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CLINICAL MEDICAL EVIDENCE OF CAUSATION IN TOXIC TORT CASES: INTO THE CRUCIBLE OF *DAUBERT*

*Jean Macchiaroli Eggen**

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* Professor of Law, Widener University School of Law; A.B., Connecticut College; M.A., Michigan State University; J.D., Syracuse University College of Law. I wish to thank John Culhane and Laura Ray for reading and commenting upon a draft of this article, and Margaret England for her research assistance. I would also like to acknowledge the research assistance of Hope Wylie, a brilliant and promising student, who should have had a long and productive legal career. This Article is dedicated to her memory.

I. INTRODUCTION

More than seven years have passed since the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[1] At that time, few could have predicted the Byzantine course the doctrine announced in *Daubert* would take on its way to the new millennium.[2] When the Supreme Court rejected the *Frye* general acceptance test[3] as the sole test for the admissibility of scientific evidence in the federal courts,[4] and offered several general observations to determine scientific reliability under the Federal Rules of Evidence,[5] both plaintiffs'

1. 509 U.S. 579 (1993).

2. I was among those observers who did not have the benefit of a crystal ball. *See* Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence After* Daubert, 55 U. PITT. L. REV. 889 (1994) [hereinafter Eggen, *Scientific Evidence*] (examining the implications of *Daubert* along with the ruling's probable effect on toxic tort litigation).

3. *See* Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923) (stating that "while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs").

4. *Daubert*, 509 U.S. at 587.

5. *See* FED. R. EVID. 702, 703. Prior to the promulgation of the Federal Rules of Evidence, the *Frye* rule was the traditional test for the admissibility of scientific evidence in the federal courts and many state courts. Eggen, *Scientific Evidence*, *supra* note 2, at 909–10. The federal circuits split over the applicability of *Frye* during the era of the Federal Rules until the United States Supreme Court decided *Daubert*. *See id*. at 910–19 (examining the scope of the circuit split and describing the various tests espoused by the

and defendants' attorneys claimed victory.[6] Defendants cheered the decision's emphasis on the gatekeeping role of the federal district courts in determining the reliability and relevancy, and hence admissibility, of scientific evidence.[7] Plaintiffs saw the decision as sympathetic to novel scientific theories, provided that those theories were based upon tested methodologies.[8] An objective reading of the *Daubert* decision reveals a clear affirmation by the Court of the jury system's ability to function effectively when confronted with scientific evidence. Indeed, the Court exhorted the values of traditional trial mechanisms—cross-examination, introduction of contrary evidence, and burden of proof instructions—as a check on the use of scientific evidence.[9]

When the dust settled,[10] however, the district courts weighed in on the side of increased exclusion of evidence.[11] Concern for

circuit courts).

6. *Compare* Ron Simon, *High Court Throws Out Rigid Rules Excluding Scientific Evidence, Says Focus Must be on Methods, Principles*, PRODUCT SAFETY & LIABILITY REP., Summer/Fall 1993, at 5, 5 (describing a plaintiff attorney's prediction that the flexible doctrine of *Daubert* would work to the advantage of parties seeking to introduce scientific evidence), *with* Clifton T. Hutchinson, Daubert *Confirms Judge's Gatekeeper Role*, PRODUCT SAFETY & LIABILITY REP., Summer/Fall 1993, at 12, 15 (describing a defense attorney praising *Daubert* for further limiting admissibility of scientific evidence in federal courts).

7. *See* Hutchinson, *supra* note 6, at 12 (declaring that *Daubert* was a victory for those desiring careful judicial scrutiny of scientific expert testimony).

8. *See* Simon, *supra* note 6, at 10.

9. *Daubert*, 509 U.S. at 596.

10. In the immediate wake of *Daubert*, nothing unexpected occurred. The decision did nothing to change the results in the Bendectin litigation from which it arose. Courts applied *Daubert* and continued to hold the Bendectin plaintiffs' scientific evidence inadmissible. *See* Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1322 (9th Cir. 1995) (affirming summary judgment for the defendant based upon exclusion of the plaintiffs' expert evidence after remand from United States Supreme Court); DeLuca v. Merrell Dow Pharms., Inc., 6 F.3d 778 (3d Cir. 1993), *aff'g without opinion*, 791 F. Supp. 1042 (D.N.J. 1992) (affirming post-*Daubert* summary judgment for defendant in Bendectin case). This was the inevitable result of the type of novel and non-peer reviewed methodology proffered by the plaintiffs within the narrow confines of those cases. The *Daubert* plaintiffs' scientific evidence consisted of the following: (1) toxicological studies conducted *in vitro* and on live animals; (2) pharmacological studies comparing the chemical structure of the drug Bendectin to other known teratogens; and (3) "reanalysis" of the existing published epidemiological studies on Bendectin. *Daubert*, 509 U.S. at 583. The numerous epidemiological studies had all concluded that no causal relationship existed between Bendectin and certain types of limb deformities occurring in humans. *See* DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 943 (3d Cir. 1990). Some early cases applying *Daubert* to other alleged toxic substances focused directly on the issues addressed in *Daubert*, weeding out proffered scientific evidence that either lacked reliability or failed to provide a precise fit with the issues in the case. For example, in the early post-*Daubert* case of *Chikovsky v. Ortho Pharmaceutical Corp.*, the court excluded expert testimony on the relationship between the prescription acne remedy Retin-A and birth defects. 832 F. Supp. 341, 345–46 (S.D. Fla. 1993). The plaintiff's expert did not cite any studies demonstrating a causal connection between Retin-A and birth defects; instead, the expert attempted to analogize the effects of Retin-A to the effects of vitamin A

the heightened gatekeeping role of the district court judge in scrutinizing expert scientific evidence led to efforts to educate the judiciary on the nature and potential weaknesses of scientific evidence.[12] Judges became more proactive in addressing and filtering scientific evidence on pretrial evidentiary challenges.[13] As a result, the doctrine has shifted and expanded beyond the narrow parameters of the *Daubert* decision, casting a progressively wider net to encompass broader categories of expert evidence. Ultimately, in *Kumho Tire Co. v. Carmichael*,[14] the Supreme Court extended *Daubert* to all expert evidence—scientific, technical, or otherwise.[15]

The development of the *Daubert* doctrine has had a dramatic impact on the viability of toxic tort claims. In toxic torts, a plaintiff often makes separate showings of general causation and specific causation.[16] Thus, the plaintiff presents evidence tending to show that the substance to which he or she was exposed was capable of causing the injury suffered, as well as evidence to prove that the particular injury was in fact caused by the exposure alleged. Specific causation is often oppressively problematic in toxic tort cases, where latency periods and generic categories of disease make causal identification difficult.[17]

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and Accutane (another acne medication) on developing fetuses. *Id.* The district court characterized this testimony as "precisely the kind of evidence that the trial judge must exclude in performing the gatekeeper function." *Id.* at 346. Cases such as this fit well into the relevancy arm of the *Daubert* test and did not present a hard question or a serious challenge to the formulation of the doctrine.

11. *See* MOLLY TREADWAY JOHNSON ET AL., FED. JUDICIAL CTR., EXPERT TESTIMONY IN FEDERAL CIVIL TRIALS: A PRELIMINARY ANALYSIS 1, 4 (2000) ("Judges were more likely to scrutinize expert testimony before trial and less likely to admit expert testimony in 1998 than in 1991."), http://air.fjc.gov/public/pdf.nsf/lookup/exptesti.pdf.

12. *See, e.g.*, FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 1–5 (1994) [hereinafter FED. JUDICIAL CTR.] (providing judges with information on specific scientific areas to assist them in dealing with expert witnesses and complex scientific evidence).

13. *See* Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 335–37 (1999) (explaining the affirmative role assumed by judges in determining the admissibility of scientific evidence and stating that "federal judges have been making significant substantive legal rules on causation by substantially raising the threshold of scientific proof plaintiffs need to get their expert causation testimony admitted").

14. 526 U.S. 137 (1999). Between *Daubert* and *Kumho Tire*, the Supreme Court decided *General Electric Co. v. Joiner*, 522 U.S. 136, 139 (1997), which held that the abuse of discretion standard applied to appellate review of district court admissibility decisions under *Daubert*. *Joiner* thus made it more difficult for appellate courts to reverse exclusion decisions.

15. *Kumho Tire*, 526 U.S. at 141.

16. *See, e.g.*, Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1200 (6th Cir. 1988).

17. *See, e.g.*, Allen v. United States, 588 F. Supp. 247, 405–06 (D. Utah 1984), *rev'd on other grounds*, 816 F.2d 1417 (10th Cir. 1987). Some courts view general causation and

Most toxic tort plaintiffs rely, at least in part, on testimony of causation proffered by treating physicians and derived from a differential diagnosis[18] performed in the clinical setting. This clinical medical evidence of causation differs from the generalized research studies proffered to show general causation in *Daubert*. Well before the *Kumho Tire* decision, district courts began to strictly apply *Daubert* to clinical medical evidence.[19] Some courts have incorrectly read *Daubert* to mean that, for causation testimony derived from the clinical setting to be admissible, the physician must demonstrate reliance upon valid "hard scientific studies,"[20] such as valid epidemiological[21] or toxicological[22]

specific causation as two separate, rigid requirements. *See Sterling*, 855 F.2d at 1200. But these elements are more properly seen to have a "dynamic interconnection" with one another that makes causation determinations—and related evidentiary admissibility decisions—complicated matters best decided on a case-by-case basis. *See* John G. Culhane, *The Emperor Has No Causation: Exposing a Judicial Misconstruction of Science*, 2 WIDENER L. SYMP. J. 185, 193 (1997). The interrelationship of proofs of general and specific causation could become an article in itself. This Article does not engage in that discussion, but rather focuses on the admissibility of clinical medical evidence of causation, the nature of which is more particularized than general. For an example of the dilemma posed when a thoroughly performed differential diagnosis provides evidence of specific causation, but when the court demands, in addition, scientific studies to support general causation, see *Glastetter v. Novartis Pharmaceuticals Corp.*, 107 F. Supp. 2d 1015 (E.D. Mo. 2000).

18. Refer to Part III.B *infra* (explaining the utility and methodology of differential diagnosis).

19. *See, e.g.*, Moore v. Ashland Chem. Inc., 151 F.3d 269 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999).

20. This Article employs the term "hard science" or "hard scientific studies" to refer to epidemiological, toxicological, or other laboratory studies. Researchers may conduct such studies to generate information regarding causal relationships between certain exposures and certain diseases or other adverse outcomes. In toxic tort terms, such studies are typically proffered to provide proof of general causation. *See generally* Eggen, *Scientific Evidence*, *supra* note 2, at 897–903.

21. Epidemiology is the statistical study of human populations to determine probabilities and relationships between exposures and diseases. *See* ABRAHAM M. LILIENFIELD & DAVID E. LILIENFIELD, FOUNDATIONS OF EPIDEMIOLOGY 3–4 (2d ed. 1980) (presenting the concepts and methods of epidemiology as applied to various disease problems). It is the "study of relationships between the frequency and distribution, and the factors that may influence frequency and distribution, of diseases and injuries in human populations." U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, REPRODUCTIVE HEALTH HAZARDS IN THE WORKPLACE 163 (1985) [hereinafter REPRODUCTIVE HEALTH HAZARDS]. These studies often raise questions of scientific validity and reliability in the context of toxic tort cases. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 584 (1993) (rejecting as unreliable the novel technique of "reanalysis" of existing epidemiological studies); Brock v. Merrell Dow Pharms., Inc., 874 F.2d 307, 311 (5th Cir. 1989) ("Undoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies."); *see generally* Eggen, *Scientific Evidence*, *supra* note 2, at 897–901 (discussing the challenges and limitations of using epidemiological and toxicological evidence to prove causation in toxic tort cases).

22. The Federal Judicial Center has offered the following definition of toxicology: "The science of toxicology attempts to determine at what doses foreign agents produce their effects. The foreign agents of interest to toxicologists are all chemicals (including

studies. These studies, in turn, must independently meet the *Daubert* criteria.[23] Similarly, some courts have attempted to force the clinical methodology of differential diagnosis into the straightjacket of the *Daubert* general observations.[24] This approach essentially creates an inadmissible per se standard that has the effect of excluding most clinical testimony of causation. Once the evidence has been excluded, many cases will fail on summary judgment motions for lack of sufficient evidence.[25]

Fortunately, not all courts have applied *Daubert* in such a restrictive manner to clinical medical evidence of causation. This Article argues that the restrictive application of *Daubert* to such testimony in fact misapplies the *Daubert* doctrine and contradicts the intent of the Supreme Court. This Article demonstrates that *Daubert* and its progeny did not intend to eliminate whole categories of valid methodologies, such as clinical medical evidence of causation. Indeed, *Kumho Tire* makes clear that the *Daubert* doctrine is intended to be flexible, precisely to accommodate methodologies that do not fall into the narrow

foods) and physical agents in the form of radiation, but not living organisms that cause infectious diseases." FED. JUDICIAL CTR., *supra* note 12, at 185. In toxic tort cases, toxicological studies, as a generic category, encompass many different kinds of laboratory studies conducted both *in vivo* (on live animals) or *in vitro* (in laboratory containers). *See* REPRODUCTIVE HEALTH HAZARDS, *supra* note 21, at 167. These studies present difficult problems of extrapolation from the study to the human plaintiff, and often raise issues of relevancy in toxic tort cases. *See id.*; *see also* Jack L. Landau & W. Hugh O'Riordan, *Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Tort Litigation*, 25 IDAHO L. REV. 521, 545–48 (1989) (stating that "there is simply no way, apart from sheer chance, that a given animal study extrapolation will accurately predict human responses under specific conditions"); Bert P. Krages II, Comment, *Rats in the Courtroom: The Admissibility of Animal Studies in Toxic Tort Cases*, 2 J. ENVTL. L. & LITIG. 229, 231, 234–37 (1987) (concluding that animal studies are unreliable predictors of the effects of toxic substances on humans and these studies should not be admitted for causation evidence).

23. *See, e.g.*, Moore v. Ashland Chem. Inc., 151 F.3d 269 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999).

24. *E.g.*, Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1412–13 (D. Or. 1996).

25. This Article emphasizes the procedural distinction between an admissibility ruling, rendered following a hearing in limine, and a sufficiency determination, typically raised prior to trial by means of a summary judgment motion. *Compare Daubert*, 509 U.S. at 592 (stating that "the trial judge must determine at the outset . . . whether the expert is proposing to testify to [reliable and relevant evidence]"), *with* FED. R. CIV. P. 56(c) (stating that summary judgment will be granted if moving party shows "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law"), *and* FED. R. CIV. P. 56(e) (stating that affidavits submitted in support of or in opposition to a motion for summary judgment shall state facts that "would be admissible in evidence"). Because of the frequently close relationship between the admissibility decision and the sufficiency decision in many toxic tort cases, some courts have improperly blended the two standards, making what are essentially sufficiency determinations during the course of considering the admissibility of evidence.

category of hard science.

This Article begins in Part II with some observations on the refinements of the *Daubert* doctrine by the Supreme Court in *Joiner* and *Kumho Tire*. Part III focuses on the problem of clinical medical testimony of causation, demonstrating the split in the circuit courts of appeals over the interpretation of *Daubert* as applied to the causation testimony of treating physicians derived through differential diagnosis in the clinical setting. This Article then proposes a reasonableness test for applying the intent of *Daubert* to this kind of evidence, and concludes that clinical medical causation testimony—when based upon validly conducted methodologies considered reliable in the clinical medical setting—should be admissible under most circumstances.

II. THE SUPREME COURT'S REFINEMENT OF THE *DAUBERT* DOCTRINE

The Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[26] has generated a considerable amount of scholarly commentary over the years.[27] The principal features of the decision are by now well known. The Supreme Court held that the Federal Rules of Evidence defined the test that the federal district courts should apply in determining the admissibility of scientific evidence.[28] In so holding, the Court explicitly rejected the earlier *Frye* admissibility test that focused solely on the general acceptance of the evidence sought to be admitted.[29] The Court held that the Federal Rules mandated that district courts examine the reliability and relevance of the scientific evidence.[30] Thus, the party offering the evidence must

26. 509 U.S. 579 (1993).

27. *See, e.g.*, Margaret A. Berger, *Procedural Paradigms for Applying the* Daubert *Test*, 78 MINN. L. REV. 1345, 1345–46 (1994) (discussing procedural issues that may affect scientific evidence admissibility after *Daubert*); Eggen, *Scientific Evidence*, *supra* note 2, at 891 (analyzing the admissibility of scientific evidence regarding causation after *Daubert*); Edward J. Imwinkelried, *Evidence Law Visits Jurassic Park: The Far-Reaching Implication of the* Daubert *Court's Recognition of the Uncertainty of the Scientific Enterprise*, 81 IOWA L. REV. 55, 58–59 (1995) (positing that "Justice Blackmun's acknowledgement of the uncertainty of the scientific enterprise has far-reaching implications for American Evidence law—implications that sweep far beyond the law of expert testimony"); Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After* Daubert, 78 MINN. L. REV. 1387, 1390 (1994) (discussing the appropriate approach to assessing the admissibility of scientific evidence and restrictions on expert opinion evidence after *Daubert*).

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

29. *Id.*

30. *Id.* at 590–91.

demonstrate that it is scientifically valid and that it closely fits the issues to be decided in the case.[31] Furthermore, the Court stated that the district court judge must assume a gatekeeping role to determine, at the outset of the action, the admissibility of the scientific evidence on which the parties rely.[32]

An important feature of *Daubert* was the nondefinitive list of "general observations" enumerated by the Court to assist trial courts in their gatekeeping task.[33] This list included the following factors: (1) whether the scientific theory or technique has been tested; (2) whether the study has been published or has undergone some other form of peer review; (3) the known or potential rate of scientific error associated with the methodology employed; and (4) whether the methodology has achieved general acceptance in its field.[34] The Court emphasized that the inquiry, particularly the general acceptance inquiry, must focus solely on the "principles and methodology" of the scientific evidence and not on the ultimate conclusion of the expert.[35]

Daubert foretold problems for toxic tort plaintiffs, whose entire cases typically hinge on the demonstration of causation through expert scientific evidence.[36] The Supreme Court's

31. *Id*. at 592.

32. *Id*. at 592–94. The mandate that the trial court assume a gatekeeping role has been strictly followed. *See, e.g.*, Padillas v. Stork-Gamco, Inc., 186 F.3d 412, 416–18 (3d Cir. 1999) (holding that the trial court failed to follow proper procedures for determining admissibility of expert evidence by failing to hold an in limine hearing before ruling inadmissible evidence that turned on factual issues).

33. *Daubert*, 509 U.S. at 593.

34. *Id*. "Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate." *Id*. Chief Justice Rehnquist, in his partial concurrence and dissent, criticized the majority's choice to offer general observations in a vacuum, that is, without putting them in the service of deciding the admissibility of the proffered evidence in the case. He stated:

> "General observations" by this Court customarily carry great weight with lower federal courts, but the ones offered here suffer from the flaw common to most such observations—they are not applied to deciding whether particular testimony was or was not admissible, and therefore they tend to be not only general, but vague and abstract.

Id. at 598 (Rehnquist, C.J., concurring in part and dissenting in part). Chief Justice Rehnquist's comments proved particularly prescient regarding the problem of clinical medical testimony of causation.

35. *Id*. at 595.

36. Long before the Supreme Court decided the *Daubert* case, Judge Jack B. Weinstein recognized the scientific difficulty faced by many toxic tort plaintiffs, particularly those advancing novel scientific theories concerning new substances or substances used in new contexts. *See In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1242 (E.D.N.Y. 1985). Judge Weinstein stated:

> [C]areful scrutiny of proposed evidence is especially appropriate in the toxic tort area. The uncertainty of the evidence in such cases, dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts and gatekeeping under Rules 403 and 703

rejection of any kind of favored status for novel scientific evidence meant that toxic tort plaintiffs claiming injuries from exposures that had not yet been substantially researched would likely have difficulty meeting the *Daubert* standard.[37] Indeed, *Daubert* itself was a toxic tort case, reaching the Supreme Court as two consolidated cases claiming birth defects as a result of maternal exposure to the prescription medication Bendectin. In the *Daubert* decision, Justice Blackmun addressed the issue of novel science to some extent.[38] When the petitioners expressed a concern that the judicial screening of scientific evidence pursuant to *Daubert* would "sanction a stifling and repressive scientific orthodoxy,"[39] the Court responded that "a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations."[40] This statement was hardly reassuring to plaintiffs.

In the years following the *Daubert* decision, the federal courts have struggled with issues relating to the application of the general observations put forth in *Daubert*. The decisions have represented a clash of professional perspectives.[41] In an

by the court.

Id. at 1260.

37. One example of the negative impact *Daubert* may have on toxic tort cases dependent upon novel scientific evidence was seen in *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607 (7th Cir. 1993), an early post-*Daubert* test of the doctrine. In *Porter*, the plaintiff claimed to have developed kidney failure from ingesting the over-the-counter medication ibuprofen after suffering a toe fracture. *Id*. at 609–10. The court held that all of the plaintiff's expert testimony was inadmissible because no studies or other similar medical cases had been reported and made available to the experts. *Id*. at 614. Moreover, the experts had characterized their opinions with such equivocal language as "curbside opinion" and "hypothesis." *Id*. at 614–15. The theory of causation in the *Porter* case was brand new in its time. *Cf.* Diane Lore, *Danger Can Lurk in Over-the-Counter Drugs*, HOUS. CHRON., Mar. 30, 1997, at A8 (reporting that ibuprofen can cause kidney damage and ulcers in the esophagus and stomach). The case points out the delicate relationship between litigation and novel science. Often litigation is the catalyst for, if not the direct generator of, studies on novel scientific theories. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA 50 (1995) ("Unsung in most academic writing on science and law is the growing influence of legal proceedings on the production of new scientific knowledge and techniques."). It would stand to reason that if courts consistently exclude novel science as unreliable, fewer studies of novel scientific theories will be generated. Ultimately, this would have a detrimental effect on the availability of accurate and reliable science in litigation.

38. *Daubert*, 509 U.S. at 593 (noting that some theories may be "too new" to have been published and that publication was "not a *sine qua non* of admissibility," but that "submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected").

39. *Id*. at 596.

40. *Id*. at 597.

41. *See* Finley, *supra* note 13, at 363 (observing that while some courts have been

identifiable trend, some courts have created a kind of objective test of scientific reliability for use in all admissibility decisions for scientific evidence,[42] whereas other courts have rejected the imposition of a bright-line test.[43] The result has been confusion and conflation. Confusion, because courts disagree over what constitutes scientific reliability, even when applying the *Daubert* general observations. Conflation, because in the tortured process of developing such standards, courts have conflated methodology with conclusions,[44] admissibility with sufficiency of the evidence,[45] and general causation with specific causation.[46]

The trend toward exclusion has become particularly burdensome for toxic tort plaintiffs. A restrictive reading of *Daubert* that would favor exclusion of evidence,[47] particularly

willing to make admissibility decisions on expert scientific evidence without insisting upon an absolute statistical threshold, other courts have set standards that are so ingrained that they have become normative standards).

42. *See, e.g.*, Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1403 (D. Or. 1996) (requiring a minimum relative risk factor of 2.0 for epidemiological evidence of causation in silicone gel breast implant litigation). *See generally* Finley, *supra* note 13, at 347–64 (discussing the trend of some courts to require rigid thresholds for admissibility of epidemiological evidence in tort actions).

43. *See, e.g.*, Heller v. Shaw Indus., Inc., 167 F.3d 146, 155 (3d Cir. 1999) (acknowledging that reliability of expert evidence may be determined from a variety of evidence, including differential diagnosis).

44. *Cf.* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (acknowledging that methodology is sometimes indistinguishable from conclusions).

45. *See, e.g.*, Merrell Dow Pharms., Inc. v. Havner, 953 S.W.2d 706, 713 (Tex. 1997) (discussing, in a Bendectin case, the use of reliability determination in a review of the legal sufficiency of scientific evidence). The tendency to fuse admissibility and sufficiency determinations derives from the following language in the *Daubert* decision: "[I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment . . . and likewise to grant summary judgment." *Daubert*, 509 U.S. at 596. The *Daubert* Court was not intending to conflate the two standards, but was rather noting that the admissibility determination is a distinct process that precedes the determination of legal sufficiency of the evidence, whether the sufficiency of the evidence issue is raised prior to trial by means of a summary judgment motion or at trial by means of a motion for judgment as a matter of law. *Cf.* Gruca v. Alpha Therapeutic Corp., 51 F.3d 638, 643 (7th Cir. 1995) (reversing the district court's decision due to its failure to conduct an admissibility hearing on the plaintiff's causation evidence prior to permitting the plaintiff's expert to testify, and directing a verdict for the defendant instead); *see also* Joiner v. Gen. Elec. Co., 78 F.3d 524, 533 (11th Cir. 1996) (criticizing the district court for excluding the plaintiff's evidence of causation on the basis that the district court simply drew different conclusions from the evidence than the plaintiff's experts had drawn), *rev'd*, 522 U.S. 136 (1997).

46. *See* Finley, *supra* note 13, at 356–58 (discussing *In re Breast Implant Litigation*, 11 F. Supp. 2d 1217 (D. Colo. 1998)). Refer to note 17 *supra* (commenting on the inherent difficulty in identifying specific causation in toxic tort cases and the interrelationship between general and specific causation).

47. A troubling manifestation of this approach has been a trend among some federal courts to require the statistical studies offered by plaintiffs to rise above a pre-ordained relative risk factor for that evidence to be admissible. One example of this phenomenon is

evidence that is directed toward novel scientific theories, would have the disparate effect of excluding large amounts of toxic tort

Hall v. Baxter Healthcare Corp., a silicone gel breast implant case in which the court determined that only testimony based upon studies on the relationship between implants and various autoimmune diseases that had a relative risk greater than 2.0 would be admissible. 947 F. Supp. at 1403–04. The relative risk is a statistically adjusted figure that represents the likelihood that a particular exposure or event caused a particular illness or other outcome. *Id.* at 1403; *see also* Bert Black & David E. Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732, 757–58 & n.105 (1984). Generally, it represents the number of persons in the exposed group in the study who have contracted a particular disease divided by the number of persons in the unexposed group who have contracted the disease. *Id.* While a relative risk factor above ten presents a strong indication of a causal relationship, *id.* at 758, lower risk factors do not necessarily mean that a causal association does not exist. A variety of reasons may justify a low risk factor even where a causal connection may exist, including the statistical difficulty of distinguishing between a low risk and background levels of the disease in the population. *See* Junius C. McElveen, Jr. & Pamela S. Eddy, *Cancer and Toxic Substances: The Problem of Causation and the Use of Epidemiology*, 33 CLEV. ST. L. REV. 29, 39 (1985). In addition, the existence of bias in the test design may make it difficult for researchers to obtain accurate data. *See* David H. Wegman & Ruthann Giusti, *Epidemiology*, *in* OCCUPATIONAL HEALTH: RECOGNIZING AND PREVENTING WORK-RELATED DISEASE 51, 63 (Barry S. Levy & David H. Wegman eds., 1983). Finally, inadequate sample size and the existence of confounding variables can deter accurate analysis of statistical information by masking a true association. *See* REPRODUCTIVE HEALTH HAZARDS, *supra* note 21, at 166–67. *See generally* Eggen, *Scientific Evidence*, *supra* note 2, at 895–905 (relating causation problems in toxic tort cases to scientific evidence issues); Jean Macchiaroli Eggen, *Toxic Reproductive and Genetic Hazards in the Workplace: Challenging the Myths of the Tort and Workers' Compensation Systems*, 60 FORDHAM L. REV. 843, 852–59 (1992) [hereinafter Eggen, *Toxic Reproductive and Genetic Hazards*] (discussing the use of epidemiological and toxicological evidence in toxic tort cases). Courts that have used a fixed relative risk standard to determine admissibility have essentially conducted a premature sufficiency analysis at the gatekeeping stage, by using a sufficiency standard to determine admissibility, rather than a validity/reliability standard. *See* Finley, *supra* note 13, at 336–37 (discussing the effects of judicial conflation of admissibility decisions and sufficiency of evidence decisions). The result has been that more evidence has been kept from the trier of fact than *Daubert* originally contemplated. *Cf.* Note, *Navigating Uncertainty: Gatekeeping in the Absence of Hard Science*, 113 HARV. L. REV. 1467, 1474–81 (2000) (devising an objective numerical test to measure threshold admissibility of testimony based upon differential diagnosis). Any efforts to create substantive thresholds for the admissibility of scientific testimony come perilously close to sufficiency determinations. Such numerical straight-jackets strictly limit admissibility. While such limits have some mathematical meaning in the discipline of epidemiology, their value is highly suspect in the legal context and certainly so when applied to evidence that is not hard science.

The *Hall* case, along with other silicone gel breast implant cases, is discussed extensively in Professor Finley's article. Finley, *supra* note 13, at 352–62. Professor Finley makes a strong argument that case law since *Daubert* has evidenced a collapsing of the standards for admissibility and sufficiency that ordinarily would be bifurcated into the two steps of motion in limine and motion for summary judgment. *See id.* at 355–58 (discussing how the *Hall* court and other breast implant cases have conflated the burden of proof with evidentiary determination). Procedurally, Professor Finley is correct. However, matters of scientific reliability and matters of sufficiency can be entwined in a complicated way. Professor Finley argues effectively that in collapsing the standards, courts are making normative decisions, thus inappropriately impacting substantive law without accounting for community values that would come into play when the evidence is weighed by a jury. *See id.* at 363–71.

plaintiffs' evidence because of the evolving nature of much toxic-exposure science.

The Supreme Court chose another toxic tort case in which to determine the standard of appellate review for admissibility decisions and provide further insight into the developing *Daubert* doctrine. *General Electric Company v. Joiner*[48] arose from a personal injury action involving exposure to polychlorinated biphenyls (PCBs).[49] The plaintiff, who had a history of cigarette smoking and a family history of lung cancer, developed small-cell lung cancer at the age of thirty-seven.[50] He alleged that the lung cancer was caused by his exposure to PCBs in his job as an electrician for a utility company.[51] The district court held that the studies proffered by the plaintiff's experts to prove causation were inadmissible under *Daubert*.[52] The Eleventh Circuit reversed, however, holding that decisions excluding expert testimony should be subject to review under a "particularly stringent standard of review."[53] The Supreme Court held that the Eleventh Circuit erred in applying an overly stringent standard of review to the district court's ruling and held that the proper standard of review was the abuse of discretion standard.[54] The Supreme Court then ruled that the district court had not abused its discretion in determining that the plaintiff's expert's testimony was inadmissible.[55]

The Supreme Court's application of the abuse of discretion standard was not unreasonable, given the fact that trial judges are in a unique position to consider the evidence offered by the parties prior to trial.[56] But the *Joiner* decision raises some more controversial and troubling issues in the second half of the opinion. The Court examined the district court's inadmissibility

48. 522 U.S. 136 (1997).

49. *Id*. at 139–40.

50. *Id*.

51. *Id*. (noting that the plaintiff's suit alleged that PCB exposure "promoted" his cancer in that he would not have developed cancer for many years, if at all, but for his exposure).

52. *Id*.

53. Joiner v. Gen. Elec. Co., 78 F.3d 524, 529 (11th Cir. 1996), *rev'd*, 522 U.S. 136 (1997). The Eleventh Circuit concluded that the Federal Rules of Evidence on expert testimony demonstrated a "preference for admissibility." *Id*.

54. *Joiner*, 522 U.S. at 143.

55. *Id*.

56. Arguably, however, an abuse of discretion standard grants too much deference to the district court. With inchoate rules regarding the factors to be used in determining the admissibility of various kinds of expert evidence, particularly in the wake of *Kumho Tire*, the abuse of discretion standard allows appellate courts to leave in place overly stringent or generally ill-conceived tests fashioned by district courts to determine admissibility. This could result in questionable precedent.

ruling on the causation evidence offered by the plaintiff.[57] The plaintiff proffered the testimony of two experts who had relied on various epidemiological and animal laboratory studies in formulating their opinions.[58] The petitioners challenged the experts' testimony, arguing that it was unsupported by the epidemiological studies and that it was not admissible solely on the basis of the animal studies because of problems with extrapolating from the animal species to humans.[59] The Supreme Court held that the district court had not abused its discretion in refusing to admit the animal studies—whether or not the epidemiological studies were admissible—because the studies were "so dissimilar to the facts presented" in the case.[60] The

57. *Joiner*, 522 U.S. at 138–41. One might well wonder why the Court, after establishing that the abuse of discretion standard applied, did not remand the case to the Eleventh Circuit for application of the standard enunciated. Instead, the Court took it upon itself to examine the district court's decision. Indeed, Justice Stevens, concurring in part and dissenting in part, refused to join the portion of the Court's opinion that analyzed whether the district court had erroneously ruled the evidence admissible. *See id.* at 150 (Stevens, J., concurring in part and dissenting in part). Justice Stevens noted that the precise question for which the Court granted review was the determination of whether the Eleventh Circuit had applied the correct standard of review. *Id*. (Stevens, J., concurring in part and dissenting in part). He questioned whether the parties had even adequately briefed the admissibility issue and opined that the kind of complete study of the record necessary to determine whether the district court had properly held the evidence inadmissible is most efficiently conducted by the court of appeals, rather than the Supreme Court. *Id*. at 150–51 (Stevens, J., concurring in part and dissenting in part).

58. *Id*. at 143–44. One of the experts had opined that it was "more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure," and the other had testified that the plaintiff's "lung cancer was caused by or contributed to in a significant degree by the materials with which he worked." *Id*. at 143.

59. *Id.* at 143–44. Animal studies present several extrapolation issues when they are offered to support or refute causation. The first is species-to-species extrapolation, in which the expert attempts to draw conclusions regarding the effect of a particular substance on humans from available laboratory animal data. *See* REPRODUCTIVE HEALTH HAZARDS, *supra* note 21, at 169. The human body may react differently from animals when exposed to a particular substance. *Id.* at 168–69. Thus, an expert relying on animal studies must demonstrate their relevancy and fit with respect to the human injuries involved in the case. *See* Landau & O'Riordan, *supra* note 22, at 548–51. Second, researchers typically expose laboratory animals to high doses of the substance under investigation to generate timely results. *Id*. at 545. Controversy exists over the reliability of extrapolation from these high exposures in animals to low-dose exposures in humans over periods of time. *See id*. at 545–48. These problems account for judicial reluctance to admit testimony based on animal studies without further corroboration and without demonstrating a close factual relationship between the animals' exposures and injuries and the exposures and injuries involved in the case. *See* Eggen, *Toxic Reproductive and Genetic Hazards*, *supra* note 47, at 856–59 (discussing the drawbacks of certain toxicological studies, including animal studies, and demonstrating the consequent problems in proving legal causation).

60. *Joiner*, 522 U.S. at 144–45. The Court cited a number of problems with the experts' use of the animal studies. *Id*. at 144. For example, the Court noted that the animal studies proffered in the case involved high doses of PCBs directly injected into infant mice. *Id.* The respondent's exposure was proportionately less and was not by direct injection. *Id*. In addition, the mice were injected with highly concentrated PCBs, whereas

Court also held that the district court had not abused its discretion in ruling the four epidemiological studies inadmissible.[61]

The respondent in *Joiner* objected that the district court had simply disagreed with the conclusions drawn by his experts from the studies upon which they relied.[62] The respondent emphasized *Daubert*'s instruction that the focus of the admissibility inquiry "'must be solely on principles and methodology, not on the conclusions that they generate.'"[63] The Supreme Court, in a statement that seemed to back-peddle from the Court's earlier position, declared that "conclusions and methodology are not entirely distinct from one another."[64] The Court proceeded to explain:

> 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 that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an *analytical gap* between the data and the opinion proffered.[65]

This "analytical gap" issue strikes at the core of virtually all admissibility questions involving expert testimony in toxic tort cases. The reality is that an analytical gap exists in every causation case. The question is not whether the analytical gap exists, but the degree of the gap.[66] Experts relying on statistical

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the respondent's exposures involved a much less concentrated PCB solution of between 0 and 500 parts per million. *Id.* Furthermore, the cancers developed by the mice were different from the type of cancer from which the respondent suffered. *Id.*

61. *Id.* at 145–47. With regard to one study, the Court observed that while the researchers had demonstrated a higher number of lung cancer deaths among workers in a plant where they were exposed to PCBs, the researchers stopped short of drawing the conclusion that exposure to the PCBs had caused the cancers. *Id.* at 145. The second study failed along similar lines because the increase in lung cancer deaths was not statistically significant. *Id.* The third and fourth studies did not connect the statistically significant increase in lung cancer deaths at the workplace studied with any particular substance, although the workers had been exposed to PCBs, among other substances. *Id.* at 145–46.

62. *Id.* at 146.

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

64. *Id. But see id.* at 154–55 (Stevens, J., concurring in part and dissenting in part).

> Because I am persuaded that the difference between methodology and conclusions is just as categorical as the distinction between means and ends, I do not think the statement that "conclusions and methodology are not entirely distinct from one another" . . . either is accurate or helps us answer the difficult admissibility question presented by this record.

Id.

65. *Id.* at 146 (emphasis added).

66. In *Allen v. United States*, 588 F. Supp. 247 (D. Utah 1984), *rev'd on other*

studies or animal testing data must necessarily provide the expert analysis that narrows the analytical gap between the studies and the circumstances of the case in question. The question then becomes: What is the role of the district court vis-à-vis the analytical gap, and how much of an analytical gap should the court tolerate before ruling that the evidence is inadmissible? Should the court strictly scrutinize the connections drawn by the expert, or should the court simply look to see if the expert drew the necessary connections and not delve any deeper? These questions were not answered in *Joiner*.

The Supreme Court's most recent pronouncement on the *Daubert* doctrine was *Kumho Tire Co. v. Carmichael*.[67] The issue decided in *Kumho Tire* was whether the rules of *Daubert* and *Joiner* applied to the testimony of experts who were not scientists, but whose testimony was nevertheless presented pursuant to Rule 702 of the Federal Rules of Evidence.[68]

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grounds, 816 F.2d 1417 (10th Cir. 1987), the court posited the following examples:

> In most cases, the factual connection between defendant's conduct and plaintiff's injury is not genuinely in dispute. Often, the cause-and-effect relationship is obvious: A's vehicle strikes B, injuring him; a bottle of A's product explodes, injuring B; water impounded on A's property flows onto B's land, causing immediate damage.

Id. at 405. Common sense, and the compression of time between the defendant's conduct and the appearance of the plaintiff's injury, tell us that the defendant's conduct must have been the cause of the injuries. In contrast, a toxic tort case typically is characterized by a more attenuated time period between exposure and injury, which creates one kind of analytical gap. Furthermore, because toxic tort cases depend on scientific studies—which often are incomplete, sparse, or nonexistent—another analytical gap exists that the plaintiff must close. Thus, the court in *Allen* addressed the causation problems presented in that case, which involved plaintiffs claiming various kinds of cancers associated with exposure to radiation during the United States's nuclear testing program, as follows:

> In this case, the factual connection singling out the defendant as the source of the plaintiffs' injuries and deaths is very much in genuine dispute. Determination of the cause-in-fact, or factual connection, issue is complicated by the nature of the injuries suffered . . . , the nature of the causation mechanism alleged . . . , the extraordinary time factors and other variables involved in tracing any causal relationship between the two.

Id. Professor David Rosenberg put the dilemma differently in his discussion of the demands courts place on plaintiffs to provide "particularistic" evidence to prove causation:

> The concept of "particularistic" evidence suggests that there exists a form of proof that can provide direct and actual knowledge of the causal relationship between the defendant's tortious conduct and the plaintiff's injury. . . . All knowledge of past as well as future events is probabilistic. Inevitably it rests on intuitive or more rigorously acquired impressions of the frequency with which similar events have occurred in like circumstances.

David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 851, 870 (1984).

67. 526 U.S. 137 (1999).

68. *Id*. at 141, 157. At the time of the Court's decision, Rule 702 provided: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert

Scientific knowledge is grouped with "technical" and "other specialized" knowledge in Rule 702, and the Court addressed whether the testimony of experts with technical or other specialized knowledge must also meet the *Daubert* and *Joiner* standards.[69] On this question, the Court was unanimous, holding that, although the *Daubert* decision addressed only "scientific" evidence, its reliability and relevancy standard applies to all expert testimony within the scope of Rule 702.[70]

The potential problems raised by *Kumho Tire* are apparent when one considers the exceptionally broad scope of the experts encompassed by Rule 702. In the *Kumho Tire* case itself, the expert whose testimony was in question was an engineer who proffered testimony that a defectively manufactured tire led to the blowout that resulted in the respondent's injuries.[71] Architects and computer specialists are other examples of this type of "technical" expert. In the broader category of "other specialized knowledge," the possibilities are endless. Such testimony frequently is experience-based. Experienced-based testimony, whether related to science or not, relies on the repetitive application of certain principles in an area of endeavor or upon professional studies.[72] Such testimony can relate to anything from mortgage banking to perfume sniffing.[73] The testimony of the clinical medical expert, who is typically the plaintiff's treating physician, may be characterized as science-related, experience-based evidence.

This broad range of experts raised the question whether the

by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." FED. R. EVID. 702.

69. *Kumho Tire*, 526 U.S. at 147.

70. *Id.* at 141. Among other things, the Court noted the difficulty district courts would have in separating scientific from technical or other expert knowledge and then applying different evidentiary standards. *Id.* at 148. Moreover, many disciplines have a basis in science. As the Court observed, "[d]isciplines such as engineering rest upon scientific knowledge." *Id.* The same can be said for clinical medical evidence of causation.

71. *Id.* at 142.

72. *See id.* at 148. "[E]xpert witnesses [are granted] testimonial latitude unavailable to other witnesses on the 'assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.' . . . The Rules grant that latitude to all experts, not just to 'scientific' ones." *Id.* (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592 (1993)).

73. *Id.* at 151. The Supreme Court specifically referenced the example of a perfume sniffer in its discussion of experienced-based testimony: "[I]t will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable." *Id.* The Court also identified other types of experienced-based experts, such as those skilled in "drug terms, handwriting analysis, criminal *modus operandi*, land valuation, agricultural practices, railroad procedures, [and] attorney's fee valuation." *Id.* at 150.

Daubert rule, developed and articulated specifically in the context of hard scientific testimony, should apply in an identical way to nonscientific or experience-based expert testimony.[74] In *Kumho Tire*, the Supreme Court held generally that it should.[75] Although stating that "some of *Daubert*'s questions can help to evaluate the reliability even of experienced-based testimony,"[76] the Court acknowledged that strict application of the *Daubert* factors to experience-based or other kinds of expert testimony may be improper.[77] Accordingly, the Court held that the trial court has "broad latitude" in deciding "whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case."[78] That decision is as much a matter of discretion as the court's determination of the reliability of the testimony and would also be subject to the abuse of discretion standard of review.[79]

Effective December 1, 2000, Rule 702 of the Federal Rules of Evidence has been amended to incorporate the *Daubert* and *Kumho Tire* doctrines.[80] Rule 702 now allows testimony to be admitted "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."[81] Rule 702 does not codify the *Daubert* factors, but references them in the Committee Note.[82] The Committee Note states that "[t]he standards set forth in the amendment are broad enough to require consideration of any or all of the specific *Daubert* factors where appropriate"[83] and cites favorably five additional factors that some courts have employed in rendering admissibility judgments on proffered expert testimony.[84]

74. *Id*. at 150–51.

75. *Id*. at 151. The trial judge must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id*. at 152.

76. *Id*. at 151.

77. *Id*. at 150–51.

78. *Id*. at 153.

79. *Id*. at 152.

80. FED. R. EVID. 702, committee note, 2000 U.S.C.C.A.N. (114 Stat.) G215. The Committee Note attached to the amendment states expressly that the amendment is in response to cases involving *Daubert* issues, including *Kumho Tire* (although the proposed amendment was in circulation before the Supreme Court's decision in *Kumho Tire*).

81. FED. R. EVID. 702 (as amended eff. Dec. 1, 2000).

82. *See* FED. R. EVID. 702, committee note, 2000 U.S.C.C.A.N. (114 Stat.) G215.

83. *Id*.

84. *Id*. The additional factors are the following: (1) whether the research that forms the basis of the testimony was generated outside of or within the litigation context; (2)

Some of the problems inherent in the *Kumho Tire* decision are showcased effectively in the Court's review of the engineer's testimony in that case.[85] The engineer had employed a "visual and tactile inspection" followed by a four-factor analysis of the results to conclude that the tire had been defective.[86] The district court objected to the engineer's methodology, and the Supreme Court held that the district court had not abused its discretion in refusing to admit the testimony.[87] In essence, the Court's fundamental objection to the expert's testimony was that it was too subjective in nature.[88] Indeed, the Court reiterated its earlier statement in *Joiner*—that a district court would not be unreasonable in excluding testimony in which the opinion is based solely on "'the *ipse dixit* of the expert.'"[89] One question *Kumho Tire* raises, which was not addressed in *Joiner*, was the degree to which objective scientific or other data must form the foundation of experienced-based or other expert testimony. The Court's level of discomfort with the engineering testimony in *Kumho Tire* leaves room for speculation that any expert opinion falling under Rule 702 must be based on objective data that resembles closely the *scientific* data underlying scientific testimony. In toxic tort litigation, this basis would require scientific data in most circumstances because of the inherently scientific or quasi-scientific nature of virtually all causation testimony in such cases.[90] This would present a problem for

whether the "analytical gap" between the methodology and the conclusion is too great; (3) whether alternative theories have been appropriately ruled out; (4) whether the expert shows appropriate professional care in testifying; and (5) the general reliability of the field of research. *Id*. at G216–17.

85. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 153–56 (1999).

86. *Id*. at 154.

87. *Id*. at 158.

88. The Supreme Court identified two problems with the engineer's proffered testimony. First, the engineer's conclusion was based upon the assumption that his visual and tactile inspection was capable of providing an appropriate basis for a determination of whether the tire had been defective. *Id*. at 154. Second, the engineer had testified in a deposition that following his inspection, he was unable to say with any certainty how far the tire had traveled. *Id*. at 154–55. In the Court's opinion, this uncertainty rendered the methodology unreliable. *Id*. at 155. The Court determined that the district court was correct in being skeptical of the second part of the expert's methodology—the multifactored test to rule out abuse of the tire. *Id*. Additionally, the Court stated that the district court was not unreasonable in objecting to the engineer's methodology because the first time he inspected the tire was for only a short time on the morning of his deposition. *Id*. At one point, the engineer stated that, under ideal circumstances, he would have examined other similar tires to determine whether the one in question was defective, but that this had not been done. *Id*. at 155–56. Furthermore, the Court noted that the record was devoid of any reference to the use of the technique by other experts and equally lacking in supporting articles or papers to lend reliability to the methodology. *Id*. at 157.

89. *Id*. at 157 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

90. Proof of causation in toxic tort cases often involves one or more of the following

experts, such as treating physicians, whose methodologies donot normally rely on scientific analysis in the same manner as the testimony addressed in the *Daubert* case.

A second problem raised by *Kumho Tire*—and foreshadowed in *Joiner*—is the blending of methodology and conclusions. A chicken-and-egg question arises here. For example, if the expert's conclusions represent a minority view, and especially if they have not undergone peer review in the literature (although this is not an absolute requirement under *Daubert*), the court may be tempted to view the methodology in the light of a novel conclusion, rather than vice versa. This could taint the methodology, even if it were long-established and well accepted. If conclusions and methodology are inextricably linked for admissibility purposes, all novel and emerging scientific theories may be in jeopardy of failing the admissibility test. Indeed, the bar would appear to be raised for such theories.

A third problem, raised by all three Supreme Court cases, is the lack of guidance regarding the application of the *Daubert* rule to experience-based and other expert testimony. In *Daubert*, the Court advanced several general observations, which amounted to factors against which the admissibility of scientific evidence was to be judged.[91] In *Kumho Tire*, however, the Court declined to modify those factors meaningfully for other kinds of expert evidence. Rather, the Court simply stated that a district court has the discretion to determine the factors to apply in making the decision for other kinds of expert testimony.[92] In *Daubert*, the Court presented some rather specific factors for district judges to consider in determining the reliability of hard scientific evidence.[93] The Court must have realized that, by declining to offer specific factors for other kinds of expert testimony, it would tempt courts to revert to the *Daubert* factors. Nevertheless, the *Daubert* factors clearly do not fit all types of evidence. Both this

issues: (1) the routes, methods, and amounts of the plaintiff's exposure to a toxic substance; (2) the amount and method of exposure capable of causing illness in humans; (3) the type of injury that the toxic substance may cause; (4) whether it actually caused the plaintiff's particular injury; (5) the physiological and/or biochemical processes by which the substance causes injury to the human body; (6) the movement of toxic substances on or in the land, water, or air; and (7) the elimination of other intervening causes for the plaintiff's injuries. *See generally* Eggen, *Scientific Evidence*, *supra* note 2, at 895–903. The experts called to present testimony on these issues could provide scientific testimony in the *Daubert* sense (for example, an epidemiologist), as quasi-scientific testimony (e.g., a workplace safety specialist testifying as to industry practices), or as clinical medical testimony (a combination of scientific and experience-based testimony).

91. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593–94 (1993).

92. *Kumho Tire*, 526 U.S. at 158.

93. *See Daubert*, 509 U.S. at 592–94.

fact, and the enhanced gatekeeping role of the trial court—to determine admissibility and establish the factors by which that admissibility is to be judged in a particular case—may set the stage for a freewheeling determination of admissibility in individual cases and an ultimate lack of consistency from circuit to circuit. The example of clinical medical testimony of causation embodies this tendency.

III. THE QUESTION OF CLINICAL MEDICAL EVIDENCE OF CAUSATION

A. Scientific Evidence and the Search for Truth

Any legal observer will say that in civil litigation, truth is a relative concept. The fact-finder determines a version of the facts to believe from an array of evidence, both physical and verbal, that is presented at trial.[94] Scientific evidence adds a further complication to the truth inquiry: every scientific field is continually evolving. Scientists themselves may not agree on what is scientific fact and, even if they do, what was believed to be fact may later turn out to be myth.[95] In *Daubert*, the Supreme

94. For example, Professor Sheila Jasanoff has stated:

> Fact-finding in law proceeds through a form of ritualized courtroom discourse that subjects the scientist's firsthand reporting of observation and experiment to additional conceptual and rhetorical filters. What the legal fact-finder "knows" is a function of what the witnesses in a proceeding choose to relate in court in answer to questions posed by lawyers.

JASANOFF, *supra* note 37, at 9.

95. A classic example of scientific (r)evolution occurred during the Renaissance with the acceptance of the Copernican concept of the solar system, according to which Earth and the other planets were determined to revolve around the sun. This concept was dramatically different from the popular Ptolemaic view of the earth as the center of the universe, which was held for centuries as "true" until replaced by the Copernican theory. *See* COSMOS, HISTORY OF HUMANITY'S PERCEPTION OF THE UNIVERSE, ENCYCLOPÆDIA BRITANNICA ONLINE, *at* http://www.eb.com (last visited Feb. 12, 2001). A more modern example of the evolution of scientific "truth" is in the area of physics. In a seminal piece relating the law to modern scientific developments, Professor Laurence Tribe summarized this evolution as follows:

> The Newtonian physics of two centuries ago took the view that objects acted on each other across the expanse of a neutral, undifferentiated space in an objective and knowable manner . . . .
>
> Since the 1920's, physics has been guided by two key shifts away from this view. On the grand scale, the general theory of relativity has demonstrated, among other things, that the physical universe, as seen through a telescope, can be explained only by realizing that objects like stars and planets *change* the space around them — they literally "warp" it — so that their effect is both complex and interactive. On the subatomic scale, quantum theory has demonstrated that . . . the very process of observation and analysis can fundamentally alter the things being observed, and can change how they will behave thereafter.

Court stated that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science."[96] At its foundation, each scientific discipline constitutes "'a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement.'"[97] Science and the law sometimes appear at odds, yet this antagonism must be resolved into a shaky truce when litigation involves the determination of scientific issues. As the *Daubert* Court stated:

> [T]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment—often of great consequence—about a particular set of events in the past.[98]

Thus, the Court recognized that the scientific enterprise is both an evolutionary and revolutionary process that nevertheless has an essential value in legal decision making. Yet, avoiding the use of scientific theories that are "probably wrong" in litigation is difficult, for it requires nonscientists (judges, juries) to make scientific and quasi-scientific judgments.[99]

Laurence H. Tribe, *The Curvature of Constitutional Space: What Lawyers Can Learn from Modern Physics*, 103 HARV. L. REV. 1, 4–5 (1989) (footnotes omitted).

96. *Daubert*, 509 U.S. at 590.

97. *Id*. (quoting the brief for the American Association for the Advancement of Science et al. as amici curiae at 7–8).

98. *Id*. at 596–97.

99. While areas of novel scientific enterprise have found numerous critics, areas of traditional expertise have enjoyed a more secure position in the *Daubert* stratum. From the *Daubert* decision, one could reasonably conclude that the Ninth Circuit was correct in determining that the reanalysis of previous epidemiological studies on Bendectin was not a reliable methodology. *Id*. at 597. The major flaw in this methodology—which was quite novel—was that the study had not been peer reviewed or otherwise generally accepted in the relevant scientific community. *See* Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1318–19 (9th Cir. 1995) (on remand). *See generally Daubert*, 509 U.S. at 593–94 (establishing peer review and general acceptance as among the factors to be considered by a trial court in determining admissibility). In contrast, some methodologies that form the basis of expert testimony have an aura of reliability about them. *See, e.g.*, Greenwell v. Boatwright, 184 F.3d 492 (6th Cir. 1999) (Merritt, J., dissenting). In his dissent in *Greenwell*, Judge Merritt observed that accident reconstruction is a "generally reliable science," but stated that evidence based upon that methodology may not be admitted if the methodology was not accurately followed. *See id*. at 501–02 (Merritt, J., dissenting). The court held that the district court erred in admitting the defendant's accident

In addressing this dualism, the rules and procedures of civil litigation have several functions. First, the rules of evidence attempt to assure the reliability of the evidence admitted for use in trial and summary judgment. Equally important are the rules of procedure that assist the trier of fact to undertake a balanced evaluation of the evidence presented at trial. Burdens of proof, cross-examination, evidentiary trial motions, and motions for judgment as a matter of law all operate in this fashion.[100] Under modern rules of civil pleading and procedure, all of these devices are intended to function harmoniously to achieve an efficient and fair result.[101] The "truth" that results is the truth of the litigation process.[102]

B. The Methodology of Differential Diagnosis

The example of clinical medical testimony reflects the above issues. Clinical medical evidence is fundamentally scientific, as it is grounded in the discipline of medical science. But this evidence strongly differs from the kind of hard scientific studies directly addressed in the *Daubert* case.[103] *Daubert* involved epidemiological and toxicological studies of the sort proffered in many toxic tort cases.[104] These research studies, when appropriate to the issues in the case, present proof of general causation by tending to demonstrate that the substance in question can or cannot cause the type of illness from which the

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reconstruction expert's testimony; but it further held that the error was harmless. *Id.* at 496. Judge Merritt agreed with the majority on the admissibility issue, but opined that the error substantially prejudiced the plaintiff. *Id*. at 503 (Merritt, J., dissenting).

100. *See* Lappe v. Am. Honda Motor Co., 857 F. Supp. 222, 228 (N.D.N.Y. 1994) (stating that the trier of fact may discount scientific evidence that is brought into question through traditional methods of challenging testimony at trial), *aff'd without opinion*, 101 F.3d 682 (2d Cir. 1996).

101. *See, e.g.*, FED. R. CIV. P. 1 ("These rules . . . shall be construed and administered to secure the just, speedy, and inexpensive determination of every action.").

102. Professor Jasanoff has stated: "A contrafactual or contrascientific conclusion can, in appropriate circumstances, be declared the 'right' conclusion from the standpoint of the law." JASANOFF, *supra* note 37, at 10.

103. Even some of the more exclusionary commentators on expert testimony acknowledge this fact. *See* KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS 133 (1997) (asserting that sometimes a strong case for causation can be developed even without direct evidence). The authors state:

> A physician who testifies that he or she relied on a standard laboratory test to diagnose a disease in a specific patient is presenting some pure science and some applied knowledge. The scientific proposition is that the test is a reliable, valid indicator of the disease. The technical half of the testimony involves the specific application of the test to a specific patient.

Id. at 311 n.26.

104. *See Daubert*, 509 U.S. at 582, 584.

plaintiff suffers.[105] Expert testimony—by the researcher or another scientist testifying about the studies[106]—is necessary to draw the connection between the ability of the substance to cause that kind of injury and the actual occurrence of the injury in the plaintiff. Typically, the expert will have read the relevant studies and examined the plaintiff's medical records, on the basis of which he or she will then offer an opinion on the causation of the plaintiff's illness.[107]

Clinical medical evidence, on the other hand, is more in the nature of eyewitness testimony. The technique of differential diagnosis,[108] in which all physicians are trained, permits physicians to develop first a working diagnosis, then a definitive diagnosis, for the treatment of a patient.[109] The process of moving from the patient's presenting complaint to a definitive diagnosis is directed by certain general principles, regardless of the patient's symptoms; the precise process will vary depending upon

105. Professor Finley has persuasively demonstrated that a current trend in the courts applies a standard of individual causation to evidence of general causation, thereby raising the bar for both admissibility and sufficiency determinations and sometimes conflating what should be two different standards. As a result, much evidence of general causation is excluded. *See* Finley, *supra* note 13, at 355–62. She further argues that the standards employed by judges in their gatekeeping roles are normative in nature and profoundly affect substantive legal doctrine in a manner inappropriate to the task at hand. *See id*. at 337–68.

106. Rule 703 of the Federal Rules of Evidence makes clear that an expert may base an opinion on "facts or data . . . perceived by or made known to the expert at or before the hearing" if they are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject," but the facts or data need not have been generated by the expert in the first instance. *See* FED. R. EVID. 703.

107. *See* R. Wade Marionneaux & Voris E. Johnson, Jr., *Differential Diagnosis: The Next* Daubert *Frontier*, Mealey's Litig. Rep.: Asbestos, Apr. 21, 2000, at 30, 31 (describing what usually comprises a differential diagnosis and noting that, in toxic tort cases, expert physicians often rely on this method both to identify the illness and its causes).

108. The technique of differential diagnosis may be defined as "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering." STEDMAN'S MEDICAL DICTIONARY 389 (5th Unabridged Lawyers' ed. 1982). In the context of cancers or other diseases potentially caused by toxic exposures, the role of the physician includes determining which, if any, toxic exposure or combination of exposures may have caused the plaintiff's illness. One court has characterized the technique as follows:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Westberry v. Gislavad Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (quoting Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 807 (3d Cir. 1997)).

109. JENNIFER J. JAMISON, DIFFERENTIAL DIAGNOSIS FOR PRIMARY PRACTICE, at ix, 3 (1999) ("Clinical diagnosis involves collecting information about the presenting patient and comparing this with blueprints of disease.").

the specific symptoms.[110] Thus, treating physicians will explore the patient's signs and symptoms, review the patient's medical history, conduct diagnostic studies, connect the results with known diseases, and develop a working diagnosis.[111] The physician will develop a protocol for managing the case, while monitoring the results and perhaps conducting further, more invasive, medical tests, with the goal of reaching a definitive diagnosis.[112]

Analysis of cause and effect is an integral part of differential diagnosis.[113] Several different analytical thought processes contribute to the ultimate diagnostic decision in an individual case. First, the physician conducts a comparative analysis of the patient's illness in relation to known patterns of disease.[114] Second, the physician applies certain diagnostic criteria to the patient to determine the probability that the diagnosis is one particular illness out of several.[115] The greater the match in diagnostic criteria between the patient and a particular disease, the higher the probability that the patient may in fact be suffering from that disease.[116] Third, the physician undertakes a cause-and-effect analysis to determine if the appearance and progress of the disease in the patient is or has been consistent with generally known physiological and pathological information regarding the disease.[117] Therefore, causation assessment is not only a routine component of differential diagnosis; it pervades the entire physician-patient treatment relationship.

A properly performed differential diagnosis of a patient typically includes, but does not necessarily require, a medical history of the patient, a physical examination, and various diagnostic tests appropriate under the circumstances.[118] As this information is being collected, the physician compiles a list of possible diagnoses, which may be refined and revised along the

110. *Id*. at 14.

111. *Id*. at 3–4.

112. *Id*. at 4.

113. *Id*. (asserting that the unilinear cause-effect relationship is an important underlying idea in diagnostic thinking).

114. *Id*.

115. *Id*. (noting that the likelihood of correct diagnosis is "increased when a number of diagnostic criteria have been met, the diagnostic tests used rarely give false-positive results, and the condition is prevalent").

116. *Id*.

117. *Id*. at 5. "These themes [of pattern recognition, probability reasoning, and causal thinking] are routinely applied in everyday practice. . . . Good clinical practice employs all three themes in diagnostic decision-making." *Id*.

118. *See* Marionneaux & Johnson, *supra* note 107, at 30.

way.[119] Diagnostic tests are a particularly important element in the process. Physicians should give preference to tests that are known to consistently produce accurate results, contain few false-negatives, and have a positive predictive value in the sense that there is a high likelihood that persons who test positive actually have the disease.[120] Authorities recognize, however, that many diagnostic tests that are used frequently in the clinical setting may not meet some of these criteria.[121] Under such circumstances, physicians typically use a combination of several tests to increase the likelihood that they have reached an accurate diagnosis.[122] The process of assuring a correct diagnosis may be complicated by other variables as well, such as the experience of the physician, physician bias, variation in disease presentation among individual patients, and the need to extrapolate from indirect data to the patient's case.[123]

In toxic tort cases, a treating physician may be asked to testify regarding the causation of the plaintiff's illness based upon the methodology of differential diagnosis. Typically, this physician has examined the plaintiff, although other physicians may also have been involved in the plaintiff's care.[124] The physician offers testimony of causation based upon his or her observations of symptoms and the disease progress in the plaintiff in relation to the physician's knowledge, experience, and performance of a differential diagnosis. While the physician may have relied upon epidemiological or toxicological studies, the physician more likely has given any such existing studies a less than probative look due to time and treatment exigencies.[125]

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119. *See* JAMISON, *supra* note 109, at 7. During this process, the physician will rule out certain diseases or conditions ("competing causes") associated with the patient's symptoms on the way to a working diagnosis. *See* 2 DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 27-2.5.2, at 295 (1997).

120. *See* JAMISON, *supra* note 109, at 8. "In order to increase the probability of a correct diagnosis, the procedures undertaken during physical examination and those requested as . . . [diagnostic tests] should be reliable, valid, sensitive, specific, and have an acceptable predictive value." *Id*. at 7.

121. *Id*. at 9.

122. *Id*.

123. *Id*.

124. *See, e.g.*, Moore v. Ashland Chem., Inc., 126 F.3d 679, 694 (5th Cir. 1997), *reh'g en banc*, 151 F.3d 269 (5th Cir. 1998), *cert. denied*, 526 U.S. 1064 (1999) (detailing the steps the expert followed in forming his opinion, including personally performing a physical examination and reviewing the medical records and reports of two other treating physicians).

125. Sometimes, the physician may be capable of treating the patient's illness without a precise determination of causation. A physician treating a person with leukemia would determine the type of leukemia from which the person is suffering and make a decision as to a course of treatment based upon the stage of the illness and the

Such studies are not the primary basis for a differential diagnosis.[126] Sometimes these studies simply do not exist; their absence, however, does not prevent a physician from developing a diagnosis in a particular case.[127]

The evidentiary challenge with regard to this kind of clinical medical testimony is to determine the appropriate standard of reliability. After *Kumho Tire*, there is no question that *Daubert* applies to this kind of experience-based testimony.[128] *Kumho Tire* leaves open a broad spectrum of interpretation on the matter of reliability.[129] Cases in the federal circuits continue to demonstrate that courts are reaching different conclusions on the standard for clinical medical evidence of causation based upon differential diagnosis.

C. The Conflict in the Circuits Over Clinical Medical Testimony of Causation

In *Moore v. Ashland Chemical Inc.*,[130] the Fifth Circuit affirmed a district court's exclusion of clinical medical testimony in a toxic tort case involving workplace exposure to hazardous chemicals.[131] The plaintiff, a truck driver who was a smoker, was exposed to various chemicals while delivering drums of chemicals in the course of his employment.[132] His exposure to the chemicals involved removal of two leaking drums and cleanup of the spilled

person's individual characteristics and history. But if, for example, the patient has been working in an industrial setting in which chemical exposure occurs on a regular basis, part of the treatment program may be assuring that the patient is removed immediately from exposures that may be causally associated with the illness. Thus, while clinical medical personnel have substantial motivation to make accurate determinations of causation, their methods of determining causation in the clinical setting are quite different from the methods of a scientific expert who offers an opinion on the basis of research studies in a particular case.

126. *See* Marionneaux & Johnson, *supra* note 107, at 31 (noting that differential diagnosis "usually consists of a physical examination, a medical history, and a review of clinical tests").

127. Professor Jamison's textbook on differential diagnosis does not discuss the role of epidemiological and toxicological studies in its general discussion of the methodology of differential diagnosis. *See* JAMISON, *supra* note 109, at 3–9.

128. *See* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (holding that "the trial judge's general 'gatekeeping' obligation . . . applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge").

129. *See id.* at 141–42 (concluding that the reliability test is "'flexible'" and that trial courts have considerable discretion in deciding "*how* to determine reliability" and in making the "ultimate reliability determination").

130. 151 F.3d 269 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999).

131. *Id.* at 271.

132. *Id.* at 271–72.

chemicals.[133] Almost immediately thereafter, the plaintiff began experiencing various symptoms, most notably difficulty breathing.[134] He was treated by several physicians, including pulmonary specialists.[135] One pulmonary specialist, Dr. Daniel Jenkins, made the initial diagnosis of reactive airways dysfunction syndrome (RADS).[136] A second specialist, Dr. B. Antonio Alvarez, became the plaintiff's primary treating physician after confirming the RADS diagnosis.[137] The plaintiff disclosed to his physicians that he had smoked approximately one pack of cigarettes per day for twenty years, and that at the time of the accident he had recently returned from sick leave due to pneumonia.[138] In addition, the plaintiff disclosed a childhood history of asthma.[139]

The district court ruled that while Dr. Jenkins could testify as to his course of treatment and general diagnosis of the plaintiff, he could not offer an opinion on causation.[140] The case went to a jury trial, with the plaintiff offering the testimony of Dr. Alvarez and the limited testimony of Dr. Jenkins.[141] The trial resulted in a verdict for the defendant.[142] On appeal, the Fifth Circuit held that the district court erroneously excluded the testimony[143] and reversed the judgment, remanding the case for a new trial.[144] Subsequently, the Fifth Circuit granted a

133. *Id*.

134. *Id*. at 272.

135. *Id*.

136. *Id*. at 273. Dr. Jenkins, whose causation testimony the district court excluded, was a board certified internist with further training and teaching experience in pulmonary disease, allergy, and environmental medicine. *Id*. The defendants did not challenge Dr. Jenkins's qualifications. *Id*. at 273 n.2.

137. *Id*. at 273.

138. *Id*.

139. *Id*.

140. *Id*. The district court was concerned about the level of toluene to which the plaintiff had been exposed and whether a threshold level was necessary for respiratory irritation to occur. *See* Moore v. Ashland Chem., Inc., 126 F.3d 679, 697–98 (5th Cir. 1997), *reh'g en banc*, 151 F.3d 269 (5th Cir. 1998), *cert. denied*, 526 U.S. 1064 (1999). The court seemed confused over Dr. Jenkins's reliance on the manufacturer-generated Material Safety Data Sheet, as well as the nature of the chemical mixture to which the plaintiff had been exposed. *See id*.

141. *Moore*, 126 F.3d at 683. The defendants also offered a causation expert, Dr. Robert Jones, who concluded that the plaintiff was not suffering from RADS, but rather from bronchial asthma. *Moore*, 151 F.3d at 274. Dr. Jones relied upon the plaintiff's medical history (smoking, asthma, and recent pneumonia) to bolster his opinion. *Id*.

142. *Moore*, 151 F.3d at 272.

143. *Moore*, 126 F.3d at 706.

144. *Id*. at 702–03, 709–10. The panel majority reasoned that because Dr. Jenkins's testimony on causation was not based upon "hard science," within the meaning of *Daubert*, the *Daubert* standard did not apply. *Id*. at 702–03. Accordingly, the panel ruled that the district court's use of *Daubert* to exclude Dr. Jenkins's causation testimony was

rehearing en banc, which resulted in affirming the district court's decision.[145]

Dr. Jenkins offered several bases for his causation opinion in his in limine testimony to the court.[146] In general, Dr. Jenkins stated that he relied upon his examination of the plaintiff, the plaintiff's medical history, and the results of numerous medical tests.[147] In interpreting the examination and test results, he also relied upon the Material Safety Data Sheet (MSDS),[148] which contained a warning that the toluene solution, to which the plaintiff had been exposed, was potentially harmful to the lungs and other organs.[149] In addition, he testified that the temporal proximity of the exposure to the onset of symptoms supported his conclusion that exposure to the toluene solution had caused the plaintiff's RADS.[150] Finally, Dr. Jenkins relied on a published study discussing RADS, which included a case study of a RADS patient who had been exposed to toluene.[151]

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erroneous. *Id*. at 702–03.

145. *Moore*, 151 F.3d at 271. Sitting en banc, the Fifth Circuit held that *Daubert* should apply to this type of causation testimony. *Id.* at 274. In the wake of *Kumho Tire*, the application of *Daubert* to the evidence was clearly correct.

146. *Moore*, 126 F.3d at 694.

147. *Id*. at 694–95. These tests included various mechanical pulmonary function tests, an arterial blood gas test, X-rays, and other laboratory tests. *Id*. at 694. Furthermore, Dr. Jenkins reviewed the reports of two other physicians who had examined and treated the plaintiff, including information that allegedly ruled out allergic or immunologic disease as a diagnosis. *Id*. Additionally, Dr. Jenkins consulted the MSDS, a medical treatise, and other medical literature. *Id*.

148. *Moore*, 151 F.3d at 278. The Occupational Safety and Health Administration (OSHA) Hazard Communication Standard imposes certain duties upon chemical manufacturers and importers, and on employers using those chemicals in the workplace. 29 C.F.R. § 1910.1200 (1999). Among other duties, the Hazard Communication Standard provides: "Chemical manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous chemical they produce or import." *Id*. § 1910.1200(g)(1). The MSDS must contain, among other things, all health hazards and physical hazards of the chemical, along with routes of entry, signs and symptoms of exposure, and medical conditions known to be caused by exposure. *Id*. § 1910.1200(g)(2)(C)(3). The manufacturer or importer of the chemical must send the MSDS with the shipment of the chemical, or provide the MSDS directly to the employer who is purchasing the chemical. *Id*. § 1910.1200(g)(6). The employer has an obligation to maintain copies of the MSDS and make the MSDS accessible to its employees in the workplace. *Id*. § 1910.1200(g)(8).

149. *Moore*, 151 F.3d at 277.

150. *Id*.

151. *Id*. at 273 (citing Stuart M. Brooks, M.D. et al., *Reactive Airways Dysfunction Syndrome (RADS)*, 88 CHEST 376, 379 (1985)). Some conflict existed between Dr. Jenkins's deposition testimony and his in limine testimony regarding this study. *Id.* at 273 & n.3. According to the Fifth Circuit, Dr. Jenkins initially stated at his deposition that he had been unaware of any published literature supporting his opinion that toluene had caused the plaintiff's RADS. *Id*. at 273. The Brooks article had been used by Dr. Alvarez, however, in reaching his conclusion on causation. *Id*. At the in limine hearing, Dr. Jenkins cited to the Brooks article, stating his reliance upon it for his conclusion. *Id.*

The Fifth Circuit held that the district court had been within its discretion in excluding the causation testimony of Dr. Jenkins.[152] In essence, the court held that the technique of differential diagnosis, absent reliance upon more traditional *Daubert* types of scientific evidence, is not sufficiently reliable to form the basis of causation testimony by a treating physician. The court's analysis of Dr. Jenkins's proffered testimony, and the efforts it made to distinguish the testimony of Dr. Alvarez, make the rejection of differential diagnosis eminently clear.

In forming his causation opinion at the time he was treating the plaintiff, Dr. Jenkins employed the standard procedures of differential diagnosis. The Fifth Circuit initially was troubled by the fact that Dr. Jenkins apparently had not presented the district court with reasons why his experience and training had assisted him in reaching his causation conclusion.[153] In particular, the court was disturbed by the fact that Dr. Jenkins had not previously treated any patient exposed to a toluene solution.[154] As a result, the court hastily concluded that Dr. Jenkins's causation testimony was "unscientific speculation offered by a genuine scientist,"[155] rather than a genuinely scientific opinion. Indeed, the en banc court did not seek to determine much of anything about Dr. Jenkins's diagnostic procedure vis-à-vis this patient or his standard diagnostic procedures vis-à-vis his patients in general.[156] Rather, the court

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at 277. Furthermore, at trial, Dr. Jenkins stated that he knew of the article and had relied on it. *Id*. The Fifth Circuit's repeated references to the disparity about the point at which Dr. Jenkins became aware of the Brooks article demonstrated a clear distrust of the assertion that the study was a basis of Dr. Jenkins's testimony. It is not altogether clear why this bothered the court so much. Dr. Jenkins clearly treated the plaintiff as a RADS patient, a course of treatment that did not depend on his awareness of the Brooks article. Dr. Alvarez was permitted to testify at trial as to his own reliance upon the Brooks article. *Id*. at 273. It may seem curious that the court would hinge so much of the outcome of the admissibility question on whether Dr. Jenkins had relied on the Brooks article in the course of conducting his differential diagnosis were it not for the fact that the court discredited the Brooks study on its own merits. The court's pre-occupation with this issue is consistent with its insistence that hard science form the basis of clinical medical testimony of causation.

152. *Id*. at 271.

153. *See id*. at 277–78.

154. *Id*. at 278.

155. *Id*. (quoting Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318 (7th Cir. 1996)) (internal quotation marks omitted).

156. This approach was in stark contrast to the analysis of the Fifth Circuit panel, which had examined in detail both Dr. Jenkins's bases for his causation opinion and the district court's rulings on admissibility. *See* Moore v. Ashland Chem., Inc., 126 F.3d 679, 694–701 (5th Cir. 1997), *reh'g en banc*, 151 F.3d 269 (5th Cir. 1998), *cert. denied*, 526 U.S. 1064 (1999).

concluded that the district court had not abused its discretion in excluding the causation testimony on this basis.[157]

The court dispensed just as hastily with the other bases of Dr. Jenkins's causation opinion. The MSDS, the court stated, was of "limited value" to Dr. Jenkins.[158] While the MSDS warned of injury to the lung associated with exposure to fumes from the toluene solution, it did not inform readers of the specific level of exposure necessary to trigger injury.[159] Rather, it suggested that the concentration of the solution and the length of time of exposure would dictate the effects.[160] Moreover, Dr. Jenkins admitted that he had no knowledge of the specific tests performed by the manufacturer in acquiring the information regarding the solution's hazards.[161] The court did not identify the "limited value" of the MSDS. But the court's perfunctory dismissal of this basis of Dr. Jenkins's testimony made clear that the court viewed it as useless without the introduction of the studies on which it was based.[162] In essence, the court demanded that Dr. Jenkins's causation testimony be supported by the kind of hard scientific studies that he was not required to use in the course of his treatment of the plaintiff.

A further issue was the temporal proximity between the plaintiff's exposure to the toluene solution and the onset of his symptoms. The court stated that "[i]n the 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."[163] Again, the court effectively demanded that the expert provide scientific studies to support a conclusion that Dr. Jenkins would normally reach on the basis of his professional medical judgment.

The court also rejected wholesale any validity for Dr. Jenkins's causation testimony because of the absence of information regarding the plaintiff's level of exposure to the solution.[164] In a dramatic statement relegated to a footnote, the

157. *Moore*, 151 F.3d at 279 (holding that the "'analytical gap' between Dr. Jenkins's causation opinion and the scientific knowledge and available data advanced to support that opinion was too wide").

158. *Id*. at 278.

159. *Id*.

160. *Id*.

161. *Id*.

162. The court further emphasized that Dr. Jenkins had offered no scientific basis—no scientific basis that the court would recognize as valid—for a determination that exposure to the toluene solution at any level could cause RADS. *Id*.

163. *Id*.

164. *See id*. at 278–79.

court said: "Given the paucity of facts Dr. Jenkins had available about the level of [the plaintiff's] exposure to the Toluene solution, his causation opinion would have been suspect even if he had scientific support . . . ."[165] But for its status as a footnote, this statement would appear to border on a de novo review of the admissibility of the expert's opinion, a matter clearly not within the scope of the court's review, pursuant to *Joiner*.[166] At the least, the court seemed to validate an improper weighing of substantive evidence by the district court. This conclusion is bolstered by the court's statement that "[t]he district court was also entitled to conclude that [the plaintiff's] personal habits and medical history made Dr. Jenkins's theory even more unreliable."[167]

The court also summarily dismissed Dr. Jenkins's reliance on an article in the medical literature. The court noted that the authors of the article admitted that their conclusion had an element of speculation.[168] In addition, the court discounted any use for the article in this case because the one study cited in the article that involved exposure to a toluene solution involved a level of exposure much higher than that of the plaintiff.[169] Thus, the court focused on the reliability and relevancy of the underlying studies, rather than on Dr. Jenkins's diagnostic process.

Finally, the court assaulted what it referred to as Dr. Jenkins's "fallback position," which was the theory that RADS could be triggered by any irritant being introduced into the lungs, when the patient is particularly susceptible to the condition.[170] Here, the court explicitly enumerated the *Daubert* factors and applied them rigidly to this theory, finding it faulty.[171] Once again, the court rejected the methodology of differential diagnosis with a requirement that the treating physician demonstrate hard scientific support for his opinion.

The Fifth Circuit's decision in *Moore* was rendered prior to the United States Supreme Court's decision in *Kumho Tire*.[172] Nevertheless, the *Moore* court's rigid adherence to the *Daubert*

165. *Id*. at 278 n.10.

166. *See* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141 (1997) ("[A]buse of discretion is the proper standard of review of a district court's evidentiary rulings.").

167. *Moore*, 151 F.3d at 279.

168. *Id*. at 278.

169. *Id*.

170. *Id*. at 279.

171. *Id*.

172. *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, was decided by the Fifth Circuit on August 14, 1998. The United States Supreme Court decided *Kumho Tire v. Carmichael*, 526 U.S. 137 (1999), on March 23, 1999.

factors probably would not have changed had it been decided post-*Kumho Tire*. Indeed, since the Court decided *Kumho Tire*, the Fifth Circuit has endorsed its previous approach in *Moore*. In *Black v. Food Lion, Inc.*,[173] a slip-and-fall case involving the question whether trauma can cause the chronic condition fibromyalgia,[174] the Fifth Circuit emphasized the Supreme Court's comments in *Kumho Tire* that while not all of the *Daubert* factors may apply in a particular case, they are relevant to the reliability of all expert testimony, including testimony based upon experience.[175] Accordingly, the court stated that "[i]n the vast majority of cases, the district court first should decide whether the factors mentioned in *Daubert* are appropriate. Once it considers the *Daubert* factors, the court then can consider whether other factors, not mentioned in *Daubert*, are relevant to the case at hand."[176] Thus, the court advocated a primary reliance on the *Daubert* factors and held that the magistrate judge's ruling to admit the treating physician's testimony constituted an abuse of discretion.[177]

The physician whose testimony was the subject of the *Black* opinion was a specialist in treating patients with persistent pain.[178] The plaintiff had been referred to her for evaluation approximately eight months after the accident.[179] She was prepared to testify that the physical trauma caused by the accident had led to hormonal changes and, subsequently, the plaintiff's development of fibromyalgia.[180] She based her conclusion on the plaintiff's complete medical history, medical tests performed during her treatment of the plaintiff as well as those performed prior to the time of the referral, and the elimination of other possible causes.[181] In holding that the magistrate judge should not have admitted the physician's testimony, the Fifth Circuit again applied the *Daubert* factors quite strictly. In particular, the court noted that the physician's theory had not been tested and, accordingly, had not undergone peer review, and that it thus had no known rate of error.[182] In

173. 171 F.3d 308 (5th Cir. 1999).

174. *Id*. at 309. The court described fibromyalgia as "characterized by complaints of generalized pain, poor sleep, an inability to concentrate, and chronic fatigue." *Id*.

175. *Id*. at 311.

176. *Id*. at 311–12.

177. *Id*. at 312.

178. *Id*. at 309.

179. *Id*.

180. *Id*.

181. *Id*. at 310.

182. *Id*. at 313. The court emphasized that the etiology of fibromyalgia is unknown, noting that the *Journal of Rheumatology* had stated that no epidemiological studies

addition, the court emphasized that the physician's theory of fibromyalgia causation was not generally accepted.[183]

Apparently, the physician had followed a diagnostic protocol, approved by specialists in the field, in making her determination that the plaintiff's fibromyalgia was related to the trauma.[184] The Fifth Circuit held that the protocol was illusory, given the absence of studies on which to base causation.[185] The sum and substance of this rather circular argument was that the court expected the physician to proffer reliable scientific studies of the sort underlying the *Daubert* opinion to legitimize her procedure of differential diagnosis. The court stated:

> No one doubts the utility of medical histories in general or the process by which doctors rule out some known causes of disease in order to finalize a diagnosis. . . . The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur. Based on such predicate knowledge, it may then be possible to fasten legal liability for a person's disease or injury.[186]

The court later stated: "Absent these critical scientific predicates, . . . no scientifically reliable conclusion on causation can be drawn."[187] Thus, even after *Kumho Tire*, the Fifth Circuit clearly has taken the position that clinical medical expert testimony regarding causation would not be admissible unless it

existed on any connection between trauma and fibromyalgia. *Id*. Thus, the court concluded that the physician's theory of traumatic causation was "isolated and unsubstantiated" and that the court below had erred in admitting the testimony. *Id*. at 313–14. The court provided further support for its conclusion by noting that the physician herself had acknowledged the lack of support for her opinion and had characterized trauma as a *contributing event*, but not a *cause* of the fibromyalgia. *Id*. at 313. Ironically, the plaintiff attempted to introduce recent studies allegedly establishing a causal relationship between trauma and fibromyalgia, but the magistrate judge ruled those studies inadmissible because they had not been made available to counsel for the defendant during the discovery process. *Id*. at 313 n.3.

183. *Id*. at 313. The court focused upon the physician's theory (or conclusion) and not her methodology. The court posited that because the etiology of fibromyalgia is unknown, any opinion on causation would be "[m]ere conjecture." *Id*.

184. *Id*. at 310.

185. *Id*. at 313–14.

186. *Id*. at 314. The court further noted that the need for underlying scientific studies goes directly to the requirement that the expert have "sufficient specialized knowledge to assist the jurors in deciding the particular issues." *Id*. at 314 n.5 (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 156 (1999)); *accord* Allison v. McGhan Med. Corp., 184 F.3d 1300, 1321 (11th Cir. 1999) (requiring underlying studies that meet the factors in *Daubert*); Porter v. Whitehall Labs., Inc., 9 F.3d 607, 614 (7th Cir. 1993) (stating that "[i]f experts cannot tie their assessment of data to known scientific conclusions, based on research or studies," then evidence should be excluded).

187. *Black*, 171 F.3d at 314.

is based upon hard scientific studies that pass the *Daubert* two-pronged test of reliability and relevancy using, as closely as possible, the specific general observations set forth in the *Daubert* opinion.

In contrast, other courts have applied a different test to clinical medical testimony. In *Westberry v. Gislaved Gummi AB*,[188] the Fourth Circuit, in a post-*Kumho Tire* decision, reached a different result regarding medical testimony that was unsupported by scientific studies. *Westberry* involved a worker who claimed serious sinus problems as the result of exposure to high concentrations of airborne talc used as a lubricant on rubber gaskets.[189] The district court, prior to the Supreme Court's decision in *Kumho Tire*, had admitted the causation testimony of the plaintiff's treating physician, Dr. Isenhower, and the jury had returned a verdict in favor of the plaintiff.[190]

It was undisputed that Dr. Isenhower had no scientific studies—of an epidemiological, animal, or other laboratory nature—to support his conclusion that the talc exposure had caused the plaintiff's sinus condition.[191] Nor did any peer-reviewed or published studies exist to support his conclusion.[192] In addition, none of the clinical tests performed on the plaintiff had yielded any firm proof of causation.[193] The sole basis for Dr. Isenhower's causation opinion was his differential diagnosis, bolstered by the close temporal relationship between the plaintiff's exposure to the talc and the onset of his serious sinus symptoms.[194]

The defendant argued that neither differential diagnosis nor a close temporal relationship was sufficient to form the basis of expert causation testimony.[195] The Fourth Circuit rejected the defendant's position, concluding that a properly conducted

188. 178 F.3d 257 (4th Cir. 1999).

189. *Id*. at 259–60.

190. *Id*. at 260. The appellate court agreed with the defendant that the district court had erred in not applying the *Daubert* test to the proffered testimony on the mistaken belief that *Daubert* applied only to novel scientific evidence. *Id.* at 262. Nevertheless, the court stated that "because we can affirm the evidentiary ruling of the district court on a ground different from that employed below, we consider whether Dr. Isenhower's testimony was sufficiently reliable and relevant to warrant admission." *Id*.

191. *Id*. at 262.

192. *Id*. Apparently no studies existed demonstrating that talc, at any level, could cause sinus problems. *See id.* at 262, 264. Nevertheless, "it was undisputed that inhalation of high levels of talc irritates mucous membranes." *Id.* at 264.

193. *See id*. at 262. The court noted that Dr. Isenhower was unable to produce any tissue samples confirming the presence of any level of talc in the plaintiff's sinuses. *Id*.

194. *Id*.

195. *Id*.

differential diagnosis is a reliable basis for such testimony.[196] The court noted that differential diagnosis is acknowledged in the medical community as yielding accurate diagnostic results in most cases.[197] Accordingly, the court held that differential diagnosis satisfied the reliability test of *Daubert*.[198]

The defendant further argued that even if differential diagnosis were deemed to be scientifically reliable, the diagnostic procedures followed by Dr. Isenhower did not meet the required level of reliability.[199] In particular, the defendant argued that merely being able to rule out other potential causes was insufficient; the physician must be able to, in essence, "rule in" talc as a possible cause.[200] The defendant argued that to "rule in" talc as a cause, the physician needed to demonstrate a level of exposure to talc in the plaintiff that could cause illness and support that determination with scientific studies demonstrating a relationship between that level of exposure and the illness present in the plaintiff.[201] The Fourth Circuit rejected this argument, noting that the Federal Judicial Center's *Reference Manual on Scientific Evidence*[202]—which was produced specifically to guide judges in making admissibility decisions on scientific and technical evidence—emphasizes that experts will only rarely be able to determine the precise level of exposure to a substance.[203] The court suggested, however, that a toxic tort

196. *Id*. at 262–63.

197. *Id*. at 262; *accord* Brown v. S.E. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 758 (3d Cir. 1994) (stating that "differential diagnosis generally is a technique that has widespread acceptance in the medical community"); Glaser v. Thompson Med. Co., 32 F.3d 969, 978 (6th Cir. 1994) (commenting that differential diagnosis is "a standard diagnostic tool used by medical professionals to diagnose the most likely cause or causes of illness, injury and disease").

198. *Westberry*, 178 F.3d at 263; *accord* Heller v. Shaw Indus., Inc., 167 F.3d 146, 154–57 (3d Cir. 1999); Kennedy v. Collagen Corp., 161 F.3d 1226, 1228–30 (9th Cir. 1998); Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248, 252–53 (1st Cir. 1998); Zuchowicz v. United States, 140 F.3d 381, 385–90 (2d Cir. 1998); Ambrosini v. Labarraque, 101 F.3d 129, 140–41 (D.C. Cir. 1996); Huffman v. SmithKline Beecham Clinical Labs., Inc., 111 F. Supp. 2d 921, 930 (N.D. Ohio 2000).

199. *Westberry*, 178 F.3d at 263.

200. *Id*.

201. *Id*.; *see also* Allen v. Pa. Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996) ("Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiff's burden in a toxic tort case.").

202. *See* FED. JUDICIAL CTR., *supra* note 12.

203. *Westberry*, 178 F.3d at 264. The court quoted from the Manual, recognizing that

> "[o]nly rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes . . . . Human exposure occurs most frequently in occupational settings where workers are exposed to industrial chemicals like lead or asbestos; however, even under these circumstances, it is usually difficult, if not impossible, to quantify the amount of exposure."

plaintiff must at least be able to demonstrate some substantial exposure to the substance.[204] In *Westberry*, although the physician could not point to a specific level of exposure in the plaintiff, evidence existed to demonstrate substantial exposure.[205]

Id. (alteration in original) (quoting FED. JUDICIAL CTR., *supra* note 12, at 187).

204. *See id*. The court stated: "Thus, this clearly is not a case in which the plaintiff was unable to establish any substantial exposure to the allegedly defective product." *Id*. The court contrasted two other cases, *Wintz v. Northrop Corp*., 110 F.3d 508 (7th Cir. 1997), and *Allen v. Pennsylvania Engineering Corp*., 102 F.3d 194 (5th Cir. 1996), in which sufficient proof of exposure was lacking. *Id*. at 264–65. In *Wintz*, the plaintiff's mother had been exposed to bromide on a daily basis in her workplace while she was pregnant with the minor plaintiff. 110 F.3d at 510. The child was born with a series of abnormalities, and the hospital neonatologist conducted various medical tests, most of which were inconclusive. *Id*. After learning of the mother's workplace exposure, he conducted a bromide test on the child, which indicated elevated bromide levels. *Id*. at 511. Because the plaintiff's condition improved somewhat, she was released from the hospital. *Id*. Several years later, a reproductive geneticist diagnosed the plaintiff's condition as Prader-Willi Syndrome, a genetic disorder that cannot be caused by environmental exposure. *Id*. The plaintiffs then consulted a toxicologist, who concluded that the plaintiff suffered from the effects of bromide exposure. *Id*. His opinion was formulated from reviewing articles on bromide and sending samples of chemicals from the mother's workplace to an independent lab for testing. *Id*. at 513. He did not examine the plaintiff, review her medical records, conduct any testing on the plaintiff, or seek information regarding the mother's workplace other than the chemical samples. *Id*. The Seventh Circuit held that the toxicologist's testimony of causation had been correctly excluded by the district court because his methodology was unreliable and his qualifications questionable. *Id*. at 514. The court then ruled that the district court had correctly granted summary judgment to the defendants on the basis that the testimony of the neonatologist was insufficient to create a triable issue of fact on causation. *Id*. at 516. The neonatologist had been unable to offer the opinion that bromide had caused the plaintiff's problems. *Id*. at 515. Although he had not ruled out this possibility while she was in his care, he never reached a conclusion regarding causation before she was discharged. *Id*. at 514–15. *Wintz* is clearly distinguishable from *Westberry*. In *Wintz*, the neonatologist had not reached the point of developing a diagnosis for the plaintiff's condition. When her condition improved, she was released from the hospital and from his care. The toxicologist, on the other hand, was not a treating physician for the plaintiff, but rather an expert consulted apart from the medical experts in the case. He had no reason to perform a differential diagnosis on the plaintiff. Thus, his testimony could be judged directly by the *Daubert* factors.

In *Allen*, the plaintiff was a hospital maintenance worker who was occasionally responsible for replacing cylinders of the chemical ethylene oxide. 102 F.3d at 195. The court rejected the evidence because, inter alia, there was a lack of direct evidence regarding the level of the plaintiff's exposure to ethylene oxide. *Id*. at 198–99. The court held that the affidavit of a coworker and extrapolations regarding the plaintiff's workplace based upon information regarding other hospitals during the same time period were insufficient evidence of exposure. *Id*. Perhaps more interesting were some of the other points made by the court in holding the causation evidence inadmissible. For example, the court noted that the experts had more specific knowledge regarding the plaintiff's exposure to ethylene oxide by his smoking a pack of cigarettes a day than they had about his workplace. *Id*. at 198. As a result, the experts were not able to effectively rule out the role of tobacco in the plaintiff's brain cancer. *Id*. at 198–99. This analysis veered in the direction of weighing the evidence, rather than ruling on the reliability of the experts' methodology. For a discussion of the disagreement among the circuits on the necessity of demonstrating levels of exposure, refer to Part IV.C.3 *infra*.

205. *Westberry*, 178 F.3d at 264. Most of this evidence consisted of the plaintiff's own testimony regarding his job duties and observations of talc so thick on the floor that

Furthermore, the court allowed Dr. Isenhower to rely upon the MSDS for talc.[206] Although the MSDS did not provide any information regarding specific exposure levels, it did provide support for general causation. This MSDS stated that "inhalation of dust in high concentrations irritates mucous membranes."[207] It did not, however, directly address the kinds of sinus consequences experienced by the plaintiff.[208] Nevertheless, the court accepted the MSDS as a sufficient basis for a causal connection between the plaintiff's exposure to talc and his sinus condition.[209] The Fourth Circuit's amenability to the use of the MSDS in this case contrasts sharply with the hostility of the Fifth Circuit to use of the MSDS in *Moore*.[210]

The *Westberry* court addressed two final issues. The first was the utility of evidence of the temporal proximity of the exposure to the onset of symptoms.[211] The court allotted few words to rejecting the defendant's argument that evidence of temporal proximity should be disregarded, stating that such evidence "can provide compelling evidence of causation."[212] Second, the court addressed the defendant's argument that the plaintiff's experts failed to rule out other potential causes—in particular, a cold and water skiing—for his sinus condition.[213] The court stated that "'[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness.'"[214] Rather, the court said that evidence of alternative causes is a matter to be considered by the jury in weighing the evidence.[215]

The *Westberry* court found persuasive an earlier decision of the Third Circuit which reached a similar conclusion regarding clinical medical testimony just prior to the United States Supreme Court's decision in *Kumho Tire*. In *Heller v. Shaw*

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footprints could be seen in it. *Id*.

206. *Id*.

207. *Id*.

208. *Id*.

209. *See id*.

210. Refer to notes 153–57 *supra* and accompanying text (discussing the Fifth Circuit's rejection of an expert's causation testimony based solely on differential diagnosis).

211. *See Westberry*, 178 F.3d at 265.

212. *Id*. Similarly, the Third Circuit considered this issue and stated: "The temporal relationship will often be (only) one factor, and how much weight it provides for the overall determination of whether an expert has 'good grounds' for his or her conclusion will differ depending on the strength of that relationship." Heller v. Shaw Indus., Inc., 167 F.3d 146, 154 (3d Cir. 1999).

213. *Westberry*, 178 F.3d at 265–66.

214. *Id*. at 265 (quoting *Heller*, 167 F.3d at 156).

215. *Id*.

Industries, Inc.,[216] the plaintiff sued a carpet manufacturer, claiming she had experienced a severe allergic reaction to volatile organic compounds (VOCs) emitted into the air of her home by newly installed carpeting manufactured by the defendant.[217] The plaintiff's treating physician, who was board certified in internal medicine and allergy-immunology, proffered the opinion that the rugs installed in the plaintiff's home were the cause of her respiratory problems.[218] His opinion was based solely upon differential diagnosis and the temporal relationship between the alleged exposure and the onset of the plaintiff's symptoms.[219] His diagnosis was founded on more than thirty years of experience as a physician seeing patients with allergy-related medical problems and his personal knowledge regarding the causes of environmental allergies.[220] But it was not founded upon scientific studies.

The court held that the technique of differential diagnosis is a reliable basis for expert testimony of causation by a treating physician.[221] In *Heller*, the physician had conducted a proper differential diagnostic analysis.[222] As part of that analysis, he was not required to rule out *all* possible alternative causes for the plaintiff's illness.[223] The fact that the physician used differential diagnosis to support a novel scientific theory was irrelevant to the admissibility inquiry. In general, the court stated that Rule 702 did not require scientific studies to support causation testimony.[224] Put in the language of *Daubert*, the court stated that the technique of "differential diagnosis 'consists of a testable hypothesis,' has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used outside of the judicial context."[225] In other words, even if a court chooses to apply the *Daubert* factors strictly, a differential diagnosis, properly conducted, should satisfy the requirements of

216. 167 F.3d 146 (3d Cir. 1999).

217. *Id*. at 150–51.

218. *Id*. at 153.

219. *Id.* at 153–54.

220. *Id*. at 154.

221. *Id*.

222. *Id.* at 156–57.

223. *Id*. at 156. The court also stated that the defendant was free to offer evidence of other potential causes of the plaintiff's illness. *Id.* In that event, the plaintiff's expert would need to offer some explanation as to why he or she concluded that the alleged cause was the sole cause of the injury.

224. *Id*. at 154.

225. *Id*. at 154–55 (paraphrasing Brown v. S.E. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 742 n.8 (3d Cir. 1994)).

those factors even in the absence of published scientific studies.[226]

The *Heller* court held that requiring a treating physician's causation testimony to be supported by scientific studies would effectively exclude all novel and emerging scientific evidence and would signal the re-emergence of the *Frye* general acceptance

226. *See* Kennedy v. Collagen Corp., 161 F.3d 1226, 1229–30 (9th Cir. 1998) (holding that the requirements set out in *Daubert* are satisfied when an expert's differential diagnosis is based on objective, verifiable evidence and scientific methodology traditionally used by other doctors in the field). *But see* Moore v. Ashland Chem. Inc., 151 F.3d 269, 278–79 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999) (holding that it is within the trial court's discretion to conclude differential diagnosis is not sufficiently reliable for a jury to consider when it is not supported by scientific studies); Cavallo v. Star Enter., 100 F.3d 1150, 1159 (4th Cir. 1996) (commenting that when the available scientific studies do not support the expert's conclusions, the differential diagnosis will be considered inadmissible hypothesis and speculation). The *Cavallo* plaintiffs alleged injuries from exposure to petroleum fuel vapors released from a distribution point owned by the defendant. *See* Cavallo v. Star Enter., 892 F. Supp. 756, 758–59 (E.D. Va. 1995), *aff'd in part and rev'd in part*, 100 F.3d 1150 (4th Cir. 1996). Mrs. Cavallo experienced an immediate reaction and was soon after diagnosed as having sinusitis, conjunctivitis, and pulmonary dysfunction. *Id.* at 759. Two of her many physicians, an immunologist who became her treating physician three years after the exposure incident and a toxicologist, opined that her exposure to the vapors caused her ailments. *Id*. They also stated that as a result of her exposure and subsequent reaction to the fumes, she had become hyper-sensitive to various organic compounds, some of which could be found in ordinary household solutions. *Id*. The physicians had no published scientific studies to support their theory, however. *Id*. The appellate court, employing an abuse of discretion standard, affirmed the district court's exclusion of the expert testimony on the ground that the causation opinion was based on "hypothesis and speculation" in the absence of support from scientific studies. *Cavallo*, 100 F.3d at 1159 (quoting district court Memorandum Opinion at 39–40). The district court had rejected the toxicologist's testimony because he had not followed an established toxicological methodology and because the scientific basis for his opinion was not clear. *Cavallo*, 892 F. Supp. at 766. The immunologist had employed the methodology of differential diagnosis in reaching his opinion. *Id.* at 771. The district court determined that, while he had ruled out causes other than the petroleum fume exposure (for example, smoking), he had failed to "rule in" the petroleum fumes by using scientifically reliable evidence of general causation. *Id*. The immunologist did not initially support his opinion with scientific studies, but later cited studies of RADS. *Id*. at 772 & n.39. He was only willing to say that the plaintiff "may" have had RADS, and expressed doubt about the validity of extrapolating from RADS studies to the plaintiff's case. *Id*. at 773. Ultimately, the district court rejected the immunologist's testimony because he failed to follow the accepted *toxicology* methodology and formed his opinion merely on "his subjective, unverified belief." *Id*. Interestingly, the district court went on to say that experts need not always rely on studies to form the basis of their opinions, but that studies were necessary in this case. *Id.* at 773–74. Immediate, acute reactions to exposures may not require studies. *Id.* But the court failed to make clear where the line should be drawn between the kind of acute reaction suffered by the plaintiff and an acute reaction that would not warrant a demonstrated basis in scientific studies. *Cavallo* may reflect the pre-*Kumho Tire* propensity of some courts to view the *Daubert* general observations as the *only* factors to be considered with regard to the reliability of expert evidence. In any event, the result in *Cavallo* seems to have come from some very idiosyncratic reactions to the proffered testimony that are less than clear in the published opinions.

standard as the primary basis for admissibility.[227] This was a result that the *Daubert* Court clearly did not intend.[228]

The Third Circuit ultimately held that the district court had not abused its discretion in excluding the testimony of the plaintiff's physicians.[229] This ruling hinged on the temporal relationship between the exposure and the onset of symptoms. The court determined that the physician's interpretation of the temporal relationship was flawed.[230] He testified that a person exposed to VOCs in the home typically would manifest reactive symptoms within twenty-four hours of the exposure.[231] Mrs. Heller, however, did not suffer a reaction until one to two weeks after exposure, and her acute symptoms persisted after the carpet was removed from the home.[232] Her husband, on the other hand, had begun to suffer allergic symptoms prior to installation of the carpet.[233] The court concluded that the physician had no reasonable explanation for these variations from the standard pattern of allergic onset.[234] As a result, the entire diagnostic

227. *Heller*, 167 F.3d at 155.

228. *Cf.* Goeb v. Tharaldson, 615 N.W.2d 800, 803 (Minn. 2000). In *Goeb*, the Supreme Court of Minnesota refused to adopt the *Daubert* doctrine of admissibility of expert testimony, preferring to retain the *Frye* general acceptance test. *Id.* The case involved pesticide exposure, and one of the plaintiff's experts was her treating physician, an internist and acknowledged expert in pesticide toxicology. *Id.* at 805–06. The court ultimately affirmed the lower court's exclusion of this expert's testimony on the ground that this physician had not appropriately followed the methodology of differential diagnosis. *Id.* at 815–16. In particular, she had not reviewed all of the plaintiff's medical records, relying mostly on her interview with the plaintiff, and had ignored test results that were within the normal range. *Id.* at 815. In refusing to adopt *Daubert*, the court acknowledged that *Daubert* may provide greater flexibility to trial courts in the face of evolving scientific knowledge, but complained that "this practice will also lead to greater variation in decisions at the district court level that may not be correctable at the appellate level under an abuse of discretion standard of review." *Id.* at 814. Thus, the court preferred the *Frye* general acceptance test for its uniformity and predictability. *Id.*; *cf.* Paul S. Miller & Bert W. Rein, *Whither* Daubert*? Reliable Resolution of Scientifically-Based Causality Issues in Toxic Tort Cases*, 50 RUTGERS L. REV. 563, 567–68 (1998) (recommending a shift to courts, rather than juries, to decide scientific causation fact issues).

229. *Heller*, 167 F.3d at 159, 165.

230. *Id.* at 157–58.

231. *Id.* at 157.

232. *Id.* The plaintiffs attempted to justify the continued reactivity with a theory that the VOCs "sink" into objects when they are initially released, and may be re-emitted into the air at a later point in time. *Id.* at 157–58. The court rejected this theory outright, noting, among other things, that on the day the plaintiff returned to her home she suffered a renewal of her symptoms, even though tests showed virtually no VOCs in the air. *Id.* at 158.

233. *Id.* at 157.

234. *Id.* at 157–58 ("Here, however, we have no problem concluding that the temporal relationship between the exposure to the Shaw carpeting and the onset of Heller's illness was questionable at best and exculpatory at worst.").

approach was deemed to be unreliable because it was based upon erroneous assumptions regarding the temporal relationship.[235]

The polarized positions demonstrated by the previously discussed cases indicate a need for clarification on the issue of the admissibility of clinical medical evidence of causation. It is a particularly timely moment to address this issue, in the wake of *Kumho Tire*, as courts are struggling with ways to handle their gatekeeping role on a broad spectrum of expert testimony, much of which is experience based. Logic and good common sense should dictate the appropriate approach to clinical evidence of causation because an overly strict adherence to the specific factors cited by the Supreme Court in *Daubert* will artificially constrict the amount and kind of evidence admitted in toxic tort cases.

IV. A REASONABLENESS APPROACH TO CLINICAL MEDICAL EVIDENCE OF CAUSATION

A. Seeking a Balance Between Extremes

To a great extent, attention to scientific evidence in the 1990s was driven by the vocal objections of a segment of the legal community who claimed that vast amounts of unreliable, so-called scientific evidence was being admitted in personal injury trials.[236] Characterizing this evidence as "junk science," these critics painted with a broad, unscientific brush:[237] they declared

235. *Id.* at 159. The court also analyzed the proffered testimony of the plaintiffs' other expert, an industrial hygienist and environmental consultant. *Id*. The court expressed an immediate aversion to allowing a nonmedical expert to testify on medical causation. *Id*. The court did not reach that issue, however, because it ruled that the expert's testimony was unreliable because his conclusions, based upon extrapolation of VOC levels obtained from a closet in the plaintiffs' home, were not supported by his methodology. *Id*. at 160. Accordingly, the court held that the district court had not abused its discretion in excluding the testimony. *Id.* at 165.

236. Coining the phrase "junk science," these critics have been most vocal in their objection to novel scientific theories. *See* PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 2–4 (1991). These views gained a considerable following in pro-industry quarters, and some legal scholars have followed suit. *See* Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 192–93 (1993) (stating that by allowing "junk science" into the courtroom, the potential costs to society are "significant, potentially even catastrophic"); Lee Loevinger, *Science and Legal Rules of Evidence: A Review of* Galileo's Revenge: Junk Science in the Courtroom, 32 JURIMETRICS J. 487, 502 (1992) (book review) (lobbying for a return to the restrictive *Frye* standard and arguing that neither judges nor juries are sophisticated enough to comprehend specialized scientific research).

237. Indeed, Huber has been criticized as having conducted his own research in a manner that would not meet the standards he seeks to impose on others. *See* Kenneth J. Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AM. U. L. REV. 1637, 1643–50 (1993) (commenting that Huber's criticism of purported errors in scholarship by others

any theories not receiving general acceptance in the relevant scientific discipline to be scientifically invalid and unreliable. Thus, novel scientific theories had no place in their universe. In *Daubert*, the Supreme Court both agreed and disagreed with this interest group. The Court agreed that strict scrutiny of scientific evidence by the trial court is appropriate in determining whether scientific evidence should be admitted at trial.[238] But the Court rejected both the general acceptance test and the sweeping characterizations of categories of evidence.[239] Indeed, in its endorsement of the traditional trial procedures for challenging

is hypocritical because Huber repeatedly violates his own standards).

238. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 (1993) (holding that all admitted evidence must ultimately be reliable).

239. *See id.* at 597. "'General acceptance' is not a necessary precondition to the admissibility of scientific evidence under the Federal Rules of Evidence . . . . *Id.* In his separate opinion in *Joiner*, concurring in part and dissenting in part, Justice Stevens reflected upon the Court's position in relation to so-called "junk science." *See* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 152–55 (1997) (Stevens, J., concurring in part and dissenting in part). One of the questions raised in *Joiner* was whether an appellate court, in reviewing a district court's admissibility decision, could appropriately apply a "weight of the evidence" standard. *Id.* at 152 & n.4 (Stevens, J., concurring in part and dissenting in part). This approach would allow the reviewing court not just to assess the reliability of each individual piece of evidence sought to be introduced, but also to evaluate the evidence in the aggregate when determining whether to uphold the district court's admissibility decision. *See id.* at 153 n.5 (Stevens, J., concurring in part and dissenting in part). Justice Stevens noted that the Court had not actually addressed the weight of the evidence methodology in ruling—correctly, in his opinion—that abuse of discretion was the appropriate standard for review. *Id.* at 155 (Stevens, J., concurring in part and dissenting in part). He consequently found the court of appeals' application of the weight of the evidence persuasive. *Id.* at 154–55 (Stevens, J., concurring in part and dissenting in part). Incorporating a reference to "junk science," Justice Stevens stated: "An example of 'junk science' that should be excluded under *Daubert* as too unreliable would be the testimony of a phrenologist who would purport to prove a defendant's future dangerousness based on the contours of the defendant's skull." *Id.* at 153 n.6 (Stevens, J., concurring in part and dissenting in part). In contrast, Justice Stevens continued, two studies of workplace PCB exposure proffered in the *Joiner* case found increased rates of lung cancer deaths among exposed workers, but at rates determined not to be statistically significant. *Id.* at 154 n.8 (Stevens, J., concurring in part and dissenting in part). In his view, the cumulative effect of this information at least raised an inference of a relationship between the exposures and the cancer deaths. *Id.* at 154 (Stevens, J., concurring in part and dissenting in part). To the extent that Justice Stevens's statements may provide some insight into the Court's assessment of the distinction between scientific validity and "junk science," it is clear that the latter category would be reserved for methodologies that fall outside of scientific orthodoxy. Some methodologies could raise a question about whether they can, under any circumstances, provide reliable evidence of causation in a toxic tort case. *See, e.g.*, Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1208 (6th Cir. 1988) (holding that the discipline of clinical ecology lacked sufficient scientific basis to permit an opinion on the plaintiffs' immune system dysfunction). In contrast, the accepted technique of differential diagnosis in the medical community does not raise any of those questions. *See* Westberry v. Gislavad Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (noting that differential diagnosis is a standard diagnostic tool used throughout the medical profession that has been subjected to peer review and rarely leads to incorrect results).

evidence—cross-examination and judgment as a matter of law, in particular—the Court made clear its belief in the ability of most juries to make reasonable judgments regarding the weight of the evidence presented at trial.

Thus, the Supreme Court sought a balance between extremes. Even though, in *Joiner*, the Court confessed to a fundamental difficulty in differentiating scientific methodology from scientific conclusions, it is worth remembering that the *Joiner* Court was again dealing with hard scientific studies.[240] In the *Kumho Tire* decision, the Court was forced to address the application of *Daubert* and *Joiner* to expert testimony of a different nature.[241] Accordingly, the Court emphasized that the general observations of *Daubert* were not intended to serve as the guideposts for all expert testimony.[242] It is perhaps a weakness of *Kumho Tire* that the Court did not offer much in the way of guidance to the trial courts who are now left to their own devices to fashion tests by which to measure each type of expert evidence. But it is significant that the Court recognized that each type of expert testimony must be judged on its own merits. This concept is assertively echoed in the Committee Note to amended Rule 702 of the Federal Rules of Evidence.[243] Therefore, engineering testimony may not be judged by the same standards as testimony based upon epidemiological studies, nor may testimony based upon the technique of differential diagnosis be judged by the same standards.

What do those courts that express an antipathy toward differential diagnosis fear? One concern seems to be that juries will misconstrue treating physician testimony of causation as indisputable certainty.[244] It is unlikely that this would happen,

240. *See Joiner*, 522 U.S. at 145–46.

241. *See* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141–42 (1999) (applying *Daubert* to the testimony of engineers and other experts who are not scientists).

242. *See id*.

243. *See* FED. R. EVID. 702, committee note, 2000 U.S.C.C.A.N. (114 Stat.) G219. The Committee Note states: "Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise." *Id*. The methodology relied upon by the expert must be "an accepted body of learning or experience in the expert's field." *Id.* The Committee Note further states that "[n]othing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony" and that "Rule 702 expressly contemplates that an expert may be qualified on the basis of experience." *Id*. at G220.

244. *See, e.g.*, *Daubert*, 509 U.S. at 595–96 (noting the respondents' fear that abandonment of the "general acceptance" requirement would "result in a 'free-for-all' in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions").

however. A competent attorney has only to cross-examine the physician on the process and purpose of differential diagnosis to make clear to the jury that the technique enables the physician to develop a diagnosis for the purpose of treating the patient. Clinical medical testimony is very different from hard scientific studies of the type offered in *Daubert* or *Joiner*, and not just because the clinical medical testimony is directed at specific causation. If the clinical medical testimony is purely experiential, and not based upon scientific studies, the opposing party is free to argue that the expert's testimony regarding causation is less persuasive because of the absence of studies to support it.[245] Whether, in fact, it will be given greater or less weight depends on the strength of association observed by the expert, the expert's own experience and knowledge of the causation issues presented by the case, and a whole host of other factors specific to the particular case. These are fact questions to be decided after a full trial on all the issues in the case.

B. The Reasonableness Argument for Clinical Medical Evidence of Causation

The court in *Heller* was correct in noting that the technique of differential diagnosis used by treating physicians does not necessarily rely upon scientific studies; rather, it is primarily experience-based.[246] The court stated:

> In the actual practice of medicine, physicians do not wait for conclusive, or even published and peer-reviewed, studies to make diagnoses to a reasonable degree of medical certainty. Such studies of course help them to make various diagnoses or to rule out prior diagnoses that the studies call into question. However, experience with hundreds of patients, discussions with peers, attendance at conferences and seminars, detailed review of a patient's family, personal, and medical histories, and thorough physical examinations are the tools of the trade, and should suffice for the making of a differential diagnosis even in those cases in which peer-reviewed studies do not exist to confirm the diagnosis of the physician.[247]

A physician should be allowed to render a professional opinion based upon the standard tools of the medical trade. If differential diagnosis was properly conducted, there should be no reason that the physician cannot testify to the causation conclusion reached

245. *See, e.g.*, Heller v. Shaw Indus., Inc., 167 F.3d 146, 155–56 (3d Cir. 1999).
246. *See id.*
247. *Id.* at 155.

through its use. The fact that the physician's working diagnosis—or even more definitive diagnosis—may have been erroneous or marginal is a matter to be explored on cross-examination and raised by the defendant at trial. This scenario was clearly, indeed explicitly, contemplated by the Supreme Court in *Daubert*.[248] Provided that the differential diagnosis was properly conducted, testimony regarding its procedures and conclusions should be admissible. At trial, the defendant can offer contradictory evidence and challenge the testimony on cross-examination.

In *In re Paoli Railroad Yard PCB Litigation*,[249] the Third Circuit observed that although "differential diagnosis involves assessing causation with respect to a particular individual[,] [t]his merely makes it a different type of science than science designed to produce general theories; it does not make it unreliable science."[250] In fact, its reliability is enhanced by the fact that differential diagnosis focuses on the particular plaintiff, not on group statistics. Because the overwhelming focus of the admissibility analysis in *Daubert* was on scientific studies that were not directed at the particular plaintiff, but at statistical probabilities gleaned from studies of human populations, it may be easy to forget the considerable advantages of the methodologies that do focus on the individual plaintiff.[251]

248. The *Daubert* Court stated:

> Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence. Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment and likewise to grant summary judgment.

509 U.S. at 596 (citations omitted).

249. 35 F.3d 717 (3d Cir. 1994).

250. *Id.* at 758.

251. A curious and ironic phenomenon has occurred in the years since the *Daubert* decision whereby courts have collapsed the standards for general and specific causation, thereby raising the bar for proof of general causation. *See* Finley, *supra* note 13, at 347–64. For example, Professor Finley has discussed in some detail the ruling by the United States District Court for the District of Colorado in *In re Breast Implant Litigation*, 11 F. Supp. 2d 1217 (D. Colo. 1998). Finley, *supra* note 13, at 356. In that case, the court held that epidemiological studies were the only relevant evidence of causation, provided that such studies concluded that exposure to the substances at least doubled the risk of the illness suffered by the plaintiff. *Breast Implant Litigation*, 11 F. Supp. 2d at 1224, 1226. Professor Finley's article demonstrates that use of a "double-risk" standard for admissibility of scientific evidence of general causation essentially imposes a preponderance-of-the-evidence standard on general causation. *See* Finley, *supra* note 13, at 359 (arguing that when a judge requires the same level of proof for causation as is required by the scientific community for a valid epidemiological study, the burden of proof rises to a preponderance of the evidence standard of more than fifty percent). This

Although the court in *Paoli* employed the *Daubert* factors in its pre-*Kumho Tire* evaluation of the clinical medical testimony of two physicians, the court acknowledged the limitations of using those factors for evidence derived from the clinical medical setting.[252] While finding that the *Daubert* factors led to a conclusion that the testimony based upon differential diagnosis should be admitted,[253] the Third Circuit's comments beyond the narrow confines of those factors were the most insightful. The court reflected upon whether specific procedures must be performed by the treating physicians for their testimony to be admissible,[254] answering the question in the negative.[255] The defendants argued that for a differential diagnosis to be considered reliable under *Daubert*, the physician must have performed a medical examination of the plaintiff, reviewed all relevant medical records, conducted a medical history, ordered laboratory tests, and demonstrated that he or she considered alternative causes.[256] The court rejected the defendants' argument that all the enumerated procedures must be performed.[257] Nevertheless, the court held that at least some of

standard is inappropriate for general causation evidence because it is the standard traditionally imposed on specific causation evidence. *Id.* Furthermore, such a standard is a standard of sufficiency of the evidence, not admissibility. *See id.* at 336. Professor Finley demonstrates that numerous courts in the wake of *Daubert* have collapsed both the general and specific causation components and the admissibility and sufficiency inquiries. *Id.* Doing so minimizes the amount of causation testimony that is admissible and inappropriately renders a sufficiency determination (and sometimes a factfinding determination) at the admissibility stage. *See id.* at 357–58. This judicial predilection is especially problematic in toxic tort cases, where the evidence of general causation may be entirely different from the evidence of specific causation. Epidemiological studies may provide the basis for proof of general causation, but only relate to specific causation by extrapolation. Medical tests and differential diagnosis remain common methodologies underlying testimony on specific causation. In toxic tort cases, exposure and manifestation of disease often are separated by long periods of time, sometimes up to several decades, thus rendering the determination of specific causation a difficult task.

252. *See Paoli*, 35 F.3d at 758. For example, the court attempted to apply the general acceptance factor to differential diagnosis and observed the following anomaly: "Unlike a methodology used in conducting a scientific study, lack of general acceptance is not a sign of unreliability, it is merely a result of the fact that the medical community will rarely have considered the reliability of a particular process of differential diagnosis used in an individual case." *Id.* Likewise, the court noted that publication and peer review would probably not have taken place for the same reasons. *Id.* In *Kumho Tire*, the Supreme Court later acknowledged that the general observations of *Daubert* may not be germane to other disciplines subject to Rule 702. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999).

253. *Paoli*, 35 F.3d at 760.

254. *Id.* at 759–60.

255. *See id.* at 758.

256. *Id.*

257. *Id.* at 759. The court acknowledged, however, that performance of all of the enumerated procedures would increase the likelihood that the testimony would be

the procedures traditionally associated with differential diagnosis must be performed for the testimony to be reliable. The court stated:

> [W]e conclude that where [the physician] offered an opinion as to the source of a party's illness, the district court abused its discretion in excluding that opinion under Rule 702 unless either (1) [the physician] engaged in very few standard diagnostic techniques by which doctors normally rule out alternative causes *and* the doctor offered no good explanation as to why his or her conclusion remained reliable, or (2) the defendants pointed to some likely cause of the plaintiff's illness other than the defendants' actions and [the physician] offered no reasonable explanation as to why he or she still believed that the defendants' actions were a substantial factor in bringing about that illness.[258]

Because of the individuality of the differential diagnosis process, the test offered by the Third Circuit makes far more sense than a rigid application, or virtually any application, of the *Daubert* factors.

Furthermore, requiring treating physicians to supply studies as the underlying basis for their opinions contradicts the traditional concept of differential diagnosis as a *clinical* methodology. If, as a matter of medical methodology, physicians were not permitted to treat patients without the benefit of specific scientifically reliable epidemiological studies that met the *Daubert* test, the result would be absurd. It is no less absurd to require a testifying physician to produce such studies before he or she is allowed to testify on the causal aspects of treatment decisions he or she made in the clinical setting. The only question that remains, then, is how courts should go about determining what constitutes a reliable differential diagnostic methodology in toxic tort cases.

C. A Gatekeeping Test for Clinical Medical Evidence of Causation

Causation testimony of treating physicians[259] based upon the technique of differential diagnosis should be judged on its own

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reliable. *Id*. at 758.

258. *Id*. at 760.

259. This discussion presumes that the physician was the plaintiff's treating physician and was testifying as to causation determined in the clinical setting. Courts should determine whether the physician is in fact seeking to testify in that role or whether the physician has been asked by the plaintiff to offer testimony in the role of a different kind of expert. This situation might arise in a toxic tort case when a treating physician offers expert toxicology testimony, for example, and has not undertaken to

standards for admissibility purposes. This follows logically from the Supreme Court's mandate in *Kumho Tire* that the district court exercise a broad latitude in determining how to judge the particular expert testimony in question.[260] The *Kumho Tire* Court stated: "[W]e can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence."[261] The Court took pains to review *Daubert* and emphasize that the general observations of *Daubert* were intended to assist the trial court, but not intended to be an exhaustive "checklist" of pertinent factors on reliability.[262] The flexible approach espoused by the Court allows the trial judge to determine the factors that are pertinent to the particular methodology at issue in the case. The factors specifically articulated in *Daubert* may be applicable, or they may be inadequate or even irrelevant.[263]

1. Differential Diagnosis as a Reliable Methodology. The first step, the Supreme Court would acknowledge, is to determine if the methodology in question meets a threshold test for reliability. Although courts are sometimes reluctant to discuss this threshold, a frequently unspoken standard sets the bottom rung of the admissibility ladder, and some methodologies are simply inherently unreliable. For example, the Supreme Court has stated, in dicta, that a court need not even consider reliability factors "where the discipline itself lacks reliability, as,

examine or otherwise diagnose and treat the patient as a clinician. Thus, the plaintiff must make clear to the court the role in which such a "double expert" may be testifying.

260. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999). In explaining the recent amendment to Federal Rule of Evidence 702 (effective Dec. 1, 2000) to conform to *Daubert* and *Kumho Tire*, the Committee Note acknowledged that "[s]ome types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise." FED. R. EVID. 702, committee note, 2000 U.S.C.C.A.N. (114 Stat.) G219. The methodology of differential diagnosis, while grounded in medical science, has little in common with the scientific methods used in laboratory or other research science. The Committee Note continues: "The expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded." *Id.* The methodology of differential diagnosis is one such "accepted body of learning."

261. *Kumho Tire*, 526 U.S. at 150.

262. *Id*. Even in *Daubert*, the Court rejected the notion that the general observations were intended to be "a definitive checklist or test." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593 (1993).

263. *Kumho Tire*, 526 U.S. at 150 (quoting Brief for United States as amicus curiae, at 19). The Court endorsed the view of the Solicitor General in the United States' amicus brief: "We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" *Id.*

for example, theories grounded in any so-called generally accepted principles of astrology or necromancy."[264] While some disciplines may raise substantial questions as to their inherent reliability,[265] differential diagnosis in the clinical medical setting is not one of them.[266] Differential diagnosis is *the* single methodology employed in the clinical setting to determine initial treatment programs for patients.[267]

In the clinical medical setting, a differential diagnosis is always performed by the treating physician.[268] It will never be the wrong thing to do. A significant part of that analysis is determining the likely cause(s) of the patient's symptoms so that the physician can determine an effective treatment protocol.[269] Expert methodologies employed in other settings are different in this respect. One example can be found in *Blue Dane Simmental Corp. v. American Simmental Ass'n*.[270] That case involved a disagreement over cattle pedigrees, with the plaintiff claiming that the introduction of the defendant's cattle's genetic line into the Simmental market caused the market value of all Simmentals in America to fall significantly.[271] The plaintiff's expert, an agricultural economist, conducted a comparative analysis, noting that prior to introduction of the defendant's cattle into the United States market, both the American and Canadian markets were dropping; after introduction of the defendant's cattle, the American market suffered a drop that was almost twice the rate of the Canadian market.[272] The court referred to the case as "analogous to *Kumho*," and held that, although the methodology employed by the expert was typically used in his area of expertise, "that method is not typically used to

264. *Id.* at 151.

265. *See, e.g.*, Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1208 (6th Cir. 1988) (holding the discipline of clinical ecology inherently unreliable because "leading professional societies . . . have rejected clinical ecology as an unproven methodology lacking any scientific base in either fact or theory").

266. *Cf.* Greenwell v. Boatwright, 184 F.3d 492, 502 (6th Cir. 1999) (Merritt, J., dissenting) (characterizing accident reconstruction as "a generally reliable science").

267. *See* JAMISON, *supra* note 109, at 3–5 (analyzing the methodological process of differential diagnosis and noting that the methodology represents the primary tool for physicians to diagnose and treat patients).

268. *Id.* at 3, 5; *cf.* Brown v. S.E. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 761 (3d Cir. 1994) (suggesting that the opinion of a physician who has not followed accepted differential diagnostic methodology may still be admissible, provided that the physician offers "good justification" for the failure to follow a methodology).

269. *See* JAMISON, *supra* note 109, at 5.

270. 178 F.3d 1035 (8th Cir. 1999).

271. *Id.* at 1039–40.

272. *Id.*

make statements regarding causation without considering all the independent variables that could affect the conclusion."[273]

Differential diagnosis differs significantly from this kind of case. All physicians employ this approach in the clinical setting, for the express purpose of developing a diagnosis that includes a causal element. Indeed, the methodology is so pervasive that a court could take judicial notice of the use of the methodology in clinical medicine. Recognizing that differential diagnosis is used for determinations of causation in the clinical setting is not the end of the inquiry, however. The court must further determine what factors reasonably should have formed the basis of the differential diagnosis in the particular case.

2. What Constitutes an Appropriate Differential Diagnostic Technique? Logically, the next issue applicable to determining the admissibility of clinical medical evidence of causation is whether the physician followed an appropriate methodology of differential diagnosis in the case in question. As previously discussed, differential diagnosis in the clinical medical setting is a combination of scientific information and experience.[274] The specificity of the methodology in relation to the facts of the case was relevant to the holding in *Kumho Tire*. In that case, the district court had held that the methodology employed by the engineering expert in analyzing the tire in question was unreliable,[275] but the Supreme Court circumscribed the issue more narrowly. The Court stated that the issue was "not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection," but was, instead, "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*."[276]

Applying this principle to differential diagnosis in the clinical medical setting, it is clear that no single protocol would necessarily suffice as a reliable differential diagnostic methodology for all clinical cases.[277] The individual nature of

273. *Id*. at 1040–41.

274. Refer to Part III.B *supra*.

275. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 145 (1999).

276. *Id*. at 153–54. In *Kumho Tire*, the expert was asked to determine whether the cause of the accident was a tire defect or abuse. *Id.* at 154. The Court raised the question whether the methodology employed by the expert was reliable to make this determination with regard to this specific tire. *Id.* As the Court stated, "[t]he relevant issue was whether the expert could reliably determine the cause of *this* tire's separation." *Id*.

277. *See* Brown v. S.E. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 758–59 (3d Cir. 1994). Refer to notes 252–58 *supra* and accompanying text.

differential diagnosis will necessitate a different mix of factors used by the physician in each case. It is reasonable to say, however, that certain basics of clinical medicine will provide at least a portion of that analysis in all cases. Thus, a physician would examine the patient, determine his or her medical history, and examine the results of all medical tests deemed to be necessary under the circumstances. Just as the number and variety of medical tests ordered in each case will vary widely according to the symptoms presented, so too will the nature of the physician's inquiry in conducting a differential diagnosis. At a minimum, the court should expect the physician to follow the general categories of procedure recommended for differential diagnosis in clinical medical practice, including ruling out alternative causes for the plaintiff's ailment.[278]

What role should the enumerated *Daubert* factors play in admissibility decisions regarding causation evidence derived from differential diagnosis? Very little, if any. As previously stated, differential diagnosis is a generally accepted methodology in treating patients in the clinical setting. Because of the individualized nature of patient treatment protocols, the nature of the differential diagnostic procedure will vary from patient to patient.[279] In contrast, the *Daubert* factors were developed in the context of generalized epidemiological and toxicological studies, which do not have the individualized component of differential diagnosis. Furthermore, the tests under scrutiny in the *Daubert* case involved statistical and laboratory research protocols that are a scientific world apart from clinical differential diagnosis. These facts render the use of the enumerated *Daubert* factors highly questionable in the context of clinical medical evidence of causation. In fact, due to the highly individualized nature of each patient and illness, factual disputes may arise as to what

278. Refer to notes 113–23 *supra* and accompanying text. The Third Circuit offered the following opinion on this matter: "We agree . . . that performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a reliable differential diagnosis, and that their absence makes it much less likely that a differential diagnosis is reliable." *Paoli*, 35 F.3d at 758. The *Paoli* court also noted that "at the core of differential diagnosis is a requirement that experts at least consider alternative causes," and that "performance of standard diagnostic techniques provides prima facie evidence that a doctor has considered such causes." *Id*. at 759; *see also* Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1208 (8th Cir. 2000) (affirming the exclusion of evidence where a physician treated acute symptoms without conducting differential diagnosis to determine the cause or to rule out alternative causes); *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1251 (E.D.N.Y. 1985) (criticizing a medical expert for failing to review the plaintiffs' medical histories or consider alternative causes).

279. *See* JAMISON, *supra* note 109, at 3–7 (detailing the various options available to a doctor in making a differential diagnosis).

procedures were appropriate in a particular case. Provided that a prima facie showing of reliability[280] of the differential diagnostic procedure has been made—that is, examination of the patient, medical history, and reasonably relevant medical tests or a reasonable explanation why a variation from this protocol was necessary—the expert need not demonstrate that every other available step was taken or every entry in the medical literature was read prior to reaching a conclusion regarding causation. That information may be introduced and explored at trial.

3. Inability to Quantify Level of Exposure. In toxic tort cases, the physician likely will not know the precise amount of the toxic substance to which the patient was exposed. Even where medical tests can confirm the presence of the substance in the patient's blood or tissues, those tests cannot accurately quantify the total exposure. Accordingly, for substances that may cause latent illness over a period of time, perhaps even decades, the entire exposure picture likely will be unavailable to the treating physician.[281]

In *Kannankeril v. Terminix International*,[282] the Third Circuit held that the district court had improperly excluded the testimony of the plaintiffs' expert witness, who had concluded that Mrs. Kannankeril had chronic toxicity related to exposure to a pesticide in the home that had been applied by the defendant.[283] She complained of physical and cognitive symptoms directly associated with the exposure; she also developed a multiple chemical sensitivity that created additional medical problems.[284] The plaintiffs' expert was a medical doctor and board certified toxicologist.[285] The district court held that the expert's lack of specific knowledge regarding Mrs. Kannankeril's level of exposure to the pesticide, among other reasons, rendered

280. *E.g.*, *Paoli*, 35 F.3d at 759.

281. *See* Borel v. Fibreboard Paper Prods. Corp., 403 F.2d 1076, 1083 (1973) (describing the difficulties in diagnosing asbestosis and noting that these difficulties "make it impossible, as a practical matter, to determine which exposure or exposures to asbestos dust caused the disease").

282. 128 F.3d 802 (3d Cir. 1997).

283. *Id.* at 809–10.

284. *Id*. at 805. Pursuant to a contractual agreement, the defendant had sprayed pesticides containing Dursban on at least twenty occasions at various intervals from May 31, 1989, through October 5, 1990 (when the plaintiffs canceled the service). *Id.*

285. *Id.* His testimony was offered only on the cause of Mrs. Kannankeril's cognitive symptoms. *Id.* at 806. In developing his opinion, he relied upon Mrs. Kannankeril's account of her symptoms, a report written by a neuropsychologist who examined her, and information regarding the times and amounts of Dursban pesticides applied to the plaintiffs' home. *Id*. He also relied generally upon his own knowledge and experience, reading background, and "standard" textbooks and references. *Id*.

his opinion unreliable.[286] In reversing, the Third Circuit held that his knowledge of the level of exposure was sufficient,[287] as the defendant's pesticide application records provided information on "when, how much, and where [the] pesticide had been applied."[288] The defendant had successfully argued to the district court that an ambient air test was the only reliable method of determining the amount of exposure.[289] In contrast, the Third Circuit held that "all factual evidence of the presence of the chemicals in the residence should be relevant in forming an expert opinion of causation," not merely an ambient air test—particularly one conducted so long after the last application.[290] The court concluded that it was for "the trier of fact to determine what weight to give" to the various sources of the exposure information.[291]

Physicians typically rely on this kind of anecdotal and recordkeeping information regarding their patients' exposures. Indeed, anecdotal information from the patient and his or her family and associates is often the only information regarding exposures immediately available in the clinical setting when treatment decisions must be made.[292] Experts have recognized

286. *Id.* at 808. The district court determined that the doctor altogether lacked knowledge regarding the level of exposure, because he was not aware of the precise levels of Dursban in the plaintiffs' home at the relevant time and was unaware of the amount of time the injured plaintiff had spent in the home. *Id*.

287. *Id. But see* Mitchell v. Gencorp Inc., 165 F.3d 778, 781 (10th Cir. 1999) ("We believe a plaintiff must prove level of the exposure using techniques subject to objective, independent validation in the scientific community."); Allen v. Pa. Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996) ("Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case."); *accord* Curtis v. M & S Petroleum, Inc., 174 F.3d 661, 671 (5th Cir. 1999) (holding a physician's opinion admissible where the physician was able to determine the plaintiffs' detailed level of benzene exposure and relate it to specific symptoms).

288. *Kannankeril*, 128 F.3d at 808.

289. *Id.* at 808–09. The expert had in fact reviewed the results of an ambient air test that had been conducted at the plaintiff's home a full nine months after the last pesticide application and showed no detectable levels of pesticides. *Id*. at 808.

290. *Id*. at 808–09.

291. *Id.* at 809 ("The issue whether an ambient air test should be given more weight than pesticide application records goes to the weight rather than the admissibility of evidence."). Moreover, the court warned, "[t]he trial judge must be careful not to mistake credibility questions for admissibility questions." *Id*.

292. The Fourth Circuit stated that "while precise information concerning the exposure necessary to cause specific harm to humans and exact details pertaining to the plaintiff's exposure are beneficial, such evidence is not always available, or necessary, to demonstrate that a substance is toxic to humans." Westberry v. Gislavad Gummi AB, 178 F.3d 257, 264 (4th Cir. 1999); *accord* Heller v. Shaw Indus., Inc., 167 F.3d 146, 155 (3d Cir. 1999) (stating that "[i]n the actual practice of medicine, physicians do not wait for conclusive, or even published and peer-reviewed, studies to make diagnoses to a reasonable degree of medical certainty").

that precise exposure data are difficult to glean under most circumstances.[293] Thus, in *Anderson v. Quality Stores, Inc.*,[294] the Fourth Circuit held that anecdotal information that the plaintiff had painted twenty-two window shutters with the allegedly toxic spray paint sold by the defendant was sufficient to support the claim that "his exposure was substantial."[295]

This kind of latitude in the admissibility of clinical medical testimony on causation is essential. Treating physicians are not, ordinarily, epidemiologists or other research scientists. To require them to undertake the duties of research scientists so as to testify would have the effect of holding them to a standard distinct from that to which they are held as medical professionals in the clinical setting. That standard could rarely, if ever, be met. The same premise is true for requiring them to have available, or determine, the precise levels of exposure experienced by their patients before developing a diagnosis. Furthermore, from a public policy standpoint, in toxic tort cases, society should want to encourage individualized proofs regarding causation of a plaintiff's illness. It would be a curious irony if the Rules of Evidence resulted in only general causation evidence being admissible, while specific causation evidence was excluded.

4. Temporal Proximity Between Exposure and Symptoms. A related issue in toxic torts is the role of the latency period between exposure and manifestation of illness in the physician's differential diagnosis. Plaintiffs and their physicians argue that a close temporal proximity between exposure and symptoms is strong evidence of a causal connection, particularly in the absence of confounding factors.[296] Defendants, on the other hand,

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293. *See* FED. JUDICIAL CTR., *supra* note 12, at 187.

> Only rarely are humans exposed to chemicals in a manner that permits a quantitative determination of adverse outcomes. . . . Human exposure occurs most frequently in occupational settings where workers are exposed to industrial chemicals like lead or asbestos; however, even under these circumstances, it is usually difficult, if not impossible, to quantify the amount of exposure.

Id.

294. No. 98-2240, 1999 WL 387827 (4th Cir. June 14, 1999).

295. *Id.* at *2.

296. *See, e.g.*, Moore v. Ashland Chem. Inc., 151 F.3d 269, 278 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999); *see also* FAIGMAN ET AL., *supra* note 119, § 27-2.5.2, at 295–96.

> A good medical history should also consider temporal relationships in probing for causality. Certain diseases, including many cancers, require a minimum lag period between the initial exposure and the onset of the cancer.... In other situations, such as acute effects, the toxicological properties of the external agent often will determine the temporal relationship [i.e., the length of time symptoms will persist] . . . . Sometimes the exposure pattern can give a clue toward assigning causality.

argue that reliance on temporal proximity can mask intervening causes that may actually have been responsible for the illness.

In *Moore v. Ashland Chemical Inc.*, the Fifth Circuit Court of Appeals held, inter alia, that the physician's reliance on the temporal proximity between the plaintiff's exposure to toluene and the onset of his symptoms did not provide a sufficient basis for his opinion that the toluene had caused the plaintiff's RADS.[297] This conclusion was in the context of the court's similar treatment of the physician's training and experience, his examination of the patient and test results, his stated reliance on a published study, and the MSDS for toluene, all of which the physician had proffered as the basis for his causation opinion.[298] The court opined that situations would be very rare where "'the temporal connection between exposure to a given chemical and subsequent injury is so compelling as to dispense with the need for reliance on standard methods of toxicology.'"[299] In the absence of such circumstances, temporal proximity must be given "little weight."[300]

In contrast, in *Westberry v. Gislavad Gummi AB*, the Fourth Circuit stated that "depending on the circumstances, a temporal relationship between exposure to a substance and the onset of a disease or a worsening of symptoms can provide compelling evidence of causation."[301] The Third Circuit, in *Heller*, explained further that temporal proximity "will often be (only) one factor, and how much weight it provides for the overall determination of whether an expert has 'good grounds' for his or her conclusion will differ depending on the strength of that relationship."[302] The Third Circuit suggested that a close temporal relationship between exposure and symptoms would reduce or eliminate the need for other associative factors, such as published studies.[303]

Id.

297. *Moore*, 151 F.3d at 278.

298. *Id.* at 277–78.

299. *Id.* at 278 (quoting Cavallo v. Star Enter., 892 F. Supp. 756, 773–74 (E.D. Va. 1995), *aff'd in part and rev'd in part*, 100 F.3d 1150 (4th Cir. 1996)). In *Cavallo*, the court noted that such compelling circumstances might be present if the plaintiff had been soaked in jet fuel or if so many people had been similarly exposed and had suffered the identical symptoms. *Cavallo*, 892 F. Supp. at 774.

300. *Moore*, 151 F.3d at 278.

301. Westberry v. Gislavad Gummi AB, 178 F.3d 257, 265 (4th Cir. 1999). The evidence in this case indicated that the plaintiff's sinus condition had commenced soon after he had begun working as a gasket cutter, when he first came into contact with the talc. *Id.* The condition improved when he was removed from the job, but resumed when he went back to the position. *Id.* The court held that this evidence was indeed compelling evidence of causation and that the trial court had appropriately admitted it. *Id.*

302. Heller v. Shaw Indus., Inc., 167 F.3d 146, 154 (3d Cir. 1999).

303. *Id.* The *Heller* court identified a problem with the temporal relationship

Temporal proximity is one factor employed by physicians in the process of differential diagnosis. Indeed, a differential diagnosis of some symptoms would not be complete without analysis of information regarding substances to which the patient had been exposed and the time periods of those exposures. Evidence of close temporal proximity is particularly relevant in acute conditions, such as the sinus condition of the plaintiff who worked with talc in *Westberry*, the respiratory distress of the plaintiff who inhaled paint fumes in *Anderson*, or the plaintiff who developed respiratory symptoms after exposure to toluene in *Moore*. In such cases, evidence of close temporal proximity should be an admissible element of testimony based upon differential diagnosis.[304]

The strength of close temporal proximity in a causation analysis does not necessarily mean, however, that the converse is true—that is, that a substantial distance in time between exposure and symptoms signifies lack of causation. Many toxic tort cases involve cancer or other latent illnesses that arise many years after exposure. The classic example of a latent toxic illness is asbestosis, which may develop up to several decades following the person's workplace exposure to asbestos.[305] In cases alleging cancer or other acknowledged latent illnesses, the lack of close temporal proximity should not be taken as prima facie evidence of lack of causation. Rather, the lack of temporal proximity in these cases diminishes the significance of temporal proximity in the causation analysis and enhances the importance of other information. Obviously, if the plaintiff has complained of symptoms that are traditionally characterized as acute—such as eye irritation or respiratory distress—and the temporal relationship between exposure and symptoms is attenuated, far more support for a conclusion of causation would be necessary. The Supreme Court gave this latter point its outer limit in *Joiner* when it stated that courts "may conclude that there is simply too

advanced by one of the plaintiff's experts, however, stating that it was "questionable at best and exculpatory at worst." *Id*. at 158. Thus, the court excluded the testimony based upon it. *Id*.

304. As the Third Circuit has stated: "[W]hen the temporal relationship is strong and is part of a standard differential diagnosis, it would fulfill many of the *Daubert/Paoli* factors." *Id*. at 158.

305. *See, e.g.*, Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1083 (5th Cir. 1973). The *Borel* court cited an important study of asbestos insulation workers, which demonstrated the long latency period between exposure to asbestos and the development of asbestosis. *Id*. at 1084–85 & n.15 (citing J. Selikoff et al., *The Occurrence of Asbestosis Among Insulation Workers in the United States*, 132 ANNALS N.Y. ACAD. SCI. 139, 146–47, 152 (1965)).

great an analytical gap between the data and opinion."[306] This determination must be made on a case-by-case basis; a bright line simply cannot be drawn due to the intensely individual nature of clinical medical procedures and diagnosis.

5. The Role of the MSDS. In toxic tort cases involving workplace injuries, the plaintiff often seeks to introduce an MSDS[307] into evidence to support causation. For example, in *Moore v. Ashland Chemical Inc.*,[308] the MSDS provided warnings regarding the health hazards associated with exposure to toluene.[309] The document contained separate warnings for short-term vapor exposure and prolonged exposure.[310] The MSDS also made clear that the effects of toluene exposure were relative to the concentration of the chemical and the length of time that the person was exposed.[311] The Fifth Circuit held that the trial court did not abuse its discretion in holding that the plaintiff's physician's opinion on causation was not reliable, in part due to his faulty reliance on the MSDS.[312] According to the Fifth Circuit, the district court could reasonably have concluded that the MSDS was of "limited value" to the physician because he was not aware of what tests the manufacturer of the chemical had conducted in developing the MSDS for its product and because he did not have specific information on the level of exposure to the chemical that could cause the health effects indicated on the MSDS.[313]

In *Westberry*, the Fourth Circuit predictably reached a different conclusion on the value of an MSDS. The MSDS for talc that was made available to the plaintiff's physician provided that "'inhalation of dust in high concentrations irritates mucous membranes.'"[314] There was no further information regarding the precise airborne levels of talc that would constitute "high concentrations." Nor did the physician have any precise information regarding the levels of airborne talc to which the plaintiff was exposed.[315] Nevertheless, the court held that the

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

307. *See* 29 C.F.R. § 1910.1200 (1999) (stating that the purpose of the MSDS is to transmit information concerning potential hazards of chemicals in the workplace).

308. 151 F.3d 269 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999).

309. *Id.* at 271–72.

310. *Id*. at 271–72 n.1.

311. *Id*. at 278.

312. *Id.* at 278–79.

313. *Id*. at 278.

314. Westberry v. Gislavad Gummi AB, 178 F.3d 257, 264 (4th Cir. 1999).

315. *Id.*

physician's testimony was admissible.[316] The plaintiff's own testimony regarding his workplace exposures was sufficient to allow a fact finder to conclude that he had been exposed to "high concentrations."[317] Thus, the court determined that the MSDS was relevant, even though no information existed regarding the precise levels of talc on which the MSDS was based or to which the plaintiff was exposed. Similarly, in *Anderson*, the Fourth Circuit concluded that the MSDS for the chemicals present in the spray paint used by the plaintiff was an appropriate basis of the expert's causation opinion.[318] The MSDS supported the conclusion that "significant amounts" of the chemicals, when inhaled, could create pulmonary hazards.[319] The fact that the plaintiff's decedent had painted twenty-two shutters with the paint gave rise to a presumption that he had been exposed to such significant amounts, even in the absence of specific data regarding levels of the chemicals.[320]

These cases suggest that objection to physician reliance on an MSDS in causation testimony has more than one basis. First, the objecting party could argue that the MSDS simply is not relevant to the particular case. If the MSDS warns of respiratory hazards, but not dermatological hazards, and the injured person complains of skin irritation, the MSDS clearly is not relevant to the case at hand and should not be used as the basis of the physician's causation opinion. Likewise, if the MSDS refers to significant or substantial exposure levels, and the information regarding the injured person's exposure to the substance demonstrates minimal or negligible exposure levels, arguably the MSDS would be irrelevant in this instance as well.

A second and more difficult question involves knowledge of the levels of exposure, as highlighted by the three cases discussed above. Those who would object to a physician's reliance on an MSDS in developing a medical causation opinion would argue that for the MSDS to provide a reliable basis of the testimony, the physician must know the exact levels of exposure forming the basis of the MSDS warnings and demonstrate that the patient

316. *Id.* at 266.

317. *Id*. at 264. The plaintiff testified to frequently observing a thick layer of talc on the gaskets. *Id.* He also testified that the talc had settled thickly in his surrounding work area, covering the floor and his clothes. *Id.* At the end of each workday, he was required to use a blower to clear the work area, which disturbed the settled talc and blew it into the air again. *Id*.

318. Anderson v. Quality Stores, Inc., No. 98-2240, 1999 WL 387827, at *2 (4th Cir. June 14, 1999).

319. *Id.*

320. *Id*.

experienced the same level of exposure.[321] This position is unreasonable in the context of clinical medical evidence of causation for several reasons. It is highly unlikely that a treating physician in the clinical setting would have access to the underlying data forming the basis of the MSDS. Moreover, as discussed previously, treating physicians often have little information regarding the level of the chemical to which the patient has been exposed. Treatment decisions must be made on the basis of reasonably available information. In many instances, the physician may not even have a copy of the MSDS or any information regarding that document at the time of initial treatment. When the MSDS is available, the physician should be able to rely on the information contained therein, to the extent that that information conforms with the patient's personal account of the incident, the symptoms, and the results of the medical examination and tests. The methodology of differential diagnosis reasonably relies on this kind of information, when available. It is wrong to require a physician to assume the role of a scientist in a different discipline to perform his or her clinical duties. Weaknesses in the physician's reliance on the MSDS may be brought out on cross-examination.

This controversy raises a familiar question: Is the physician's causation testimony valuable in its own right, or only where it is supported by hard scientific evidence of studies conducted by researchers? As stated earlier, the treating physician's testimony has a unique value in determining causation apart from scientific studies. While scientific studies can only provide evidence of general causation, the treating physician's testimony is a means of demonstrating specific causation of the illness in the individual plaintiff. Specific causation typically is the most difficult element of a causation case for a plaintiff to prove, and such individualized causation evidence should not be routinely excluded, even where it is imperfect. Permitting the physician to rely on an MSDS in offering causation testimony, just as he or she may have done in reaching an initial diagnosis or in refining a working diagnosis at a later date, is a crucial step in the process of demonstrating specific causation.

321. *See, e.g.*, Moore v. Ashland Chem. Inc., 151 F.3d 269, 278 (5th Cir. 1998) (en banc), *cert. denied*, 526 U.S. 1064 (1999).

V. CONCLUSION

The United States Supreme Court has revisited the *Daubert* decision twice, apparently expanding its holding and granting district court judges great leeway and discretion in determining the admissibility of testimony from a wide array of experts and other specialized witnesses.[322] Far from facilitating scrutiny of expert evidence, these decisions have complicated the landscape. Guidance is necessary to avoid conflicting results among the federal circuits and to assist trial courts in their gatekeeping role.

One of the most problematic areas necessitating expert testimony is causation in toxic tort cases. While both *Daubert* and *Joiner* addressed evidentiary issues in toxic tort litigation, both cases directly involved hard scientific studies typically offered to demonstrate general causation. Indeed, the general observations suggested by the Court in *Daubert* to assist trial courts in determining the admissibility of scientific evidence are addressed specifically to those hard scientific studies. In *Kumho Tire*, the Supreme Court made clear that the nature of the expert testimony in a particular case may render the specific *Daubert* factors inapplicable and that the court must determine the appropriate factors to use in evaluating the reliability of the testimony in each case.[323] Nevertheless, some courts have clung to the *Daubert* factors and attempted to force certain kinds of evidence into the *Daubert* mold where that mold is clearly inapplicable.

Clinical medical evidence offered as proof of causation in toxic tort cases is one such category of evidence. Some courts have interpreted *Daubert* and its progeny to require that the testifying physician support his or her causation opinion with hard scientific studies or meet the specific factors set forth in *Daubert*. Yet, physicians providing clinical medical evidence are not research scientists. Their methodology of differential diagnosis is universally accepted in the medical profession and forms the basis of their treatment decisions.[324] Physicians develop a causation theory and diagnosis based upon this methodology. A properly performed differential diagnosis should meet the reliability and relevancy criteria of *Daubert* and its progeny in most cases.

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322. *See* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 148 (1998) (expanding *Daubert* to include all expert witnesses, not just scientific experts).

323. *Id.* at 150–51.

324. *See* JAMISON, *supra* note 109, at 5.

Differential diagnosis is an important methodology in many toxic tort cases because it is directed at the specific patient. Whereas the hard scientific studies offered in *Daubert* and *Joiner* were offered to prove general causation, differential diagnosis goes to specific causation. Evidence of specific causation is particularly hard to come by in latent illness toxic tort cases. But even in acute illness cases, direct specific causation evidence—such as the presence of the alleged toxic substance in the patient's blood or tissues—frequently is not present. Thus, testimony based upon differential diagnosis should be allowed to support causation. A test of reasonableness should apply to clinical medical causation testimony. Physicians should be permitted to base their expert testimony upon the same information they relied upon in conducting their differential diagnoses. This information may properly include general information regarding substances to which the patient has been exposed, the temporal relationship between the patient's exposure to a substance and the onset of symptoms, and the information contained in any relevant MSDS regarding health hazards associated with the substance.

Our judicial system provides a variety of procedural safeguards to expose weak evidence during the trial process. These safeguards include summary judgment, cross-examination of witnesses, motions for judgment as a matter of law, and the production of witnesses to refute the opposing party's evidence. Weak clinical medical evidence of causation, unaccompanied by other proof, may be addressed on a summary judgment motion or at trial. Because clinical medical testimony of causation is typically restricted to plaintiffs' witnesses, overly zealous exclusion of the testimony is especially harmful to toxic tort plaintiffs, who often are already disadvantaged from the start in building a causation case. The individualized nature of clinical medical testimony of causation should make it a welcome presence in the courtroom.