NO SECOND CHANCES: BEST PRACTICES FOR EXPERT PRACTICE

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I. INTRODUCTION

Strategic rules governing the handling of expert-witness testimony must be revisited in light of the *Daubert* evolution referred to as Daubertization—over the past fifteen years.¹ The risk of losing a post-*Daubert*² admissibility challenge is a daunting threat for trial lawyers and other attorneys practicing in the pretrial trenches where the battle often takes place. Many lawyers who do not consider themselves "trial lawyers" must retool their thinking when dealing with pretrial discovery involving any proposed expert witness where the Federal Rule of Evidence, Rule 104 admissibility proceeding is a virtual trial subject to an abuseof-discretion standard on appellate review.³ This becomes increasingly important as the number and scope of admissibility challenges escalate, as well as when trial courts take judicial notice of prior expert admissibility rulings.⁴ As the Supreme Court has

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^{1.} Infra pts. II–VI (revisiting the strategic rules governing the handling of expert witnesses after Daubert).

^{2.} See Fed. R. Evid. 702 (amending the Federal Rules of Evidence to incorporate Daubert's factors); Daubert v. Merrell Dow Pharms. (Daubert I), 509 U.S. 579 (1993) (establishing the legal standard for admitting expert witness testimony).

^{3.} See Gen. Electric Co. v. Joiner, 522 U.S. 136, 141 (1977) (holding the abuse-ofdiscretion standard applies to appellate review of rulings excluding expert-witness testimony).

^{4.} See e.g. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 151–152 (1999) (noting that the trial judge has discretion to avoid unnecessary "reliability" proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted and requiring "reliability" proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises); U.S. v. Downing, 753 F.2d 1224, 1234 (3d Cir. 1985) (noting "[o]nce a novel form of expertise is judicially recognized, this foundational requirement can be eliminated, as is done when, for example, fingerprint, ballistics, or x-

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admonished, "[i]t is implausible to suggest, post-*Daubert*, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail."⁵

"Best expert evidence" must comply with Federal Rule of Evidence 702, and the burden of satisfying *Daubert* is clearly on the proponent.⁶ Expert witness admissibility issues should be resolved prior to trial, pursuant to Federal Rule of Evidence 104.⁷ A pretrial motion and an appropriate showing that the science is valid are in order.⁸ If the proffer is unsuccessful, and the testimony is precluded, a motion for summary judgment may follow.⁹ Significantly, even if the litigant is successful at the trial level, the appellate court can revisit the expert admissibility issue and reverse, awarding judgment as a matter of law to the appellant.¹⁰ In that respect, success at the Rule 104 proceeding is more critical than at trial, after which litigants may receive a second chance in the event of reversal and remand.

The Supreme Court has upped the ante for all lawyers handling expert-opinion testimony.¹¹ However, in some specific practice areas, *Daubert* has had a measurable effect.¹² This Article revisits the role of expert-witness advocacy in the Age of Dauber-

ray evidence is offered."); *State v. Kinney*, 762 A.2d 833, 841–842 (Vt. 2000) (noting that trial courts can take judicial notice of post-traumatic stress disorder evidence and rape-trauma syndrome evidence without making an independent *Daubert*-reliability determination and explaining that "scientific or technical evidence which is novel to us is frequently not novel to many other state and federal courts... To the extent the evaluation of these courts is complete and persuasive, we can affirmatively rely upon it in reaching our own decision." (citations omitted)).

^{5.} Weisgram v. Marley Co., 528 U.S. 440, 442 (2000) (finding no abuse of discretion in the appellate court's reversal of a jury verdict on *Daubert* grounds without remand for determination of whether plaintiff was entitled to a new trial).

^{6.} U.S. v. Williams, 95 F.3d 723, 729 (8th Cir. 1996) (holding that proponent bears the burden of laying the *Daubert* foundation); *Daubert v. Merrell Dow Pharms. (Daubert* II), 43 F.3d 1311, 1316 (9th Cir. 1995) (precluding the proffered expert testimony after following the Supreme Court's *Daubert* decision to note that on remand the proponent must show that findings are "based on sound science"), cert. denied, 516 U.S. 869 (1995).

^{7.} Fed. R. Evid. 104.

^{8.} Id.

^{9.} Fed. R. Civ. P. 56(e).

^{10.} *Daubert II*, 43 F.3d at 1315 (explaining the appellate court's authority when reviewing a district court's ruling on admitting expert testimony).

^{11.} See generally Daubert I, 509 U.S. 579; Fed. R. Evid. 702.

^{12.} Infra pts. II–VI (discussing the effects of Daubert on Rule 702 admissibility proceedings).

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tization where the Rule 104 proceeding is often the virtual trial and there is no guaranteed second chance to get it right.

II. THE EXPERT–LAWYER CONFERENCE: A CRUCIAL MEETING OF THE MINDS

In 1993, *Daubert* created the application of reliability gatekeeping to "scientific evidence" and sometimes, but not always, to areas of technical and specialized knowledge as well.¹³ With *Kumho*, as reinforced by Federal Rule of Evidence 702 as amended in 2000, this flexible approach to reliability gatekeeping was extended to all areas of expert-opinion testimony.¹⁴ Challenges to the reliability of expert-opinion testimony, which was never before scrutinized as a practical matter, must be anticipated in light of the flexible approach set forth in *Kumho*.

Armed with a working knowledge of the basic law,¹⁵ you must develop a new game plan for handling expert witnesses today. Best practice requires that you engage in a conversation with the expert to determine what *Daubert* factors are relevant in order to translate the expert's opinion into an admissible one.¹⁶ Do not assume the treating physician or even the most seasoned expert is familiar with the factors necessary to provide a foundation for testimony in court. The critical question of whether your expert's opinion is reliable is no longer a matter for the expert; it is a matter for the gatekeeper of the court. Your expert's methodology used to arrive at his or her opinion may be the undoing of your case unless you proceed with extreme caution through the reliability process.¹⁷

Federal Rule of Evidence 104(a) embodies the general common-law doctrine that the judge, not the jury, decides preliminary

^{13.} See generally Daubert I, 509 U.S. 579; Fed. R. Evid. 702.

^{14.} See generally Kumho, 526 U.S. 137.

^{15.} See e.g. Ronald L. Carlson et al., Evidence: Teaching Materials for an Age of Science and Statutes 293–324 (Matthew Bender 2007); Thomas A. Mauet & Warren D. Wolfson, Trial Evidence 287–319 (Aspen Publishers 2005); Charles H. Rose III & James M. Underwood, Fundamentals of Trial Advocacy 243–254 (West 2007); Olin Guy Wellborn III, Cases and Materials on the Rules of Evidence 431–493 (West 2007).

^{16.} E.g. Mauet & Wolfson, supra n. 15, at 292–294 (providing sample Daubert hearings).

^{17.} E.g. id. at 305–308 (providing sample direct examinations for determining an expert's reliability).

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questions of fact under the rules of evidence with a preponderance-of-the-evidence standard governing the determination.¹⁸ Under Rule 702, when evidence is offered as science or on technical matters, the courts must assess its "validity" by reference to multiple factors before any substantive testimony is given.¹⁹ Specifically, the Supreme Court in *Daubert*, drawing on a wide array of sources (from philosophers of science to practicing scientists), crafted what have become known as the *Daubert factors* to guide the trial court in determining evidentiary reliability.²⁰ Simply stated, the following questions, if applicable, should be discussed with your witness concerning his or her theory or technique:

- (1) Can it be (and has it been) tested?
- (2) Has it been subjected to peer review and publication?
- (3) What is the known or potential error rate of the technique?
- (4) Are there standards controlling its operation?
- (5) Can you explicitly identify a relevant scientific community that has accepted this theory? Can you quantify the scope of its acceptance?²¹

The inquiry is "flexible," and admissibility does not require a "yes" answer to each of the factors cited by the *Daubert* Court.²² Failure to address relevant factors, however, is courting disaster in the wake of *Weisgram*, wherein the appellant was awarded judgment

^{18.} Steele v. Taylor, 684 F.2d 1193, 1202 (6th Cir. 1982).

^{19.} Fed. R. Evid. 702.

^{20.} Kumho, 526 U.S. at 153 (extending *Daubert* in scope beyond scientific evidence to embrace all experts when the trial judge determines that one or more factors enumerated in *Daubert* are "reasonable measures of reliability in a particular case"); *Daubert I*, 509 U.S. at 591.

^{21.} Daubert I, 509 U.S. at 589 (ruling that the standard established by *Frye v. U.S.*, 293 F. 1013 (D.C. App. 1923), does not survive the enactment of FRE 702 and that "wide-spread acceptance," a term undefined but arguably less than general acceptance, can be an important factor in the admissibility determination).

^{22.} See e.g. Mark McCormick, Scientific Evidence: Defining a New Approach to Admissibility, 67 Iowa L. Rev. 879 (1982); J. Weinstein & M. Berger, Weinstein's Evidence, 702[3] (1988).

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as a matter of law on appeal because of the appellee's failure to Daubertize the trial experts.²³

Other basic Rule 104(a) preliminary questions include the following: whether a witness is qualified to testify as an expert;²⁴ whether the testimony will assist the trier of fact;²⁵ and whether facts and data the expert relied upon are of a type reasonably relied upon by experts in the field.²⁶ When a judge exercises this gatekeeping function pursuant to Federal Rule of Evidence 104(a), the rules of evidence do not apply.²⁷

A word to the wise: do not assume the trial court will hold a hearing when a *Daubert* challenge is raised. When making a reliability determination under Federal Rule of Evidence 702, the process is within the discretion of the trial court.²⁸ District courts are empowered to make the reliability determination on offers of proof, affidavits, stipulations, learned treatises, testimonials, or other evidence.²⁹ One circuit court made the *Daubert* determination on a record where the challenge to the expert opinion came in a reply brief on a motion for summary judgment.³⁰ And although I

26. U.S. v. Lawson, 653 F.2d 299, 302 n. 7 (7th Cir. 1981).

27. Fed. R. Evid. 104(a).

28. *Kumho*, 526 U.S. at 142 (holding that an abuse-of-discretion standard applies when reviewing a trial court's decision to admit or exclude expert testimony and to the trial court's decision).

29. Downing, 753 F.2d at 1241.

30. Kirstein v. Parks Corp., 159 F.3d 1065, 1067–1069 (7th Cir. 1998). In Kirstein, the court held:

As a preliminary matter, the Kirsteins claim they were entitled to a hearing on the admissibility of the expert opinion pursuant to *In Re Paoli Yard R.R. PCB Litig.*, 916 F.2d 829 (3rd Cir. 1990). We are convinced, however, that the district court had a sufficient basis for her decision without holding a hearing. We have not required that the *Daubert* inquiry take any specific form and have, in fact, upheld a judge's sua sponte consideration of the admissibility of expert testimony. O'Conner v. Cmmw. Edison Co., 13 F.3d. 1090 (7th Cir. 1994)

The Kirsteins say they were not given a chance to respond to Parks' attack on Dr. Nelson because the attack came in reply briefs on the motion for summary judgment. We disagree. . . . The way the issue was presented comes close to sandbagging. But on the facts of this case, we see no abuse of discretion in the way the judge resolved the issue.

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^{23.} Weisgram, 528 U.S. 440.

^{24.} See U.S. v. Diallo, 40 F.3d 32, 34 (2d Cir. 1994) (addressing a witness' qualification to testify as an expert).

^{25.} *Bridger v. Union Ry. Co.*, 355 F.2d 382, 388 (6th Cir. 1966) (explaining that the admissibility of expert-opinion testimony requires an ad hoc determination predicated on the probable value of testimony in relation to the intricacies of the particular suit).

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have argued that only a hearing fully protects the litigants' due process rights,³¹ I temper this view by recognizing that economic restraints may lead some litigants to proceed in alternative ways short of a full-blown hearing.³² However, the proponent of expert opinion proceeds at her peril if she fails to *Daubert*-proof the opinion early on.³³ Today, lawyers must proffer nothing less than their best *Daubert*-proof expert-witness evidence prior to trial.³⁴ The challenge is to present the best in a culture where the deep-pocket will gladly force the issue.³⁵

Best practices must be tailored to the economic realities of the case. If you want to preempt the inevitable motion challenging your expert's reliability, a very detailed report should be provided up front and early-on. The details and supporting material provided in the report must be tailored to the reality of the *Daubert* threat after making a cost-benefit analysis concerning the economic realities of your case.

III. THE EXPERT REPORT: NO MORE "BARE-BONES" WRITTEN DISCLOSURES

Discovery rules define the game, and under the old rules little crucial information was exchanged about proffered expert-witness opinions.³⁶ Reports were not routinely exchanged and it was difficult to obtain disclosure of the data relied upon absent a motion to compel.³⁷ Zealous representation—defined as following the rules—often translated into obstructionist tactics designed to provide only the bare-bones of what a litigant would like to know.³⁸

^{31.} Sandra F. Gavin, *Managerial Justice in a Post*-Daubert *World: A Reliability Paradigm*, 234 F.R.D. 196, 197 (2006) (arguing that the better practice requires the trial judge to afford the resisting party a due process opportunity to be heard).

^{32.} See generally id. (arguing that the hearing in *outcome-determinative* cases should be at the option of the proponent of the expert-opinion testimony).

^{33.} *Id.* at 209 (noting that post-*Daubert* parties will present their best expert evidence initially).

^{34.} See generally id.

^{35.} Id.

^{36.} See generally Steven K. Sims, Treat Experts Like Ordinary Witnesses: Recent Trends in Discovery of Testifying Experts under Federal Rule of Civil Procedure 26(b)(4), 66 Wash. U. L.Q. 787, 787–788 (1988) (explaining that Fed. R. Civ. P. 26(b)(4) sought to remove the restrictions on the discovery of testifying experts).

^{37.} Id.

^{38.} Id. at 787–788 n. 2.

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The purpose of the 1993 amendments to the discovery rules was to change abusive discovery pretrial practices and to promote early disclosure of crucial information.³⁹ Despite the intent of the discovery amendments, it is possible today to comply by disclosing only a minimal amount of information about the opinion of the expert you intend to call in court.

Under modern practice, the Federal Rules of Civil Procedure require each party to disclose "the identity of any witness it may use at trial to present evidence"⁴⁰ as an expert under Federal Rules of Evidence 702, 703, and 705. These Rules also require a signed written report for testifying expert witnesses.⁴¹ Drafting the expert disclosures and report should not be a matter of merely following the language of the rule; presenting your best expert evidence requires disclosure of much more than just the expert's ultimate opinion. To *Daubert*-proof your expert witness you must go well beyond the "bare-bones"; indeed, you must fully address foundation and methodology, and support each with learned writings.

The line between legal reasoning and the reasoning of the engineer, statistician, biochemist, or other scientific or technical expert is highly attenuated.⁴² Much has been written about junkscience; however, some science is considered "junk" today simply because the lawyer presenting the expert has not followed the rules to ensure that the proposed opinion satisfies Rule 702.⁴³

In the right case, a *Daubert*-proof expert report may, at best, facilitate settlement and preempt a costly motion challenge.⁴⁴ If

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^{39.} In addition to disclosing the identity of experts, a party's disclosure must "be accompanied by a written report—prepared and signed by the witness—if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony." Fed. R. Civ. P. 26(a)(2)(B).

^{40.} Id.

^{41.} Id.

^{42.} See Bonner v. ISP Techs., Inc., 259 F.3d 924, 928–929 (8th Cir. 2001) (explaining that Rule 702 is a flexible standard aimed at ensuring the scientific validity of proposed expert testimony).

^{43.} E.g. David E. Colmenero, A Dose of Daubert to Alleviate "Junk Science" in Texas Courtrooms: Texas Adopts the Federal Standard for Determining the Admissibility of Scientific Expert Testimony, 27 Tex. Tech L. Rev. 293 (1996) (discussing the use of junk-science as a basis for an expert witness' opinion).

^{44.} Justin P. Murphy, Student Author, *Expert Witnesses at Trial: Where Are the Ethics*? 14 Geo. J. Leg. Ethics 217, 237 n. 154 (2000) (noting commentators argue that experts facilitate settlement offers).

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vour cost-benefit analysis does not justify prolonged motion practice, better practice may demand a detailed report addressing all foundational factors relevant to your case. At a minimum, it could alleviate the need for a lengthy expert-witness discovery deposition. Rule 26 provides a right to take the deposition following the issuance of the report.⁴⁵ If it is impossible or strategically undesirable to preempt a *Daubert* challenge through the report, you must take all necessary steps to address the factors at the discovery deposition.⁴⁶ Do not assume that your adversary will be conducting the deposition merely to gain information; he may be conducting the deposition for the sole purpose of preparing a motion to exclude your expert's testimony. If successful, your opponent may file a summary judgment motion to end the case. Since there is no guarantee you will get a second chance to satisfy *Daubert* at a hearing, you must treat the expert-witness deposition as you would a trial; the same care and preparation that go into witness preparation for trial must be put into this crucial expert-witness deposition.

IV. THE PROACTIVE EXPERT–WITNESS DISCOVERY DEPOSITION

Prior to the amended rules, discovery depositions of expert witnesses took place by court order.⁴⁷ Little law exists on the frequency of expert-witness depositions under the old rules, primarily due to the interlocutory nature of the rulings not appealable until final judgment. However, in my experience, the expertwitness discovery depositions were the exception rather than the rule in the average case. Now the rules contemplate broad discovery of specially retained expert witnesses, but the culture of providing "bare-bones" information persists.⁴⁸ The conventional rule appears to be:

^{45.} Fed. R. Civ. P. 26(b)(A).

^{46.} *E.g. Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607, 615 (7th Cir. 1993) (demonstrating the court's use of expert-witness depositions in determining whether to uphold a grant of summary judgment).

^{47.} E.g. Fed. R. Civ. P. 26(b)(4)(A)(ii) (1991) (permitting the expert witness' deposition by court order).

^{48.} Roger S. Haydock, David F. Herr & Jeffrey W. Stempel, *Fundamentals of Pretrial Litigation* 341 (6th ed., West 2007).

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[T]he more questions you ask, the more information you provide the other side; the more questions you ask, the more time the other attorney has to think about what else to ask; and the more questions you ask, the more chances the other attorney has to ask still more questions.⁴⁹

With this mindset, the deposition defender's preparation does not routinely include preparing questions for the witness. This is a particularly dangerous mindset for proponents of expert-witness testimony vulnerable to Daubertization. If the Rule 104(a) proceeding is the virtual trial, then the deposition is the dress rehearsal, and the proponent of the expert testimony must take a more active role in ensuring that the transcript is *Daubert*-proof.

If the attorney who noticed the deposition does not elicit factors relevant to your expert, you need to be prepared with questions to protect the record in the event a Rule 702 Motion to Preclude is filed. While the inquiry is flexible, and the court may consider all or none of the factors, do not let the deposition conclude without addressing the following, if relevant:

- (1) The empirical validity of your expert's theory or technique. If the technique is truly novel make sure the expert is prepared to reference other similar scientific techniques yielding results that have been found admissible.
- (2) The existence of specialized literature concerning the technique, regardless of whether the literature has yet to receive peer-review status.
- (3) The potential error rate in using this technique.
- (4) The existence and maintenance of standards governing the use of the technique and the care with which the technique was employed in this case.
- (5) The relevant scientific community that utilizes this technique. "Widespread acceptance" in that community is required.

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^{49.} Infra pt. V(A)–(B) (discussing numerous contexts in which issues regarding the expert's reliability were raised).

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In addition, consider eliciting the following additional factors:

- (1) The extent to which the technique relies on objective versus subjective interpretation by your expert.
- (2) The extent to which the theory or technique was established apart from litigation.
- (3) The probative value of the evidence in your case.
- (4) Other causes of the injury in your case and the necessary steps taken to rule them out.
- (5) How the technique fits to the facts of your case.

V. VULNERABLE PRACTICES AREAS

As the number and scope of reliability-admissibility challenges escalate, the number of pitfalls increases for expert practice. Issues regarding expert-witness reliability have arisen in numerous contexts where gatekeeping was not previously undertaken.⁵⁰ Prior to 1993, gatekeeping involved the application of *Frye*, and primarily involved forensic evidence in criminal cases.⁵¹ Thus, it is in the area of civil practice in which gatekeeping may present new and unexpected challenges for the unwary.⁵² When the reliability challenge is successful, summary judgment follows subject to the nearly insurmountable abuse-of-discretion standard on appeal.⁵³

Measurable change has occurred in product liability and toxic-tort litigation, and to a lesser extent in other areas where medical causation is at issue.⁵⁴ In some instances, otherwise admissible testimony may have been precluded due to the proffering

^{50.} See Jay P. Kesan, An Autopsy of Scientific Evidence in a Post-Daubert World, 84 Geo. L.J. 1985, 1987 (1996) (offering an example of a Frye hearing in the context of a criminal case).

^{51.} See Frye, 293 F. at 1013, 1014 (holding that a scientific principal or discovery on which an expert bases his or her testimony must be sufficiently established and have gained general acceptance in the particular field in which it belongs).

^{52.} Compare Frye, 293 F. at 1014 with Daubert I, 509 U.S. at 588–589 (demonstrating the shift in standards for admitting expert testimony).

^{53.} See Gen. Electric Co., 522 U.S. at 144.

^{54.} Michael H. Graham, Handbook of Federal Evidence vol. 3, § 702:6, 191 (6th ed. West 2006).

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lawyer's lack of attention to the reliability factors.⁵⁵ Conversely, potentially inadmissible evidence may have been admitted because it went unchallenged.⁵⁶ A non-exclusive list of potentially vulnerable criminal and civil practice areas appears in the Appendix. The remainder of this Article, however, is devoted to the following three areas in which the reliability challenge has provoked the most change: products-liability practice; toxic-tort litigation; and medical causation.

A. Products-Liability Practice

When the gatekeeping function is applied to expert testimony in products-liability litigation, special care must be taken in addressing the relevant *Daubert* factors. The report, affidavit, or deposition—or any combination thereof—must address when the theory or technique can be tested. When a product defect is involved, this factor has been referred to as "*Daubert*'s most significant guidepost."⁵⁷A series of Seventh Circuit cases illustrates the importance of this factor to the point of requiring actual testing.⁵⁸ While the failure to test may not constitute a per se ground to exclude in all jurisdictions, it is likely to prove fatal if your expert fails to test a theory or technique that "can be tested," as we will see in the discussion below.

This critical point can best be illustrated by examining the record in *Porter v. Whitehall Laboratories, Inc.*⁵⁹ The issue involved whether the record before the court established a genuine issue of fact that ibuprofen (Motrin and Advil) was capable of causing the kidney failure, rapidly progressive glomerulonephritis (RPGN), or interstitial nephritis and RPGN that allegedly killed

^{55.} See Moore v. Ashland Chem., Inc., 151 F.3d 269, 281 n. 2 (5th Cir. 1998) (noting that a party must show that the expert who testifies to a hard scientific opinion can show that the opinion is reliable).

^{56.} See *id.* at 275, 279 (explaining the safeguards in place to prevent potentially inadmissible evidence from being admitted); *see also Daubert*, 509 U.S. at 597 (stating that the gatekeeping role of judges will inevitably allow potentially admissible evidence to be excluded and potentially inadmissible evidence to be admitted).

^{57.} Chapman v. Maytag Corp., 297 F.3d 682, 688 (7th Cir. 2002).

^{58.} Id.; Weir v. Crown Equip. Corp., 217 F.3d 453, 460 (7th Cir. 2000); Cummins v. Lyle Indus., 93 F.3d 362, 368 (7th Cir. 1996); Deimer v. Cincinnati Sub-Zero Prods. Inc., 58 F.3d. 341, 345 (7th Cir. 1995); Bradley v. Brown, 42 F.3d 434, 438 (7th Cir. 1994); O'Conner, 13 F.3d at 1107.

^{59. 9} F.3d 607.

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the plaintiff.⁶⁰ In *Porter*, the court granted summary judgment following a successful motion in limine precluding the proffered testimony of five witnesses on reliability grounds.⁶¹

The court did not hold a hearing. Instead, it decided the case on deposition testimony taken pretrial of Dr. Diane Wells, Dr. Richard Combs, Dr. Francesco Del Greco, Dr. Fred Ferris, and Dr. David Benjamin, finding that all five failed to satisfy Daubert.⁶² The court found that Dr. Wells' "curb-side opinion" testimony did not provide the "scientific" opinion Federal Rule of Evidence 702, as interpreted in *Daubert*, requires.⁶³ Similarly, the court rejected Dr. Combs' first-hand observations due to the absence of supporting literature.⁶⁴ The court likewise found that Dr. Del Greco's testimony concerning his hypothesis was only a "subjective belief" in violation of *Daubert*⁶⁵ and that Dr. Ferris' general theory that ibuprofen can aggravate independently developed kidney problems did not fit the facts of the case.⁶⁶ And finally, because Dr. Benjamin admitted that his causation conclusion based on a progression theory was outside his area of expertise, the court properly excluded his testimony.⁶⁷

In *Porter*, the appellate court reviewed the record and found the district court properly applied the criteria for evaluating an expert, as outlined in *Daubert*, to all of the relevant experts, stating:

^{60.} Id. at 609–610.

^{61.} Id. at 611–612.

^{62.} Id.

^{63.} Id. at 614 (quoting the trial record that stated: "What I'm giving you now is kind of a curb side opinion. If . . . you were asking me to give you an analytical, scientific opinion, then, I would have to research it, and I have neither the time nor the inclination to do that." (omissions in original)).

^{64.} *Id.* at 614 (discussing Dr. Combs' testimony that he had encountered only five cases of anti-GBM RPGN in his career, that he could not cite a single study that linked ibuprofen to any type of RPGN, and that he had never encountered such a case in practice).

^{65.} *Id.* at 614–615 (explaining that Dr. Del Greco agreed that his causation opinion was a "hypothesis, the proof of which remains to be made," and that if the hypothesis turned out to be right, "it would be the first case in history in which ibuprofen caused RPGN").

^{66.} Id. at 615 (discussing Dr. Ferris' deposition that this aggravation would be doserelated and would require a far greater dose than the dose in the plaintiff's case).

^{67.} *Id.* (wherein his deposition testimony revealed he admitted that this aggravation would be dose-related and would require a far greater dose that the dose in the plaintiffs case).

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The first is whether the testimony lends itself to verification by the scientific method. Clearly, the statements offered by the plaintiff's experts could be verified scientifically; however, none of them had been tested. The second criterion is whether the theory has been subjected to peer review. The district court evaluated plaintiff's expert testimony according to this criterion and took into account the fact that there were no published scientific data or evidence in the various studies that had been done, that linked ibuprofen to RPGN, or linked ibuprofen to the progression of interstitial nephritis to RPGN.⁶⁸

The court next considered the relevance between the scientific theory and the facts to determine the "fit"⁶⁹ of the case and again found the record lacking. With regard to the testimony of Dr. Benjamin, the pharmacologist, the court found his methodology inapplicable to the facts of the case because of his failure to rule out other causes of RPGN.⁷⁰ Likewise, Dr. Del Greco's belief that, based on animal studies, interstitial nephritis was the primary event causing the plaintiff's anti-GBM RPGN failed to provide the "fit" *Daubert* requires.⁷¹

In *Porter*, the appellate court affirmed the district court's grant of summary judgment based upon the pretrial record.⁷² Therefore, it appears that better expert practice calls for you to address the relevant factors early on with your expert witness. Do not assume that you will get an opportunity at a hearing to fix your expert case. It is significant to consider that at one time the *Porter* experts made statements in support of establishing a causal link between ibuprofen and RPGN.⁷³ However, the record was not *Daubert*-proof and therefore failed the reliability challenge.⁷⁴

^{68.} *Id.* (citations omitted).

^{69.} Porter, 9 F.3d at 616 (citing Daubert I, 509 U.S. at 591).

^{70.} Id. (stating that Dr. Benjamin could not apply his methodology to the plaintiff because the record revealed that "by his own admission, he did not know what those causes were").

^{71.} *Id*.

^{72.} Id. at 616–617 (noting that although "the district court could not apply the exact test set forth in *Daubert*," the court made the requisite *Daubert* inquiries and applied them consistently).

^{73.} Id. at 611.

^{74.} Notably, there was no scientific evidence or data establishing a causal link be-

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The initial expert-lawyer conference should reveal potential holes in the reliability analysis, whether the witness can provide the necessary reliability foundation, or whether the matters are outside his or her expertise. When the case progresses to the deposition stage, the lawyer producing the witness must be proactive to ensure that the transcript is *Daubert*-proof. Conventional wisdom concerning the deposition must be set aside, and the witness must be prepared to lay the same foundation for his or her opinion that would be set forth at trial, because as *Porter* illustrates, the expert-witness deposition in many products-liability cases is the virtual trial.⁷⁵ There seems little excuse today for proffering a "curb-side opinion,"⁷⁶ an opinion based on a "hypothesis, the proof of which remains to be made,"⁷⁷ or witnesses with opinion testimony admittedly outside the area of that expert's expertise.⁷⁸

Further, although the court in *Porter* did not go so far as to require actual testing or verification in all cases,⁷⁹ it seems clear that if the proffered opinion lends itself to verification by a scientific method, the lawyer is responsible for making sure that verification has taken place. And, if a witness has not taken steps to rule out other causes, at a minimum the witness should be familiar with any other causes relevant to the causation issue before the court. However, if your products-liability case involves expert testimony in support of a reasonable-alternative design (RAD) you may have to do more.⁸⁰ Failure to test will apparently always result in preclusion of an expert's testimony in the Seventh Cir-

tween ibuprofen and RPGN, and none of the doctors could support their statements suggesting such a link with personal research or other scientific evidence. *Id*.

^{75.} See Porter, 9 F.3d at 615 (demonstrating the court's reliance on Dr. Benjamin's deposition in determining whether or not to uphold a grant of summary judgment).

^{76.} Porter, 9 F.3d at 614.

^{77.} Id. at 615.

^{78.} Id.

^{79.} *Id.* at 613 (noting that an initial determination of "whether the theory or technique can be or has been tested" is important in establishing the theory or technique as scientific knowledge).

^{80.} See supra n. 4 and accompanying text; Jaurequi v. Carter Mfg. Co., Inc., 173 F.3d 1076, 1084 (8th Cir. 1999) (finding that the expert's failure to test the utility of a proposed alternative design was a permissible reason for the district court to exclude that expert's testimony); *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996) (finding no factual basis for assertions of feasibility).

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cuit,⁸¹ especially if the case involves a forklift.⁸² And while "duct tape" as an alternative design may work in the field, it will not get the job done when *Daubert* is applied in court.⁸³

Actual testing may not be required in all types of cases by all circuit courts,⁸⁴ but given the prohibitive cost of the "actual testing" in the context of most product-liability litigation, better practice involves being aware of alternative arguments.⁸⁵

B. Toxic-Tort Litigation

Post-*Daubert* reliability hearings are to be anticipated in toxic-tort litigation and a whole sub-body of *Daubert* law has developed with respect to the reliability and admissibility of the "differential diagnosis" methodology.⁸⁶ Lawyers practicing in this area must be familiar with the foundational requirement for this process to pass muster under *Daubert*.⁸⁷ This type of "causal di-

83. *Giles v. Miners, Inc.*, 242 F.3d 810, 812–813 (8th Cir. 2001) (holding that the trial court did not abuse its discretion under *Daubert* in excluding expert testimony that a freezer was unreasonably dangerous because it lacked a mesh safety guard which would attach with duct tape to prevent parties from touching the freezer's bare metal walls and sustaining frostbite).

^{81.} See e.g. Bourelle v. Crown Equip. Corp., 220 F.3d 532, 535–538 (7th Cir. 2000) (noting that Seventh Circuit cases "have recognized the importance of testing in alternative design cases").

^{82.} See Dhillon v. Crown Controls Corp., 269 F.3d. 865, 869–671 (7th Cir. 2001) (wherein the court summarized its position with regard to expert proof of alternative designs in forklift cases, finding such testimony inadmissible under *Daubert* when such experts admit the following: (1) they have not prepared a model of the alternative design or warning; (2) they have not done any testing to show the alternative design or warning were both safer and economically feasible; (3) that no lab or organization as tested the designs; (4) that no manufacturer has incorporated the proposed designs; and (5) that no organization has approved of the expert's theories).

^{84.} See e.g. Clay v. Ford Motor Co., 215 F.3d 663, 668–669 (6th Cir. 2000), cert. denied, 531 U.S. 1044 (2000) (holding the expert's failure to test his theories that the Bronco II over-steers and jacks was subject to cross-examination by Ford and was not a violation of *Daubert*); Sikora v. AFD Indus., Inc., 221 F. Supp. 2d 920, 923 (N.D. Ill. 2002) (finding an expert opinion involving elevators reliable based on methodology that did not include testing).

^{85.} See Martin v. Shell Oil Co., 180 F. Supp. 2d 313, 319 (D. Conn. 2002) (finding that the *Daubert* factors require only that the opinion be testable, not that it necessarily be tested in light of the cost (i.e. \$70,000-\$100,000) to perform hydrogeologic surveys).

^{86.} Michael Graham, Handbook of Federal Evidence vol. 3, § 702.6 (Thomson/West 2006).

^{87.} Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (listing the steps physicians typically go through to reach a reliable differential diagnosis); Kennedy v. Collagen Corp., 161 F.3d 1226, 1228–1230 (9th Cir. 1998) (holding that a reliable differential diagnosis passes muster under Daubert where the issue was whether Zyderm injec-

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agnosis which the legal community calls 'differential'" is not the same differential-diagnosis process that treating physicians use in the practice of medicine, so it would be unwise to leave the foundation up to the expert.⁸⁸ Better practice involves discussing this methodology at the expert-lawyer conference. Thus, while the methodology in the abstract may prove sound in the general practice of medicine,⁸⁹ it must comport with *Daubert* when it is used in the practice of science.⁹⁰

Litigation involving Parlodel (R) prescribed for postpartum lactation illustrates how *Daubert* applies in toxic-tort litigation.⁹¹ Prior to Daubert, most courts would have ruled that it is the function of the jury to evaluate the relevance and reliability of such proffered expert testimony.⁹² In Glastetter v. Norvartis Pharma*ceuticals Corp.*, the two proffered experts set forth what they described as the generally accepted methodology⁹³ for diagnosing the cause of plaintiff's intracerebral hemorrhage (ICH). They referred to their methodology as "differential diagnosis." According to the court, "[d]ifferential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes."94 However, although the court's record revealed that the experts had analyzed the patient's record, ruling out possible "other causes," the court found the methodology scientifically unreliable.95

With regard to a reliable "scientific methodology," the court explained the importance of "ruling in" the suspected cause of the

tions cause systemic lupus erythematosus (SLE)).

^{88.} Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1208 (8th Cir. 2000) (emphasis in original).

^{89.} Id.

^{90.} See Glastetter v. Novartis Pharms. Corp., 107 F. Supp. 2d 1015, 1019, 1021–1022, 1024, 1027, 1044–1045 (E.D. Mo. 2000) (discussing "differential diagnosis" and its relationship to "specific causation" and "general causation" in the context of toxic tort litigation).

^{91.} See generally id. at 1015.

^{92.} Id. at 1018 (citing Daubert I, 509 U.S. at 589) (pointing out that trial courts must screen proffered expert testimony for relevance and reliability).

^{93.} Id. at 1022 (stating that the Bradford-Hill criteria, a generally accepted test for analyzing causation, was utilized).

^{94.} Id. at 1019 (citing Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1413 (D. Or. 1996)).

^{95.} Id. at 1028.

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injury.⁹⁶ It is not sufficient to simply "rule out" alternative causes for the condition that the plaintiff claims is related to a particular substance.⁹⁷ The critical "ruling in" must be addressed.⁹⁸ In addressing this legal concept of "general causation" the court stated:

The process of differential diagnosis is undoubtedly important to the question of "specific causation." If other possible causes of an injury cannot be ruled out . . . the "more likely than not" threshold for proving causation may not be met. But, it is also important to recognize that a fundamental assumption underlying this method is that the final, suspected "cause" remaining after this process of elimination must actually be capable of causing the injury. That is, the expert must "rule in" the suspected cause as well as "rule out" other possible causes. And, of course, expert opinion on the issue of "general causation" must be derived from scientifically valid methodology.⁹⁹

Thus, while the physician's "differential diagnosis" technique may be a reliable methodology in his or her medical practice, it is only when the applied methodology is *Daubert*-proof that it will survive the reliability challenge.¹⁰⁰ However, the "differential diagnosis" technique for establishing specific causation is not free from attack.

VI. THE MEDICAL-CAUSATION OPINION

As a practical matter, traditional medical-causation testimony that was rarely scrutinized prior to *Daubert* is now vulnerable to attack on reliability grounds, and treating physicians are not exempt from the requirements of Federal Rules of Evidence 702 and 703.¹⁰¹ The "differential diagnosis" methodology—critical

101. See Porter, 9 F.3d at 613 (citing *Daubert I*, 509 U.S. at 589) (noting that the Federal Rules of Evidence's standards for the admissibility of scientific evidence encompass "some degree of regulation of the subjects and theories about which an expert may tes-

^{96.} Id. at 1027.

^{97.} Id.

^{98.} Id.

^{99.} Id. (citing Hall, 947 F. Supp. at 1413).

^{100.} Brasher v. Sandoz Pharms. Corp., 160 F. Supp. 2d 1291, 1299 (N.D. Ala. 2001) (admitting expert opinion causally relating strokes to post-partum ingestion of Parlodel); Globetti v. Sandoz Pharms. Corp., 111 F. Supp. 2d 1174, 1180 (N.D. Ala. 2000) (admitting expert opinion causally relating acute-myocardial infarction with ingestion of Parlodel).

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to establishing general causation in the toxic-tort area—is playing a role, albeit to a lesser extent, in the traditional medical causation case.¹⁰² Some courts even hold that failure to engage in "differential diagnosis" may be fatal to admissibility.¹⁰³

The United States District Court for the District of New Jersey found expert testimony unreliable as to both "general" and "specific causation," holding:

The unreliability of Dr. Panitz's opinion as to general causation is sufficient to render her testimony inadmissible. However, even if she had succeeded in demonstrating that her conclusion as to general causation is based on scientifically acceptable methodology, the Court could not permit her opinion as to specific causation to be submitted to a jury. Like her general causation theory, Dr. Panitz's theory that Rutigliano's CCP use caused her symptoms is not based on reliable scientific methods.

Courts have insisted time and time again that an expert may not give opinion testimony to a jury regarding specific causation if the expert has not engaged in the process of differential diagnosis \dots ¹⁰⁴

The court precluded testimony from Dr. Panitz proffered to causally relate the plaintiff's formaldehyde sensitivity to carbonless paper.¹⁰⁵ Summary judgment followed accordingly.¹⁰⁶

The record in the case below offers guidance on how to establish a *Daubert*-proof record. In this case, the "general causation" issue of whether repetitive hand-intensive work could cause carpal tunnel syndrome (CTS) was not in dispute.¹⁰⁷ What was at

tify"); *but see Marron v. Stromstad*, 123 P.3d 992, 1002 (Alaska 2005) (holding "that when a treating physician testifies regarding a course of treatment, the physician's testimony need not be subjected to a *Daubert* analysis").

^{102.} See Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1276, 1282–1283, n. 5 (N.D. Okla. 2000) (noting that "[o]ther courts have found that some sort of differential diagnosis or attempted elimination of other causes is an important, if not necessary, factor in determining the reliability of a medical causation opinion").

^{103.} See Rutigliano v. Valley Bus. Forms, 929 F. Supp. 779, 786 (D.N.J. 1996) (requiring differential diagnosis before an expert may give opinion testimony regarding specific causation).

^{104.} Id. (citations omitted).

^{105.} Id.

^{106.} Id. at 791–792.

^{107.} Hardyman v. Norfolk & W. Ry. Co., 243 F.3d 255, 263 (6th Cir. 2001) (reviewing

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issue was whether the experts could reliably opine that plaintiff's work as a brakeman/conductor at the railroad caused CTS in his specific case.¹⁰⁸ In Hardyman v. Norfolk and Western Railway Co.,¹⁰⁹ the Sixth Circuit appellate panel found the district court abused its discretion when it excluded the expert-causation testimony based on differential diagnosis. The relevant portions of the summary judgment record include the proffered opinions of Dr. Linz, a specialist in occupational and environmental medicine, and James A. Dewees, M.S. CPE, a certified professional ergonomist.¹¹⁰ Dr. Lintz and Mr. Dewees took extensive nonoccupational work histories in order to rule out other causes of plaintiff's CTS.¹¹¹ In the absence of epidemiological literature establishing a dose/risk response for brakeman like Mr. Hardyman, the court put great emphasis on the experts' quantification of the hand-intensive work involving known risk factors for the development of CTS.¹¹² For example, Mr. Dewees made some of the following findings which he related to risk factors for CTS according to the literature:

- (1) Frequent repetitive use of the same or similar movements of the hand or wrist.
- (2) Regular tasks requiring the generation of high force by hand.
- (3) Regular or sustained tasks requiring awkward hand positions.
- (4) Regular use of vibrating hand-held tools.

CTS risk factors and noting that "[t]he greater the numbers of these factors that are present in a task, the greater the risk of developing CTS").

^{108.} *Id.* at 260 (noting that the trial court granted the former employer's motion for summary judgment based on the plaintiff's failure to establish causation as a matter of law).

^{109.} Id. at 255.

^{110.} Id. at 261-265.

^{111.} Id. at 261, 263.

^{112.} *Id.* at 265 (deciding that in light of the experts' conclusions that the plaintiff's work activities caused his CTS, it was unnecessary for the plaintiff to establish a dose/response relationship or threshold level because such a requirement would prohibit plaintiffs from recovering against negligent employers unless their specific job has been subject to national CTS epidemiological studies).

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(5) Frequent or prolonged pressure over the wrist or base of the palm.¹¹³

He then went on to objectively quantify plaintiff's evidence of exposure to tasks involving these risks, conservatively estimating that over his twenty years of service that he spent at least 15,000 hours performing such hand- and wrist-intensive tasks.¹¹⁴ This expert, as well as Dr. Lintz, also considered plaintiff's non-work risk factors, including his activities outside of his work with the railroad.¹¹⁵ Based on such a reliability record, the appellate court found that exclusion of the expert-causation testimony based on differential diagnosis was an abuse of discretion.¹¹⁶ In contrast to this record, the court distinguished cases from other jurisdictions excluding such proffered expert testimony as unreliable under *Daubert*.¹¹⁷

The failure to gather any quantitative data surrounding the individual plaintiff's occupational activities and the failure to analyze non-work factors appear fatal to the differential diagnosis methodology.¹¹⁸

Treating physicians are not immune from challenge when testifying as to causation on behalf of their patients.¹¹⁹ For in-

119. See O'Conner, 13 F.3d at 1105 n. 14 (stating "we do not distinguish the treating physician from other experts when the treating physician is offering expert testimony regarding causation").

^{113.} Id.

^{114.} *Id*.

^{115.} Id. at 265.

^{116.} Id. at 269.

^{117.} Id. at 266–267.

^{118.} See Stasior v. Natl. R.R. Passenger Corp., 19 F. Supp. 2d 835, 851–852 (N.D. Ill. 1998) (holding that ergonomist experts were qualified to testify concerning causal connection between occupational risk factors and CTS but that their proffered testimony was not reliable under *Daubert* when one of the experts failed to gather any quantitative data about plaintiff's work); *Magdaleno v. Burlington N. R.R. Co.*, 5 F. Supp. 2d 899, 905 (D. Colo. 1998) (excluding expert-causation testimony as conclusory and unsupported by scientific evidence on a record where the expert made no on-site analysis); *Dukes v. Ill. C. R.R. Co.*, 934 F. Supp. 939, 948 (N.D. Ill. 1996) (excluding expert-causation testimony for lack of objective methodology on a record where the expert did not perform any independent studies or review any existing research); *Bennett v. PRC Pub. Sector, Inc.*, 931 F. Supp. 484, 497–500 (S.D. Tex. 1996) (excluding expert-causation testimony on a record where the expert did not interview any of the plaintiffs; took no measurements from them; did no analysis of potential work-related causes; did not investigate personal histories or nonwork factors; nor did he make any meaningful attempt to rule out other causes of plaintiffs' injuries).

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stance, the proffered testimony of a treating physician causally relating his patient's cataracts to radiation exposure was excluded on *Daubert* grounds because his methodology was found unreliable:

We have interpreted *Daubert* to require that the district court undertake a two-step inquiry. *Daubert* first "directs the district court to determine whether the expert's testimony pertains to scientific knowledge. This task requires that the district court consider whether the testimony has been subjected to the scientific method; it must rule out 'subjective belief or unsupported speculation." Second, the district court must "determine whether the evidence or testimony assists the trier of fact in understanding the evidence or in determining a fact in issue. That is, the suggested scientific testimony must 'fit' the issue to which the expert is testifying."¹²⁰

The appellate court then reviewed Dr. Scheribel's methodology.¹²¹ The summary judgment record included his deposition, wherein he stated: "I know what cataracts look like when they've been induced by radiation, by whatever dosage or time of exposure there was."¹²² Citing articles, which the court found wanting, he further testified: "Radiation cataracts are clinically describable and definable condition which, when present, cannot be mistaken for anything else."¹²³ Excluding this causation testimony on reliability grounds, the court noted his methodology failed to include ruling out other causes of cataracts, as well as a failure to include a complete examination of the medical literature on radiationinduced cataracts.¹²⁴

Thus, when medical-causation testimony is a contested issue in the case, *Daubert* may be invoked,¹²⁵ and the lawyer proffering the opinion testimony must be prepared to establish a reliability foundation that may go well beyond the foundation the expert

^{120.} Id. at 1106 (citations omitted).

^{121.} Id.

^{122.} *Id*.

^{123.} Id.

^{124.} Id.

^{125.} See supra nn. 101–124 and accompanying text (discussing courts' use of *Daubert* to assess the admissibility of expert testimony concerning causation).

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would regularly provide without legal counsel. The expert witness who appears at a deposition without this counsel testifies at his or her peril. Times have changed and better expert practice demands careful attention to expert opinion as it is proffered not only in expert reports, but also as it is explained at depositions by lawyers practicing not only in the areas of products liability and toxic torts, but increasingly in any type of litigation involving medical causation.¹²⁶

VII. CONCLUSION

In Weisgram v. Marley $Co.,^{127}$ the United States Supreme Court raised the ante for all lawyers practicing in the pretrial stage of litigation involving expert witnesses.¹²⁸ In that case the trial court lawyer resisting the expert witness reliability challenge thought he did everything right—he survived the reliability determination and his expert witnesses were permitted to testify at trial.¹²⁹ Unfortunately, his witnesses were not *Daubert*-proof and the appellate court found them unreliable and refused to grant an opportunity for a new hearing and trial.¹³⁰

As the scope broadens, the number of admissibility challenges escalates, and trial courts increasingly take judicial notice of prior expert rulings, lawyers are on notice to address the foundational reliability factors or ignore them at their peril. All lawyers who deal with expert witness testimony must take note of the Dauber-

^{126.} See e.g. Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 783–786 (3d Cir. 1996) (discussing the requirements with respect to a treating physician's testimony regarding cancer diagnosis); Vargas v. Lee, 317 F.3d 498, 501 (5th Cir. 2003) (discussing the reliability of expert testimony regarding traumatic injury and fibromyalgia syndrome); Cooper v. Carl A. Nelson & Co., 211 F.3d 1008, 1019–1021 (7th Cir. 2000) (addressing the admissibility of expert testimony with respect to clinical examinations and Chronic Pain Syndrome diagnosis); Metabolife Intl., Inc. v. Wornick, 264 F.3d 832, 844 (9th Cir. 2001) (noting the stages of risk assessment in toxic-tort litigation); McClain v. Metabolife Intl., Inc., 401 F.3d 1233, 1242–1243 (11th Cir. 2005) (listing factors that courts should consider when determining specific causation in toxic-tort cases); Yarchak v. Trek Bicycle Corp., 208 F. Supp. 2d 470, 499 (D.N.J. 2002) (holding that Daubert does not require experts to cite published studies linking bicycle riding to impotence).

^{127. 528} U.S. 440.

^{128.} See supra nn. 5–12 and accompanying text (arguing that pre-trial determinations of the admissibility of expert-witness testimony are increasingly important in light of current U.S. Supreme Court jurisprudence).

^{129.} Weisgram, 528 U.S. at 440.

^{130.} Id.

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tized practice and implement best practices for meeting reliability challenges. They must consider presenting nothing less than their best expert evidence because there is no "expectation of a second chance should their first try fail."¹³¹

131. Id. at 455.