physician, he was deemed not qualified to testify that asbestos exposure caused the plaintiff’s colon cancer; and that of a second expert witness, a physician who had never examined the decedent and did not account for other risk factors that could have caused the cancer); *Rubanick v. Witco Chem. Corp.*, 593 A.2d 733, 738, 747-48 (N.J. 1991) (adopting a liberal standard for the admission of scientific evidence in toxic tort cases, and finding that a trial court erred in excluding the testimony of a non-physician who sought to testify on causation and present a theory that had not been “accepted by at least a substantial minority of the applicable scientific community”).

305. Cullens, *supra* note 28, at 352.

306. *Id.* at 356.

stark contrast to the RAND study of federal court judges, the LCJ study found that state court judges rarely excluded expert evidence.<sup>307</sup> By a three-to-one margin, respondents thought their state court judges were not serving an appropriate “gatekeeper” function regarding the admissibility of expert evidence.

Plaintiffs’ lawyers recognize that *Daubert* sets a higher standard for admissibility of expert testimony. For example, Senior Counsel Ned Miltenberg of the Association of Trial Lawyers of America (recently renamed the American Association for Justice) has recognized that, “[b]efore *Daubert*, federal courts rarely scrutinized the scientific validity of expert opinion testimony in any kind of case and were particularly reluctant to do so in civil cases.”<sup>308</sup> Mr. Miltenberg describes his strategy to avoid *Daubert*:

In a nutshell, because it’s difficult to see light at the end of the *Daubert* tunnel, plaintiffs must take another tunnel. In fact, there are 51 other tunnels, 51 other venues where lawsuits can be tried, and 51 other jurisdictions where the odds against plaintiffs’ experts and plaintiffs’ fortunes can hardly be worse than they are in federal court and . . . are often better.<sup>309</sup>

As Mr. Miltenberg correctly observes, when *Daubert* is not applied, “[p]laintiffs enjoy a greater chance of having a jury hear their experts testify, and they are spared the considerable expense of conducting endless admissibility hearings.”<sup>310</sup> When *Daubert* is not applied, “trial judges do not evaluate the reliability of all proffered testimony. They merely assess whether a restricted class of testimony is based on generally accepted principles and is therefore admissible.”<sup>311</sup> Mr. Miltenberg advises plaintiffs’ lawyers to file cases in states that continue to apply the *Frye* “general acceptance” test and suggests they name a local defendant to avoid the diversity jurisdiction of the federal courts.<sup>312</sup> Mr. Miltenberg, a very experienced plaintiffs’ advocate, has issued a not-so-subtle clarion call to his plaintiff-lawyer sisters and brothers: Forum shop if you have a weak case on expert evidence. Mr. Miltenberg

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307. LAWYERS FOR CIVIL JUSTICE, STATE EVIDENCE REPORT ON COMBINED SURVEY RESPONSES (Dec. 2004).

308. Ned Miltenberg, *Out of the Fire and Into the Fryeing Pan or Back to the Future*, TRIAL, Mar. 2001, at 18, 19.

309. *Id.* at 23.

310. *Id.* at 24.

311. *Id.*

312. *Id.* at 19, 25 n.35; see also Ned Miltenberg, *How to Prevail in Daubert Challenges*, 2 ATLA ANNUAL CONVENTION REFERENCE MATERIALS 2517, 2520-21 (2003).

did not use those words, but that is the message that is heard, and it is a practice that state or federal courts should discourage.

Regardless of whether a state follows *Daubert*, *Frye*, something in between, or its own unique standard, trial court judges have the ability and duty to guard against unreliable expert testimony.<sup>313</sup> Expert testimony requires a decision on admissibility that is very different from other evidentiary issues, such as hearsay or privilege. General background and experience, in the case of expert testimony, are insufficient bases on which to make a determination of admissibility. Each proffered expert presents a unique question as to his or her qualifications, the reliability of the methodology employed, and the conclusions that are reached. State judges who believe in fair justice should require challenges to expert testimony to be briefed and argued before trial, as they often may be outcome determinative and can disrupt the jury if objections are presented in the midst of a trial. This is true for witnesses presented by both plaintiff and defense counsel.

VI. THE AMERICAN LAW INSTITUTE'S RESTATEMENT OF THE LAW OF TORTS (THIRD): LIABILITY FOR PHYSICAL HARM SECTION 28, COMMENT C: AN UNWISE BEACON FOR THE RETURN OF JUNK SCIENCE

The ALI is a highly regarded organization composed of prominent judges, lawyers, and professors formed to promote the clarification and simplification of the law.<sup>314</sup> One co-author of this Article is a lifetime member and considers his tenure with ALI to be a great learning experience. The ALI is probably best known to lawyers and jurists for its publication of various Restatements, in which it "restates" the law in a given area by reviewing case law and distilling it into a series of "black letter" rules. These rules are "followed by explanatory 'Comments,' which are, in turn, followed by 'Reporter's Notes,' which show the case law basis" for the rules themselves.<sup>315</sup> The Restatements are not binding on the courts, but are generally very persuasive. A current ALI project, the "Restatement of the Law, Torts: Liability for Physical Harm" ("Physical Harm Restatement") may, however, unintentionally

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313. See Michael Hoenig, *Products Liability: Speculative, Unfounded Expert Opinions*, N.Y.L.J., July 10, 2006, at 3, 7 (recounting cases decided under New York law that demonstrate how judges may exclude speculative expert testimony irrespective of *Frye* or *Daubert*).

314. For more information about ALI, see <http://www.ali.org/> (last visited Jan. 18, 2007).

315. See Victor E. Schwartz, *The Restatement (Third) of Torts: Product Liability—The American Law Institute's Process of Democracy and Deliberation*, 26 HOFSTRA L. REV. 743, 743 (1998).

encourage courts to admit unreliable expert evidence, further draining the crucial gatekeeping function of *Daubert*.<sup>316</sup>

In that regard, section 28 of the Physical Harm Restatement sets forth the uncontroversial principle that a plaintiff has the burden of proof in showing that the defendant's tortious conduct was the cause of the plaintiff's harm.<sup>317</sup> It then provides that when the plaintiff claims that multiple parties exposed him to a risk of physical harm, but he cannot reasonably show which one of them caused the harm, the burden of proof shifts to the defendants.<sup>318</sup> This is an unusual incursion on a fundamental principle of evidence law: The plaintiff has the burden of proof. It is also much more a rule of procedure than a substantive rule of tort law, which has been for decades the province of the three Restatements of the Law of Torts.

Comment C of section 28 drifts further away from the basics of evidence rules about the burden of proof and provides a lengthy discussion of evidentiary admissibility standards for causation in toxic tort cases.<sup>319</sup> It begins by observing the difficulties associated with proving a causal connection between a substance and a specific disease, and then side-steps *Daubert's* judicial gatekeeping function in commenting that "[c]ausation is a question of fact normally left to the jury, unless reasonable minds cannot differ."<sup>320</sup> Certainly, causation is a question for the jury, but only after the judge, as a gatekeeper, has considered the *Daubert* factors and found the proposed expert testimony both relevant and reliable.

The comment goes on to minimize the *Daubert* line of cases by referring to them as "some courts" making decisions in "[a] few celebrated cases."<sup>321</sup> What the commentary does not make clear is that *Daubert* is established, well-reasoned, and respected law today in most federal courts. While application may vary in each circuit, the gatekeeper function is widely accepted, as countless decisions interpret and apply *Daubert's* judicial gatekeeping function. In addition, *Daubert*, and cases after it, did not announce a "blanket rule" as the comment suggests. Instead, it set forth several factors for courts to consider in measuring the admissibility of expert testimony. By glossing over a

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316. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM (Proposed Final Draft No. 1 2005).

317. *Id.* § 28(a).

318. *Id.* § 28(b).

319. *See id.* § 28(a) cmt. c.

320. *Id.* § 28 cmt. c(1).

321. *Id.*

substantial body of procedural law, the comment may confuse courts about the current state of the law governing admission of expert witness testimony.

Moreover, comment C suggests that, in at least two instances, admissibility standards should be relaxed. It observes that epidemiologic evidence is sometimes unavailable, costly, and time consuming.<sup>322</sup> For this reason, it favors an approach that forgives the lack of epidemiologic evidence on grounds that “some plaintiffs may be forced to litigate long before epidemiologic research is available.”<sup>323</sup> As discussed earlier, however, scientists generally consider epidemiology “the best evidence of general causation in a toxic tort case.”<sup>324</sup> Although there may be reasons why such evidence has not developed, unavailability is an insufficient basis on which to do away with legitimate criteria and hold a defendant liable for a harm it did not cause.

In addition, the Physical Harm Restatement commentary suggests that general causation can be excused so long as there is a “reasonable explanation for the lack of general-causation evidence.”<sup>325</sup> Under this approach, plaintiffs would be allowed, in fact, encouraged, to bring premature causes of action against defendant manufacturers without *any* evidence that defendant’s product is capable of causing plaintiff’s ailment.

In a similar draining of basic science, the comment states that occasionally “general and specific causation issues may merge into a single inquiry.”<sup>326</sup> This is fundamentally incorrect. General causation addresses whether the agent is *capable* of causing harm; specific causation addresses whether the agent in fact *did* cause the harm to the individual at issue. Since each calls for a separate analysis, it would take more than the fabled magician Houdini to show how the two could harmoniously merge into one inquiry. In fact, cases after *Daubert* recognize general and specific causation as two distinct tests that must be separately considered. These courts require that a “[p]laintiff must first demonstrate general causation because without general causation, there can be no specific causation.”<sup>327</sup> In other words, if a product or substance is incapable of causing a certain injury in anyone, it follows

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322. *Id.* § 28 cmt. c(3).

323. *Id.*

324. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005); *see also supra* note 207.

325. RESTATEMENT OF TORTS: LIABILITY FOR PHYSICAL HARM § 28 cmt. c(4) (Proposed Final Draft No. 1 2005).

326. *Id.* § 28 cmt. c(1).

327. *Norris*, 397 F.3d at 881.

even more strongly that that product or substance could not have caused a specific injury to the plaintiff.<sup>328</sup>

Not only is comment C misplaced, since it has little to do with section 28 (“Burden of Proof”), which it purports to expound, but also it minimizes a substantial body of law stemming from *Daubert* and loosens general and specific causation requirements to such an extent that they are rendered meaningless. If the Physical Harm Restatement was adopted and this comment followed, it could move courts toward to a pre-*Daubert* era, where unsupported expert testimony would be permissible, and juries could be inundated with junk science.

Although Restatements are not binding on courts, they are lauded as compelling secondary authority. Since some courts have misapplied the *Daubert* test by draining it of meaning, it is particularly important that the Restatement correctly reflects the current state of the law. Otherwise, judges in already confused jurisdictions may fail to give *Daubert* sufficient weight and may serve as inadequate gatekeepers.

## VII. CONCLUSION

The “battle of experts” continues in full force today. The need for *Daubert* protections is as great, if not more so, as it was twenty years ago. As Justice Breyer has recognized: “[T]here is an increasingly important need for law to reflect sound science.”<sup>329</sup> Overall, federal and state courts have followed *Daubert*’s guidance and satisfied that need. There are five general areas, however, where courts have in some cases drained *Daubert* of its meaning: (1) failure to apply the closer fit test for relevance; (2) misinterpretation of their flexibility in applying *Daubert* to the point of abdication; (3) admission of expert conclusions that do not flow from the methodology; (4) disparate application of *Daubert* hearings; and (5) application of varying standards of review. In order to prevent forum shopping and encourage consistency and predictability, both federal and state court judges should carefully adhere to the “gatekeeping” function outlined in *Daubert*, and avoid decisions that drain *Daubert* of its logic, sound science, and meaning.

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328. *See id.*

329. Stephen Breyer, *The Interdependence of Science and Law*, 280 SCI. 537, 538 (1998).