



Challenges to Plaintiffs'
Experts in Toxic Tort Cases
*“De-Bunking the Junk in Medical
Causation Opinions”*

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Challenges to Plaintiffs' Experts in Toxic Tort Cases “De-Bunking the Junk in Medical Causation Opinions”

Challenging plaintiff expert testimony in toxic tort cases is a necessary undertaking. Expert testimony admissibility is subject to differing standards, including the *Daubert* trilogy, amended FED R. EVID. 702 and the so-called *Frye* and *Robinson-Havner* tests, and is subject to local variances on these general principles. Such doctrinal variances can lead to confusion and inconsistent results.

Regardless of the court in which the case arises, however, multiple mechanisms exist for mounting successful challenges to expert testimony. Creative strategy and sound preparation can effectively limit or exclude opposing expert opinions, and significantly weaken, if not terminate, the plaintiff's case. This article describes the backdrop for such challenges in toxic tort cases, and presents practice pointers useful to both the novice and experienced defense trial attorney. Effectively debunking junk science that the plaintiffs present as “support” for their cases can facilitate an earlier and more favorable resolution of toxic tort litigation and trials for you and your clients.

Why Defendants Must Challenge Plaintiff Expert Testimony

Proof of medical causation is the critical element in a toxic tort case. In order to prevail, the plaintiff must prove both general causation—that the agent¹ at issue is capable of causing the plaintiff's particular disease, and specific causation—that the plaintiff's exposure to the agent, at the dose received, actually caused the disease. Because such matters are beyond the capacity of the average person to understand and appreciate, expert testimony must inform the trier of fact on issues of radical causation. *See, e.g.*, FED. R. EVID. 702.² The expert must explain

¹ For purposes of this article, any chemical, prescription or over-the-counter drug, or other substance that is the basis for litigation will be referred to an “agent.”

² FED. R. EVID. 702 provides that “[if] scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to

the nature, impact and potential toxicity of the agent at issue, as well as whether and how the agent could and did cause the disease.³ Without expert testimony, the plaintiff cannot prove general or specific causation, or prevail.⁴ Because a successful challenge to the plaintiff's expert testimony may dispose of a case, the defendants must oppose that testimony if any rational, legally justifiable reason exists to do so.⁵ Due to the

determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based 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." In some instances the experts can also be fact witnesses, requiring satisfaction of Rule 701 of the Federal Rules of Evidence covering opinions of non-experts. *See* FED. R. EVID. 701.

³ Aside from special defenses such as statute of limitations and product identification, toxic tort cases routinely hinge on successful expert testimony or its challenge. As a Texas court previously has held, a decision on general causation properly resides with a jury, but it should not be permitted to make such a decision without expert assistance. *Merrell Dow Pharms., Inc. v. Havner*, 907 S.W.2d 535, 551 (Tex. App. 1994), *rev'd on other grounds*, 953 S.W.2d 706 (Tex. 1997).

⁴ Two of the three seminal cases establishing the current federal standard for the admissibility of expert testimony were toxic tort cases, the third falling more broadly in the product liability category. *See* discussion below. All three required expert testimony for the plaintiff to prevail in their case on the issue of causation. When the testimony of the causation expert was precluded, the plaintiffs lost. *See* Margaret A. Berger, *What Has a Decade of Daubert Wrought*, AMER. J. PUB. HEALTH, Vol. 95, No.1 at S59 (Supp. 1 2005) (hereinafter "*What Daubert Has Wrought*"), discussing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

⁵ In addition to the medical aspects of general causation, there are other aspects of toxic tort cases where expert testimony is appropriate, *e.g.*, the method and dose of plaintiff's alleged exposure to the substance at issue for purposes of proving specific causation. *See generally* In re Hanford Nuclear Reservation Litig., No. CY-91-3015, 1998 WL 775340 (E.D. Wash.) (describing multiple areas of expert testimony, including state of the art).

inherently complex nature of disputed scientific issues, the outcome of such challenges may be difficult to predict, but success is demonstrably achievable.⁶

Framework for Admissibility: Two Principal Standards—One “Rigid,” One “Liberal”

*Daubert*⁷ and *Frye*⁸ are the two primary tests by which federal and state courts adjudicate the admissibility of expert testimony.⁹ Three core concepts underscore both of these tests: qualifications, reliability and relevance. Reliability is the area of most controversy. The judicial lenses through which these concepts are applied differ significantly. *Daubert* relies on the trial court as a “gatekeeper” to determine the reliability of expert testimony; *Frye* relies on the scientific community to ensure reliability based on the “general acceptance” of the theory and methodology in the relevant scientific field.

The *Frye* “general acceptance” standard was applied in federal and state courts from 1923 until the Supreme Court’s *Daubert* decision in

Although challenges to expert testimony in these areas may not be dispositive, they may weaken the plaintiff’s case and significantly impact his or her ability to prevail.

⁶ In 1998, approximately 45 percent of cases tried in the federal courts’ civil docket, where the trial involved expert testimony, were tort cases. The testimony of approximately 41 percent of the experts was either limited or excluded. These figures correspond only to cases that went to trial so the figures are probably underrepresented when all civil suit are considered, including those settled. See Carol Krafka, *et al.*, *Judicial and Attorney Experiences, Practices, and Concerns Regarding Expert Testimony in Federal Civil Trials*, 8 PSYCHOL. PUB. POL’Y & L. 309, 318, 323 (Sept. 2002).

⁷ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

⁸ *Frye v. U.S.*, 293 F. 1013 (D.C. Cir. 1923) (addressed the admissibility of polygraph evidence).

⁹ Despite 80 years of evolution, these standards still remain unclear. For an expansive description of the “confusion” that *Daubert* is thought to have wrought, see Cassandra H. Welch, *Flexible Standards, Deferential Review: Daubert’s Legacy of Confusion*, 29 HARV. J. L. & PUB. POL’Y 1085 (Summer 2006) (hereinafter referred to as “*Legacy of Confusion*”).

1993.¹⁰ Calling the *Frye* test “rigid,” *Daubert* held it was inconsistent with the more “permissive” and “liberal” Rule 702. *Id.* The holdings of that decision and two other cases, commonly known as the “*Daubert* trilogy,” thus became the admissibility test for expert testimony in the federal courts.¹¹

Daubert established the trial judge as the gatekeeper who must determine the reliability and relevance, and thus admissibility, of proffered expert testimony. Reliability under Rule 702 requires that the subject of expert evidence be scientific “knowledge” grounded “in methods and procedures of science.” FED. R. EVID. 702. Relevance requires that the expert evidence or testimony assist the trier of fact to understand the evidence or to determine a disputed issue in the case. *Id.*

Daubert enumerated several factors intended to ensure the reliability, *i.e.*, scientific validity and trustworthiness, of expert testimony.¹² These factors provide the trial court with “permissive” and “flexible” guidance, rather than a litmus test or exhaustive checklist.¹³ In *Kumho*, the

¹⁰ *Daubert* overruled *Frye* as to federal courts. It held that *Frye* was superseded by, and not incorporated into, Rule 702 of the Federal Rules of Evidence when it was promulgated in 1975. *Daubert*, 509 U.S. at 588–89.

¹¹ The other components of the trilogy include *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Courts of approximately 25 states adopted the *Daubert* test standard. States accepting the essential principles of *Daubert* are Alaska, Arkansas, Connecticut, Delaware, District of Columbia, Georgia, Kentucky, Louisiana, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Vermont, West Virginia, Wyoming. *Frye/Daubert: A State Reference Guide*, The DRI Defense Library Series (2005).

¹² *Daubert*, 509 U.S. at 594. “Reliability” measures address issues of the technique’s testing, peer review or publication, error rates, standards of operation, and general acceptance in the scientific community.

¹³ However, part of the criticism of *Daubert* is that some courts indeed have considered these factors a checklist or “technical hurdles,” rather than flexible guidelines. See *Legacy of Confusion*, 29 HARV. J. L. & PUB. POL’Y at 1097–98 & n.107, citing an article by a respected trial judge who described *Daubert* as establishing “eight gates” for admissibility of expert testimony,

third prong of the *Daubert* trilogy, the Supreme Court refused to pronounce an exhaustive laundry list of criteria for the reliability of scientific evidence, stressing instead the trial court's "considerable leeway... to go about determining whether particular expert testimony is reliable." *Kumho*, 526 U.S. at 152.¹⁴ In short, the *Daubert* trilogy, augmented by amended FED. R. EVID. 702, provides a more flexible and permissive standard for weighing the admissibility of expert opinions than its predecessor. It does not, however, delineate a "single factor" by which to test the reliability of expert testimony.¹⁵

By contrast, *Frye* remains the standard for gauging the reliability of expert testimony in many state courts.¹⁶ For expert scientific testimony

namely Judge Harvey Brown, *Eight Gates for Expert Witnesses*, 36 HOU. L. REV. 743 (1999).

¹⁴ After *Daubert*, FED. R. EVID. 702 was amended to mandate that the expert's testimony be (1) "based upon sufficient facts or data," (2) "the product of reliable principles and methods," (3) the result of the "appli[cation of] the principles and methods reliably to the facts of the case." FED. R. EVID. 702. The Advisory Note to the 2000 Amendments to Rule 702 highlights other factors that are relevant to a reliability determination, including (1) whether the expert's proffered testimony relates to research "conducted independent of the litigation" (*Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)); (2) whether the expert unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*Joiner*, 522 U.S. at 146); (3) whether the expert "adequately accounted for obvious alternative explanation;" (4) whether the expert exhibited a level of care consistent with his typical professional work not with his paid litigation consultancy (*Kumho*, 119 S. Ct. at 1176); and (5) whether the expert's claimed field of expertise is known to produce reliable results. FED. R. EVID. 702 Advisory Committee's Note.

¹⁵ FED. R. EVID. 702 Advisory Committee's Note, quoting *Kumho*, 119 S. Ct. at 1176. *Daubert* also addresses relevance—will the expert testimony assist the trier of fact to understand or determine a fact at issue in the case. Is the testimony relevant to issues raised in the case? Does it fit? See *Kumho*, 119 S. Ct. at 1176.

¹⁶ That factor may speak to the lack of clarity, consistency, or ease of application that some believe the *Daubert* test represents. See generally *Is Frye Still Generally Accepted*, 78-May N.Y. State Bar J. 22 (May 2006) (hereinafter

to be admitted under *Frye*, the theory or methodology underlying the testimony must have “gained general acceptance in the particular field in which it belongs.” *Frye*, 293 F. at 1015. Since the Supreme Court’s decision in *Daubert*, several state courts have repeatedly reaffirmed *Frye*.¹⁷ Some states, however, recognize some flexibility in its application.¹⁸

Primary Grounds for Challenges— Reliability and Relevance

Though the qualifications of an expert witness, or lack thereof, can be challenged,¹⁹ the most important and frequently raised grounds for

referred to as “*Is Frye Accepted*”). States which continue to apply *Frye* are Arizona, California, Florida, Illinois, Kansas, Maryland, Minnesota, New Jersey, New York, North Dakota, Pennsylvania, Washington. States that have developed a combination of *Daubert* and *Frye* tests include Alabama, Nevada, Tennessee, Virginia. States that apply their own standard, without expressly adopting or rejecting either *Daubert* or *Frye* are Colorado, Hawaii, Idaho, Indiana, Iowa, Maine, Missouri, New Jersey, North Carolina, South Carolina, Utah, Wisconsin. *Frye/Daubert: A State Reference Guide*, The DRI Defense Library Series (2005).

¹⁷ In New York alone, it has been reaffirmed at least twice. See *Is Frye Accepted*, 78-May N.Y. State Bar J. at 23.

¹⁸ See *Zito v. Zabarksy*, 28 A.D.3d 42, 46, 812 N.Y.S.2d 535, 2006 WL 205067 (N.Y.A.D. 2d Dep’t Jan. 24, 2006) (appellate court, in reversing exclusion of expert testimony “the trial court . . . believed that the *Frye* test could only be satisfied with medical texts, studies, or other literature which supported the plaintiff’s theory of causation under circumstances virtually identical to those of plaintiff. However, the *Frye* test is not that exacting.”); *Parker v. Mobil Oil Corp.*, 2006 WL 2945397 (N.Y. Oct. 17, 2006) (affirming the exclusion of expert testimony: recognizing “danger in allowing unreliable or speculative information (or ‘junk science’) to go before the jury with the weight of an impressively credentialed expert behind it,” expressing concern about “depriv[ing] toxic tort plaintiffs of their day in court,” concluding need “to find a balance between these two extremes.”

¹⁹ Rule 702 requires that the proffered expert witness be “qualified as an expert by knowledge, skill, experience, training or education.” Although courts have been generally liberal in passing on the qualifications of expert witnesses to render an opinion, there appears to be some tightening of requirements since

challenging the admissibility of expert opinion testimony are reliability and relevance.

Reliability

Reliability is now the most important prerequisite for the admissibility of expert testimony, and derives from the desire to prevent “junk

the *Daubert* trilogy and amendments to Rule 702 that demand that experts be qualified in the specific issue before the court. *See, e.g.*, Barbara Jacobs Rothstein, *Opinion and Expert Testimony in Federal and State Courts*, SL084 ALI-ABA 189 (Feb. 23–24, 2006) at 198 & n.1573; *Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 303 (6th Cir. 1997), *reh’g and reh’g en banc denied*, 1997, (in a case involving a defective seat belt, the Sixth Circuit reasoned that “[w]hen making a preliminary finding regarding an expert’s qualifications. . . , the court is to examine ‘not the qualifications of the witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.’”); *U.S. v. Brown*, 415 F.3d 1257, 1269 (11th Cir. 2005), quoting *U.S. v. Brown*, 279 F. Supp. 2d 1238, 1244–45 (S.D. Ala. 2003) (refusal in a criminal drug case to qualify a witness as an expert regarding whether 1,4-butanediol and gamma hydroxybutyric acid (“GHB”) were chemical analogues for purposes of controlled substances laws, finding that his “academic work and professional experience related more to plant pathology and botany than chemistry,” he had “only worked with 1,4-butanediol and GHB ‘on isolated projects’ and [] ‘he does not possess a license to work with controlled substances.’”). *See also* *In re TMI Litig.*, 193 F.3d 613, 683 (3d Cir. 1999) (affirming the trial court’s exclusion of plaintiff’s retained expert on specific causation because the expert was not a medical doctor), *amended by* 199 F.3d 158 (3d Cir. 2000); *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672 (W.D. Tex. 2002) (excluding expert’s testimony that acne drug caused psychiatric injury because, though he held himself out as a pharmacologist, expert had no degree in pharmacology and had conducted no clinical research); *Plourde v. Gladstone*, 190 F. Supp. 2d 708 (D. Vt. 2002) (holding toxicologist not competent to perform “differential diagnosis”), *aff’d*, No. 02-9136, 2003 WL 21511764 (2d Cir. June 27, 2003); *Magdaleno v. Burlington N. R.R.*, 5 F. Supp. 2d 899 (D. Colo. 1998) (holding non-physician ergonomist unqualified to opine as to cause of plaintiff’s carpal tunnel syndrome); *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 19 & n.30 (D. Mass. 1995) (holding epidemiologist unqualified to testify as to specific cause of a person’s disease).

science” from reaching the courtroom and the jury. See *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 190 (S.D.N.Y. 2005). Defense challenges to reliability fall into three broad categories: (1) the *foundation* upon which the expert bases the opinion; (2) the *methodology* used by the expert to analyze the foundational data; and (3) the *nexus* drawn between the results of the analysis and the ultimate opinion. Each type of challenge (e.g., insufficiency of the data set chosen as a foundation for the opinion testimony) applies to multiple bases for the challenge (e.g., epidemiological studies that fail to demonstrate general causation or inability to prove the dose necessary to establish specific causation).²⁰

The *Federal Reference Manual on Scientific Evidence* can assist the defense practitioner in understanding how to analyze the underlying data, processes and methodologies used by experts to determine whether opinion testimony can withstand challenges to its reliability and admissibility.²¹ In planning a challenge to the reliability of expert testimony,

²⁰ See *Kumho*, 526 U.S. at 149 (concluding that a court must determine the reliability of expert testimony, “where such testimony’s factual basis, data, principles, methods, or their application are called sufficiently into question...” (citing *Daubert*, 509 U.S. at 592)). For a good discussion of these issues from a judge’s perspective in the context of the *Daubert* standard for admissibility, see Judge Harvey Brown, *Procedural Issues Under Daubert*, 36 HOU. L. REV. 1133 (1999) (hereinafter “*Brown on Procedural Issues*”). As noted above, *Daubert* and its progeny provide no definitive guidance for how the trial court should determine the expert opinion’s reliability, but establish four factors to be used as guides in its evaluation. See *supra*, note 14.

²¹ See generally *Reference Manual on Scientific Evidence* (Federal Judicial Center (2d ed. 2000) (hereinafter referred to as “*Scientific Reference Manual*”). In anticipating the need for expert testimony and therefore the need to mount a challenge to it, advance planning is essential. Early in the case, a defense counsel should consider the potential need for, and types of, expert testimony the practitioner might expect, understand the scientific underpinnings of the case and therefore the likely testimony (and establish whether there has been a judicial determination that the substance in question causes the disease at issue), and expeditiously do due diligence on the experts the plaintiff selects. This timely preparation will facilitate successful challenges to plaintiff’s expert testimony.

counsel must appreciate that the scientific community may perceive the strength and reliability of certain elements of the foundation for an expert's opinion very differently than the legal community.²² For example, the scientific community may not be as dismissive of the value of animal studies to the issues of medical causation as are certain courts.²³

Courts have broad discretion to determine the reliability of expert testimony using the *Daubert* factors and other sets of reasonable criteria, in light of the specific facts and circumstances in a particular case. See *Kumho*, 526 U.S. at 156–58. Because a single flaw in an expert's foundation generally will not warrant blanket exclusion of an opinion as unreliable, the practitioner should consider the advantages and disadvantages of raising all credible and reasonably demonstrable foundational flaws.²⁴

Is the foundation sound?

The asserted foundation for an expert's opinion presents multiple opportunities for challenge. The foundation encompasses the “hard” data on which the expert's opinion rests, in addition to various assumptions made, and the methodology into which both the data and assumptions must reasonably fit. Under Rule 702, the expert's testimony must rest on reliable data and a reliable methodology. See FED. R. EVID. 702. “[T]here must be a link between the fact or data the expert has worked with and the conclusion the expert testimony is intended to support.”

²² For a thoughtful discussion of differences between how scientists and judges consider foundational issues, such as the use of animal and cases studies as opposed to statistically significant epidemiological studies, in challenging the reliability of causation evidence and expert opinion, see Cranor, C., *Scientific Inferences in the Laboratory and the Law*, 95 AMER. J. PUB. HEALTH S121 (Supp. 1, 2005) (hereinafter “*Scientific Inferences*”).

²³ See generally *Scientific Inferences* at S122.

²⁴ Some commentators argue for the need for more uniformity in the level of scrutiny and burden of proof required to establish the reliability of expert testimony. At least one commentator argues that expert testimony should only be excluded based on lack of reliability if the flaw in the methodology is material. See generally John Hein, *When Reliable is Reliable Enough: The Use of Expert Testimony After Kumho Tire v. Carmichael*, 6 WASH. U. J.L. & POL'Y 223, 247 (2001) (hereinafter “*Reliable Enough*”).

See *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997). (“A court may conclude there is simply too great an analytical gap between the data and the opinion proffered.”).

Threshold questions related to the reliability of such fundamental data are: (1) whether the data are of the type typically relied upon by experts in the field in which this expert is rendering an opinion; (2) whether the data are insufficient, incomplete or inaccurate in any way; and (3) whether the data appropriately relate to, and actually support, the subject of the expert’s opinion. If the foundational data are unreliable, the expert will not be allowed to base an opinion on them because any opinion based on unreliable data is likewise unreliable. See, e.g., *Allgood v. Gen. Motors Corp.*, No 102CV1077 DFHTAB, 2006 WL 2669337 at *4–10 (S.D. Ind. Sept. 18, 2006) (excluding expert opinion regarding causation because of selection bias).

The topic of the *disease* at issue alone raises multiple potential areas of challenge. For example, proof of general causation in a toxic tort case—where the injury alleged to have occurred as the result of a toxic exposure is a form of cancer—typically requires that the pertinent expert testimony include studies which demonstrate that specific Agent A can cause specific Cancer Y. Some areas to challenge include: (1) the type of studies relied upon to prove that exposure to chemical A can cause Cancer Y: epidemiologic studies, animal bioassays, *in vitro* experiments; (2) the strengths and weaknesses of how the studies were designed and conducted; (3) the actual results of the studies: the reported finding of an association between Agent A and Cancer Y (positive, negative or none); and (4) the strength and statistical significance of the results.²⁵ If an expert undertakes his own study rather than rely-

²⁵ See *Scientific Reference Manual (Reference Guide on Epidemiology)* at 333–38. See also *Lust v. Merrell Dow Pharms.*, 89 F.3d 594, 597–98 (9th Cir. 1996) (holding that an expert’s reasoning, which concluded from the fact that the drug in question caused some types of birth defects that it also caused hemifacial microsomia, was not scientific). The *Lust* court noted that the expert’s testimony “was influenced by litigation-driven by financial incentive” and that the expert’s premise was not recognized by even a “relevant minority.” *Id.*

ing on studies published in the peer-reviewed scientific literature, questions may be raised as to the completeness of data used in the study, and the nature of the study population (does it include persons whose ages differ significantly from the plaintiff, are of different races and genders and have risk factors which the plaintiff does not). *See, e.g., Allgood*, 2006 WL 2669337 at *11 (holding selection bias rendered expert testimony on risk of cancer inadmissible.)

Examples—epidemiological studies

Epidemiology is the study of the incidence, distribution and cause (etiology) of disease in humans. Epidemiological studies attempt to determine the cause of disease as precisely as possible. Courts routinely address epidemiological studies as the basis for an expert opinion that a certain agent caused the disease at issue.²⁶ However, care must be taken to accurately understand and represent the weight of epidemiological evidence. Although an epidemiological study may find an association between an agent and a disease, that association does not necessarily mean that exposure to the agent caused the disease, whether for scientific or legal purposes.

Epidemiological studies raise three issues that impact their reliability as bases for expert testimony: (1) whether the results of the study reveal an “association” between the disease and agent at issue; (2) whether errors in the study may have contributed to inaccurate results; and (3) if the agent at issue is associated with the relevant disease, whether that association is causal—namely, did the agent actually cause the disease.²⁷

Courts routinely praise the utility of sound epidemiological studies in toxic tort cases, and exclude expert testimony not based on such studies, especially where a substantial group of studies exist. For example, the Tenth Circuit recently stressed in *Norris v. Baxter Healthcare Corp.*, one in a series of silicone breast implant cases, that

[E]pidemiology is the best evidence of general causation in a toxic tort case... While the presence of epidemiology does not necessarily end

²⁶ *Scientific Reference Manual (Reference Guide on Epidemiology)* at 335.

²⁷ *Id.* at 337.

the inquiry, where epidemiology is available, it cannot be ignored. As the best evidence of general causation, it must be addressed. 397 F.3d 878, 882 (10th Cir. 2005) (citations omitted) (hereinafter referred to as “*Norris*”).²⁸ In upholding the trial court’s exclusion of the testimony of two plaintiff experts, the appeals court noted that those experts ignored epidemiological studies that found no link between exposure to silicone breast implants and systemic autoimmune disease. *Id.* at 884.²⁹ This omission rendered the experts’ methodology not “medically and scientifically valid... [and their] opinions... reliably grounded in the knowledge and experience of their discipline.” *Id.* (citing *Daubert*, 509 U.S. at 592–93).

Conversely, courts have rejected expert testimony based upon an insufficient number of valid epidemiological studies. For example, in *Merrell Dow Pharms., Inc. v. Havner*, a suit alleging a link between Bendectin and limb reduction birth defects, the Texas Supreme Court found that an isolated study finding a statistically significant association between ingestion of that prescription drug and limb defects was legally insufficient to prove causation. 953 S.W.2d 706, 722 (Tex. 1997). It reasoned that, “it is important that any conclusions about causation be reached only after an association has been observed in studies among

²⁸ Accord, *Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) (trial court properly excluded expert testimony for failing to use valid, statistically significant epidemiological studies showing ethylene oxide associated with brain cancer; quoting *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 [products liability] case is epidemiological studies”); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (lack of epidemiological studies a determinant factor in addressing reliability of expert testimony); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1484 (D.V.I. 1994) (excluding plaintiffs’ expert testimony for failure to rely on valid epidemiological studies finding an association between asthma medication and birth defects).

²⁹ Accord, *Grant v. Bristol Myers Squibb*, 97 F. Supp. 2d 986, 992 (D. Ariz. 2000).

different groups and that the association continues to hold when the effects of other variables are taken into account.” *Id.* at 727.³⁰

In *Blum v. Merrell Dow Pharms., Inc.*, another Bendectin case, a Pennsylvania state trial court also noted that “[r]eplicated epidemiological studies consistently finding a strong association are necessary to find causation. . .” 705 A.2d 1314, 1323 (Pa. Super. Ct. 1997).³¹ In short, the reliability of an expert’s testimony can be successfully challenged based on the failure to distinguish opposing epidemiological studies, or failure to rely on any, or an insufficient number of, relevant epidemiological studies.

Testimony based on improper extrapolations from epidemiological studies can also be effectively challenged. Expert opinions based on studies that address the relationship between *diseases* and *agents* different from those at issue in the litigation are vulnerable to exclusion. *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 781–83 (10th Cir. 1999), presents both grounds as bases for the exclusion of expert testimony. There, the Tenth Circuit upheld the trial court’s exclusion of expert testimony that relied on studies of benzene, rather than the specific chemicals at issue in the case (toluene, xylene, hexane and haptene). *Id.* The court also affirmed the trial court’s exclusion of the plaintiff’s expert’s testimony because the studies on which the expert related to a disease other than the one at issue in the litigation (chronic myelogenous leukemia as opposed to acute myelogenous leukemia).³² *See id.*

³⁰ Indeed the court found that “if scientific methodology is followed, a single study would not be viewed as indicating that it is ‘more probable than not’ that an association exists. *See, e.g.*, *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 802 n. 10 (D.D.C. 1986) (noting that no single study would be sufficient to exonerate or to implicate Bendectin with certainty and that studies become ‘conclusive’ only in the aggregate, *aff’d*, 857 F.2d 823 (D.C. Cir. 1988).” 953 S.W.3d at 727.

³¹ The ability to replicate research results is the hallmark of a sound finding of causation based on epidemiological proof. *See Scientific Reference Manual (Reference Guide on Epidemiology)* at 377.

³² *Compare also* *Cavallo v. Star Enter.*, 892 F. Supp. 756, 766 (E.D. Va. 1995) (Rule 702 requires “that the expert demonstrate a scientifically valid basis for projecting the findings of a study identifying a different chemical-

Similarly, in *Siharath v. Sandoz Pharm. Corp.*, a federal trial court excluded expert testimony where the plaintiffs' experts attempted to extrapolate causation from studies of a class of drugs—ergot alkaloids—rather than the specific drug at issue in this case, Parlodel. In addition, the disease reflected in the studies was ischemic stroke (the result of insufficient blood supply to the brain), whereas the injury at issue in the litigation was a hemorrhagic stroke (the result of a ruptured blood vessel in the brain). The court found, “[s]ignificant physiological distinctions exist between ischemic and hemorrhagic strokes.” The plaintiffs’ experts presented no evidence that ergot alkaloids caused hemorrhagic strokes. In short, the court excluded the proffered expert testimony because both the agent and the disease at issue were not the same as those discussed in the studies on which the plaintiffs’ experts relied. 131 F. Supp. 2d 1347, 1365 (N.D. Ga. 2001).

Courts also have rejected expert testimony purposefully based on epidemiological studies where the disease studied is different from the one that is the subject of the litigation, even where the chemicals are the same. For example, the Texas Supreme Court in *Havner* reflected a basic tenet of acceptable methodology that, to be reliable, expert testimony regarding causation must be grounded in appropriate epidemiological studies that address the specific disease at issue in the litigation. In *Havner*, although the agent at issue, Bendectin, had been shown in published epidemiological studies to cause certain birth defects, the defects in the studies were not the same that in the litigation, namely limb reduction. Thus, the court stressed that “[t]hese studies cannot of course support a finding that Bendectin causes *limb reduction defects*.” *Havner*, 953 S.W.2d at 725 (emphasis in original).

And studies concerning different forms of cancer cannot be used interchangeably; cancer is not one disease but a collection of different

illness relationship to the proffered causal theory.”), *aff'd in part, rev'd in part on other grounds*, 100 F.3d 1150 (4th Cir. 1996), *cert. denied*, 522 U.S. 1044 (1998) and *Savage v. Union Pac. R.R. Co.*, 67 F. Supp. 2d 1021, 1038 (E.D. Ark. 1999) (whether coal exposure in general can cause basal cell carcinoma differs from whether exposure to creosote can cause it).

diseases with different causes.³³ Thus, in *Savage v. Union Pac. R.R. Co.*, a case involving claims that exposure to creosote caused the plaintiff's basal cell carcinoma, the court rejected the opinion of the plaintiff's expert based on "articles dealing with exposure to hydrocarbons and skin cancer generally." The court found that "these articles are of little use [to causation] because they do not deal with the specific situation presented here [in that case]. *One simply cannot assume that just because a substance causes a particular kind of cancer, it will cause another type.* There has to be some sort of scientific evidence linking the particular cause and the particular effect, and as described above, that evidence is lacking in this case." 67 F. Supp. 2d 1021, 1036 (E.D. Ark. 1999) (emphasis added). Thus, the court held the expert's opinion was inadmissible as unreliable.³⁴

Courts also routinely exclude expert testimony based on epidemiological studies involving chemicals not at issue in the litigation. For example, in *Lofgren v. Motorola, Inc.*, an Arizona state court following *Frye* refused to admit expert testimony based on studies concerning unrelated chemicals. The court reasoned that:

It does not appear to be generally accepted methodology amongst scientists to base a causation opinion about TCE on studies of other chemicals. It is apparently well known that small differences in chemicals and molecular structure can and do result in substantial differences in toxicity and carcinogenicity... Thus, it does not appear to be generally accepted methodology to argue by analogy under the circumstances of this case.

1998 WL 299925 (Ariz. Super. June 1, 1998) at 22 (citations omitted).

³³ See David Schottenfeld & Joseph F. Fraumeni, *Cancer Epidemiology and Prevention* 80 (1996) ("Cancer is a complex family of diseases... From a clinical point of view, cancer is a large group of diseases, perhaps up to a hundred or more, that vary in their age at onset, rate of growth, state of cellular differentiation, diagnostic detectability, invasiveness, metastatic potential, prognosis and responses to various therapeutic modalities.")

³⁴ See also *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) (holding studies suggesting chemical exposure causes lymphatic and hematopoietic cancer not probative to cause of brain cancer.)

Expert opinion based on epidemiological studies plagued by inadequate quality or methodologic deficiencies also raise admissibility issues. Because the execution and interpretation of epidemiological studies are multifaceted and complex, there are numerous ways in which the quality of an epidemiological study, and hence its conclusions, can be questioned. Those challenges range from the strength of the results related to causation³⁵ to the confidence that the results are real (as opposed to error or chance). Reported study results can also be due to bias. Errors in execution can derive from the selection of study participants, as well as how and what information was obtained from them.

Studies that fail to provide statistically significant conclusions or measure whether the results are due to error or chance are subject to challenge and exclusion.³⁶ A statistical significance determination is required to evaluate the strength of the study's results and to exclude the possibility that the outcome is the result of random chance or error.³⁷ Courts have routinely excluded expert testimony based upon epide-

³⁵ The strength of an association between an agent and a disease can be measured in a number of ways, one of the most common is called a "relative risk" ("RR"). The RR is a ratio that compares those people exposed to an agent to the non-exposed population to determine if the chance of developing the disease is greater in the exposed versus non-exposed populations. For an exposure to be considered to "cause" the disease in question, the RR has to be more than 2. A lower RR indicates that the risk of contracting the disease from the exposure at issue is either 50/50 (if the RR is 2.0) or none at all (if the RR is 1.0). See *Scientific Reference Manual (Reference Guide on Epidemiology)* at 348–49.

³⁶ In statistics, a result is called significant if it is unlikely to have occurred by chance. For an extensive explanation of the scope and use of epidemiological studies in litigation, see *Scientific Reference Manual (Reference Guide on Epidemiology)*.

³⁷ *Scientific Reference Manual*, at 356. Significance analysis includes a determination of the confidence interval into which the results of a study fall. If the confidence interval includes the number 1.0 or if the range of the interval is too wide, e.g., 1.9–135.4, these factors undercut the validity of the study results. As one court found, "[i]f the confidence interval is so great that it includes 1.0, then the study will be said to show no statistically sig-

miological studies reporting conclusions that were not statistically significant. *See, e.g., Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 312 (5th Cir. 1989); *Norris*, 397 F.3d at 887 (“We cannot allow the jury to speculate based on an expert’s opinion which relies only on clinical experience in the absence of showing a consistent, statistically significant association between breast implants and systemic disease.”). *See also Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 691 (W.D.N.C. 2003) (“[E]pidemiological data cannot support an inference that a suspected risk factor caused an injury unless... the analysis of the data is statistically significant under scientifically accepted statistical norms...”).³⁸

In *Wade-Greaux v. Whitehall Labs., Inc.*, the court excluded expert testimony because of serious flaws in the quality of the pertinent epidemiological studies, including failure to submit “repeated, consistent epidemiologic studies” supporting the experts’ conclusions, and failure to submit studies finding a statistically significant association between limb defects and the use of any ingredients in the agents at issue in the litigation. 874 F. Supp. 1441, 1456, 1466–68 (D.V.I. 1994). In addition, the court observed significant caveats in the studies relied upon by the experts, which undermined them as support for the experts’ position. For example, one study “cautioned that, because of significant confounding factors, additional questions needed to be ‘answered before drawing even tentative conclusions about the teratogenicity [*i.e.*, the ability to cause birth defects] of vasoactive medications.’... ‘We were not able to rule out whether an underlying illness, perhaps an influenza virus, could have accounted for the finding, or for the elevated risks for analgesic/antipyretic use. There may be confounding by other factors, such as cocaine use.’”³⁹ *Id.* at 1456. The court found that, for other studies, “each has express limitations and cautions which advise that one should not rely upon their

nificant association between the factor and the disease.” *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 312 (5th Cir. 1989).

³⁸ *See also Relative Risk Greater than Two in Proof & Causation in Toxic Tort Litigation*, 41 JURIMETRICS J. 195–209 (2000).

³⁹ A “confounding factor” masks actual associations or falsely demonstrates an apparent association between variables where no real association between them exists.

observations as conclusions.” *Id.* at 1468. In sum, flaws in both the subject matter and quality of underlying epidemiological studies can cause a court to exclude expert testimony as unreliable.

Examples—animal studies

Grounds for challenge also exist where animal studies are relied upon to prove the alleged toxicity to humans of the agent in question. “[L]aboratory animal studies are generally viewed with more suspicion than epidemiological studies, because they require making the assumption that chemicals behave similarly in different species.” See *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223, 1241 (E.D.N.Y.1985), *aff’d*, 818 F.2d 187 (2d Cir.1987), *cert. denied*, 487 U.S. 1234, 108 S. Ct. 2898, 101 L. Ed. 2d 932 (1988). “Because of the dose-response differential between animals and humans... extrapolating to humans from animal studies is problematic.” *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 646 n. 12 (8th Cir. 1994). A court, therefore, is likely to require proof that the species studied is an appropriate model for the human disease in question, and that the animal data can be otherwise appropriately extrapolated from animals to humans.⁴⁰ The testimony of an expert who relies only on such animal studies should be challenged as unreliable. See *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997) (holding animal studies showing one type of cancer in mice to establish causation of another type of cancer in humans presented “too great of an analytical gap between the data and the opinion offered”).

In *Bourne ex rel. Bourne v. E.I. Dupont de Nemours and Co., Inc.*, 189 F. Supp. 2d 482, 496 (S.D. W. Va. 2002), the court excluded expert testimony linking a fungicide, Benlate, with birth defects based solely on studies of live animals and with animal cells.⁴¹ The court explained that

⁴⁰ For a broad analysis of emerging issues related to scientific evidence, see Barbara Jacobs Rothstein, *Opinion and Expert Testimony in Federal and State Courts*, SL084 ALI-ABA 189 (Feb. 23–24, 2006).

⁴¹ Primates are believed to render the most reliable results with respect to extrapolation of the results to humans, followed by other mammals, then birds, followed by reptiles. See Erica Beecher-Monas, *The Heuristics of Intellectual Due Process: A Primer for Triers of Science*, 75 N.Y.U.L. REV.

the “extrapolations of [plaintiffs experts], from high-dosage, single species *in vivo* testing and lengthy benomyl exposure *in vitro* testing, to conclude that benomyl is a human teratogen and to establish the levels at which it is alleged to be teratogenic, are neither reliable, pursuant to the first prong of *Daubert*, nor relevant, under the second prong.” *See id.*

In *Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996), the Fifth Circuit upheld the district court’s ruling that the plaintiffs’ experts were not qualified to render an opinion that ethylene oxide caused the plaintiff’s cancer. The court discussed the limited usefulness of studies conducted on rats, noting that other studies in mice did not show an association between exposure and cancer. *Id.* *See also Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 311 (5th Cir. 1989) (noting the very limited usefulness of animal studies to questions of toxicity); *Valentine v. PPG Indus.*, 821 N.E.2d 580, 593 (Ohio App. 1994) (“In order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate to humans. . .”). *See, e.g., Raynor v. Merrell Pharms., Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997) (concluding it was not methodologically sound for experts to draw inference from chemical structure studies, *in vivo* animal studies, and *in vitro* studies, that Bendectin caused human birth defects, when epidemiological evidence was to the contrary); *Lynch v. Merrell-Nat’l Labs.*, 830 F.2d 1190, 1195–97 (1st Cir. 1987) (analysis of chemical structure and effect on animals incapable of proving causation in human beings in the absence of any confirmatory epidemiological data).

Example—dose

Expert opinions regarding the agent at issue in the case, including the dose that the plaintiff allegedly received, have also been challenged as unreliable. Authorities exist on both sides of the “dose” issue. For example, a Minnesota state court excluded the testimony of two expert witnesses for the plaintiffs where they could not determine the plaintiffs’

1563, 1608 (2000) (citing Larry C. Gilstrap & Bertis B. Little eds, *Drugs and Pregnancy* 9 (2d ed. 1998) (noting that “nonhuman primates are better predictors than are nonprimate models because they are phylogenetically close to humans”)).

precise dose. *See Goeb v. Tharldson*, No. CX-98-2275, 1999 WL 561956 (Minn. App. Oct. 21, 1999). Indeed, even where one expert clearly explained his thorough methodology, the court still excluded his testimony as insufficiently reliable. *See id.*; *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995) (holding expert's reconstruction of the plaintiff's exposure to ionizing radiation "not science, but a figment of convenient invention").

On the other hand, the Fourth Circuit overturned the exclusion of expert testimony related to an injury based on inhalation of chemicals in spray paint, finding that precise exposure data was unnecessary where there was evidence that the exposure (whatever it was) was harmful and that the plaintiff was exposed.⁴² Thus, it may be problematic in some courts to argue that, in order to be reliable and thus an acceptable ground for expert testimony, dose determinations are essential and must be precise. For example, in *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 928 (8th Cir. 2001), the Eighth Circuit held that it is not necessary that an expert quantify the amount of the substance to which the plaintiff was exposed in order to demonstrate that she was exposed to a toxic level. Rather, the court found it sufficient for a plaintiff to prove that she was exposed to a quantity of the toxin that exceeded safe levels. *See id.*; *City of Greenville v. W.R. Grace & Co.*, 827 F.2d 975, 980 n. 2 (4th Cir. 1987) (admitting expert testimony that "in the absence of scientific studies concerning exposure to low levels of asbestos, one technique accepted in the scientific community for predicting the risks associated with low-level exposures is to extrapolate the risk downward from results obtained in studies involving high level exposures").

⁴² For a full discussion of these cases and others as examples of challenges to the reliability of expert testimony, *see Reliable Enough* at 231–36, comparing *Goeb v. Tharldson*, No. CX-98-2275, 1999 WL 561956 (Minn. App. Oct. 21, 1999) with *Anderson v. Quality Stores, Inc.*, No. 98-2240, 1999 WL 387827 (4th Cir. June 14, 1999). This article argues for less precision in the information required of an expert for his testimony to be considered reliable. On the other hand, practitioners attempting to exclude plaintiff's expert testimony should argue for the most precision possible to ensure reliability.

However, in a case alleging that exposure to benzene in gasoline caused the plaintiff's acute myelogenous leukemia, the New York Court of Appeals recently affirmed the exclusion of expert testimony suggesting that, while an expert need not "pinpoint exposure with complete precision," there should be "a scientific expression of [the plaintiff's] exposure level." *Parker v. Mobil Oil Corp.*, 2006 WL 2945397 at *8 (N.Y. Oct. 17, 2006).

To avoid issues of dose, plaintiffs may try to argue the "no safe threshold" or "linear model" predicated on the notion that any exposure to a toxic substance is harmful. For example, in *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996), the plaintiff argued that, because one molecule of aflatoxin could cause cancer, he need not prove the level of exposure required to cause laryngeal cancer. The court disagreed, observing: "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." *Id.* at 198.

Likewise, in *Sutera v. The Perrier Group of Am.*, 986 F. Supp. 655, 660 (D. Mass. 1997), the plaintiff argued that chronic, life long exposure to low levels of benzene caused his acute promyelocytic leukemia ("APL"). *Id.* The court rejected the "no threshold" model, and held that the plaintiff's expert was not qualified to render an opinion regarding whether the plaintiff's exposure to low doses of benzene caused his illness. *Id.* In addition, in *Nat'l Bank of Commerce v. Associated Milk Producers*, the plaintiff sued a milk supplier alleging that the supplier's contaminated milk caused his laryngeal cancer. 22 F. Supp. 2d 942, 916 (N.D. Ark. 1998). The plaintiff argued that he need not show the level of exposure to the toxic agent necessary to cause laryngeal cancer because one molecule of the toxic agent could produce alterations in genetic material leading to cancer. The court granted the defendant's motion to exclude the plaintiff's expert testimony. It observed that "[e]stablishing that the risk of causation 'is not zero' falls woefully short of the degree of proof required by *Daubert* and its progeny." *Id.* at 961.

Is the methodology appropriate?

Not only will improper and inadequate foundational data doom expert testimony to limitation or exclusion, use of an improper methodology

is equally fatal.⁴³ Indeed, some courts underscore the need to scrutinize every aspect of the expert's methodology when determining the reliability of the proffered testimony.⁴⁴ In assessing the strength of an expert's methodology, at least three issues merit this scrutiny: whether the expert's analysis displays the "same level of intellectual rigor" that characterizes the actual practice of an expert in the relevant field (*Kumho*, 119 S. Ct. at 1176); whether the expert's analysis and conclusions are consistent with the positions he or she has presented in scholarly and other writings, and in other litigation; and whether the expert's analysis and opinion were written or significantly influenced by the plaintiff's counsel.

Departures from appropriate methodological processes in the scientific discipline at issue should raise red flags about the legitimacy of the expert's opinions. For example, the court in *Lofgren*, in excluding the expert's testimony, found that his extrapolation from studies of different, unrelated chemicals is not accepted methodology in the field of epidemiology, especially where no scientific and appropriate basis exists for doing so.⁴⁵ Even more significantly, the court in *Lofgren* criticized the plaintiff experts' handling of various studies as support for their theory, held the methodology they used was unreliable, and stated that,

relying on some low-dose studies as positive while judging findings of high-dose cohort studies as weak, inconsistent, non-specific, and 'negative' *i.e.*, those which were inconsistent with the proposition that TCE causes cancer in humans, is *not simply a difference in expert judgment; it is a serious methodological flaw* and demonstrates that... [the expert's] opinions were not based on data or methodology generally accepted by experts in the field as reliable...

⁴³ Although some flaws in the expert testimony may relate solely or primarily to the foundational data on which the expert rests his opinion, frequently there is an overlap between inadequacies in the foundational data and flaws in the methodology applied to that data.

⁴⁴ *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1401 (D. Ore. 1996) ("This court need not and should not ignore any step in that process, but must ensure that in each step, from initial premise to ultimate conclusion, the expert faithfully followed valid scientific methodology.").

⁴⁵ 1998 WL 299925 at *17.

Lofgren, 1998 WL 299925, at *23 (emphasis added).⁴⁶ See also *Frias v. Atl. Richfield Co.*, 104 S.W.3d 925, 930 (Tex. App. 2003) (holding that where an expert opinion as to causation is based on studies conducted by others, the underlying studies supporting conclusion must be scientifically reliable in order for the opinion to be reliable).

Professional and scholarly writings of an expert inconsistent with his litigation position are also likely indicative of a divergence from acceptable methodology. Due diligence in reading the expert's prior published materials may reveal that positions adopted there are contrary to the testimony. Since these works were, in many instances, peer-reviewed before publication, such inconsistencies suggest either sloppy analysis or purposeful divergence from previous methodologies and positions. Both of these possibilities suggest the expert is utilizing an inappropriate methodology in an effort to advance the plaintiff's litigation strategy. In *Burleson v. Glass*, 268 F. Supp. 2d 699, 705 (W.D. Tex. 2003), for example, the plaintiffs' causation expert was excluded in part where the plaintiffs' theory that welding rods caused cancer had never been tested and was never subjected to peer review.

Indeed, to the extent it is demonstrated in discovery that the expert's opinion or report was significantly drafted, or its contents influenced, by the plaintiff counsel should suggest that it may also represent inappropriate deviations from the expert's typical methodology and/or intellectual rigor. This, in turn, indicates bias and undercuts the legitimacy of the expert's opinion. See *Solaia Tech. v. ArvinMeritor, Inc.*, 361 F. Supp. 2d 797 (N.D. Ill. 2005) (striking portions of an expert report where they contradicted the expert's prior sworn testimony in his deposition).

**Is there a rational nexus between the data/
methodology and the expert's conclusions?**

In addition to utilizing an appropriate foundation and methodology, an expert's opinion must exhibit a rational nexus between those

⁴⁶ For a discussion of the "intellectual rigor" standard as compared to *Frye's* "generally accepted" standard, see Margaret A. Berger, The Supreme Court's Trilogy on the Admissibility of Expert Testimony, in *Scientific Reference Manual* at 23–26.

two components and the expert's ultimate opinion. As several courts have stated, a reliable and therefore admissible expert opinion cannot have "too great an analytical gap between the data or observations and the expert's conclusions." *Joiner*, 522 U.S. at 146.⁴⁷ For example, in the silicone breast implant litigation, the Tenth Circuit affirmed the trial court's exclusion of expert testimony, noting that,

The district court did not abuse its discretion in exercising its *Daubert* gatekeeping role. 'Although it is *not always a straightforward exercise to disaggregate method and conclusion*, when conclusion simply does not follow from the data, a district court is free to determine that an impermissible analytical gap exists between premises and conclusion.' *Bitler [v. A.O. Smith Corp.]*, 391 F.3d [1114 (10th Cir. 2004)] at 1121 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *Dodge [v. Cotter Corp.]*, 328 F.3d [1212 (10th Cir. 2003)] at 1222; *see also Bragdon v. Abbott*, 524 U.S. 624, 653 (1998) ('Scientific evidence and expert testimony must have a traceable, analytical basis and objective fact before it may be considered on summary judgment.') (citing *Joiner*, 522 U.S. 136, 144–46 (1997)). Although '[t]rained experts commonly extrapolate from existing data,' neither *Daubert* nor the Federal Rules of Evidence 'require[] a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert.' *Joiner*, 522 U.S. at 146. 'A court may conclude that there is simply too great of an analytical gap between the data and the opinion proffered.' *Id.*

Norris v. Baxter Healthcare Corp., 397 F.3d 878 (10th Cir. 2005). In *Norris*, the court found that the plaintiff's experts ignored a substantial body of epidemiological studies at odds with their opinion that silicone breast implants caused systemic autoimmune disease, while favoring anecdotal clinical observations and differential diagnosis. As such, the court concluded, consistent with the trial court, that '[p]laintiff's

⁴⁷ *See Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 782 (10th Cir. 1999) (exclusion of expert opinion and dismissal of suit by warehouse worker alleging exposure-related chronic myelogenous leukemia affirmed, court noting no scientific data that chemicals in question caused injury and no appropriate extrapolation from similar chemicals or disease).

expert's opinions were not reliably grounded in the knowledge and experience of their discipline... [and] [t]he foundational evidence that the doctors relied upon do not reach conclusions based on accepted scientific methodology." *Id.* at 884–85. In short, although the line between the expert's methodology and conclusion may blur, a court can legitimately reject both where there are disconnects between the data, the methodology and the conclusion that are unsupported, unjustified and unexplained other than perhaps by whim or bias.

Relevance

In addition to being reliable, expert opinion testimony must also be relevant.⁴⁸ For purposes of Rule 702, relevance means the expert's testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702. The notion of relevance also encompasses whether the expert testimony "fits" the facts of the case. *Daubert*, 509 U.S. at 591. Although more challenges to expert opinion may rest on the reliability prong of an admissibility determination, relevance must still be scrutinized. There may be overlap between the issues of how the methodology is utilized to lead to the conclusions that form the basis for the expert testimony and of its relevance to the case at bar.

In *Siharath*, a medical product liability case, the court excluded the plaintiffs' experts and granted summary judgment for the defendants, noting that:

The final element of admissibility, set forth in *Daubert*, is an appropriate relevance, or 'fit,' between the expert's opinion and the facts of the case... Scientific testimony does not assist the trier of fact unless the testimony has a valid scientific connection to the pertinent inquiry... There is no 'fit' where there is 'simply too great an ana-

⁴⁸ FED. R. CIV. P. Rule 402 dictates that all relevant evidence is admissible unless otherwise provided by law. The definition of "relevant evidence" is found in Rule 401, which defines it as evidence having "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." *Bowen v. E.I. DuPont De Nemours and Co.*, 2005 WL 1952859, *8 (Del. Super. June 23, 2005).

lytical gap between data and the opinion offered,' as when an expert offers animal studies showing one type of cancer in laboratory mice to support causation of another type of cancer in humans. 131 F. Supp. 2d at 1352 (citations omitted). There, the court found that the animal studies on which the plaintiff's expert relied did not "fit." The court stressed that the experts were not able to "rule in" the product in question as the cause of the injury, but merely to "rule out" other causes. *Id.* at 1372.

In *Hall v. Baxter*, the court also described the concept of "fit" or relevance using *Daubert*.⁴⁹ There, the court excluded expert testimony on the alleged causal connection between silicone implants and a broad systemic disease:

Even if the proponents meet their burden of establishing that an expert's testimony qualifies as scientific knowledge [*i.e.*, is "reliable"], the court must still exclude the evidence if it does not '*fit*' the matters at issue in the case. *Daubert I*, 509 U.S. at 591, . . . As the Ninth Circuit in *Daubert II*, explained, to '*fit*,' testimony must '*logically advance a material aspect of the proposing party's case.*' *Daubert II*, 43 F.3d at 1315; *see also In re Paoli R.R. Yard PCB Litig.*, 35 F. 3d 717, 743 (3d Cir. 1994). . . .

947 F. Supp. at 1396 (emphasis added). It is unlikely that the issue of relevance will be completely separable from considerations governing the reliability of testimony. Accordingly, it is better to challenge both reliability and relevance to ensure that both issues are scrutinized by the court.

Practical Aspects of Challenging Expert Testimony

Defense counsel should undertake several levels of analysis to ensure that challenges to opposing experts are effective.

Perform Due Diligence on All Plaintiff Experts

It is important to focus on what the expert has really done in the particular field in which the expert seeks to testify. Thus, know the expert's qualifications, including education, experience, reputation in the scientific community, both generally and in his or her specific field of

⁴⁹ 947 F. Supp. 1387 (D. Ore. 1996).

expertise (including special honors, such as induction into the National Academy of Sciences or the Institutes of Medicine), and the scope and subject matter of the expert's bibliography (especially peer-reviewed articles) and scientific presentations. Be particularly careful to read any articles that the expert has written that pertain to the subject matter of the case, namely the disease, agent and scientific methodology at issue. This can be helpful both in determining whether the individual is really an "expert" in the field, and can provide ammunition for a challenge if the expert has taken positions in writings that are inconsistent with the proffered testimony. Obtain copies of any previous testimony. Contradiction of sworn testimony can serve as a basis for impeachment, if not exclusion.

Undertake a Case Litigation Review

Determine whether the expert has had prior testimony excluded in other litigation and identify the grounds for exclusion. This will suggest grounds or strategies for exclusion in a case. In addition, evidence that the expert's testimony was excluded in another case may weigh in your favor with the court in attempting to get similar testimony or other testimony excluded. For example, the Tenth Circuit noted in *Norris* that the testimony of the same witnesses for whose testimony it affirmed exclusion had previously been excluded in other litigation. *See Norris*, 397 F.3d at 886 n. 4 (citing *Bushore v. Dow Corning-Wright Corp.*, No. 92-344-CIV-T-26C, 1999 WL 1116920, at *7 (M.D. Fla. Nov. 15, 1999)).

Determine whether the scientific issues in your case are pending, or have been adjudicated favorably, in another jurisdiction. That information may provide grist for a challenge to similar expert testimony and garner support with the trial judge. Know how your jurisdiction has previously addressed foundational weaknesses such as dose, reliance on animal studies, lack of epidemiology and attempts to use chemical analogies.

Carefully Read the Studies on Which the Expert Bases His or Her Opinion

Make sure that the expert has properly characterized each study and its conclusions. Determine whether the conclusions of the primary studies

are statistically significant. Ensure the studies actually support the proposition for which the expert cites it.

It is critical that you understand the strength of the conclusions reached in the study. For example, does the study find an association between exposure to the specific agent and specific disease, and if so, is it a positive association rather than a neutral or negative association, and is the association strong or weak. Keep in mind, however, that the finding of an “association” does not equate with “causation.”⁵⁰ Equally important, one must focus on the limitations that the study authors report are inherent in their methodology and results. Frequently, the study will highlight areas that it does not discuss, and conclusions that cannot be drawn. If the plaintiff’s expert is attempting to rely on the study to reach the very conclusion that the study itself says it cannot reach, this is a basis to challenge the reliability of the expert’s testimony.

Determine If There Are Other Statistically Significant Epidemiological Studies, and Other Data, That Reach Conclusions Contradicting the Expert’s Opinions

To the extent that “opposing” studies exist, they may undercut both the methodology and conclusions of the plaintiff’s expert. In addition, such studies may provide both a template and support for a challenge to the expert’s proffered testimony.

Scrutinize Carefully All Cited Bases for the Expert’s Testimony

An expert’s reliance on animal or other experimental studies, especially in the presence of contrary epidemiological studies, may well suggest weakness in the foundation for the testimony. An expert’s opinion may also be based on conclusions of another expert—for example exposure modeling or dosage calculations. Do not forget to challenge opinions that predicate their conclusions on other expert opinions that are themselves scientifically unsound.

⁵⁰ For a good discussion of epidemiological studies, see *Scientific Reference Manual* (Reference Guide on Epidemiology), §III.

Don't Forget to Challenge Specific Causation Conclusions

The plaintiffs' experts routinely fail to account for confounding and risk factors such as pre-existing conditions, drug and alcohol use, genetic predisposition and other exposures in developing their opinions. Failure to adequately consider the precise factual circumstances surrounding an individual plaintiff should serve as a ground for excluding an expert's opinion as unreliable.

Consider Hiring Non-testifying Consultants

It is often useful to hire non-testifying experts in the same field to serve as consultants, and to assist in preparation where such assistance can be shielded under the attorney work product doctrine. Their experience and insights can be invaluable in dealing with complex and esoteric matters.

In short, thorough due diligence is a must for any successful challenge to plaintiffs' expert testimony.

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