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TOWARD A MORE APPARENT APPROACH TO CONSIDERING THE ADMISSION OF EXPERT TESTIMONY

*Thomas D. Schroeder**

INTRODUCTION

Over a quarter century ago, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* reaffirmed the trial court's role as "gatekeeper" for the admission of scientific expert evidence, to screen it not only for relevance, but for reliability.¹ To discharge this gatekeeper role, a trial court must make a preliminary determination whether the expert's opinion evidence meets the admissibility standards of Federal Rule of Evidence 702, which in turn requires application of Federal Rule of Evidence 104(a)'s preponderance test. Trial judges are cautioned not to unduly assess the validity or strength of an expert's scientific conclusions, and the Supreme Court has said that "shaky but admissible evidence"² should be left for a jury's consideration where it can be tested by cross-examination and contrary evidence. But application of these principles can be difficult, and appellate review can be frustrated, even under a deferential abuse of discretion standard, where trial courts are not clear about what standard they are applying. Worse, some trial and appellate courts misstate and muddle the *admissibility* standard, suggesting that questions of the sufficiency of the expert's basis and the reliability of the application of the expert's method raise questions of weight that should be resolved by a jury, where they can be subject to cross-examination and competing evidence.

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* Chief United States District Judge for the Middle District of North Carolina. Member, United States Judicial Conference Advisory Committee on the Federal Rules of Evidence, and Chair of Subcommittee on Rule 702; Senior Lecturer, Duke University School of Law; Member, American Law Institute. The views expressed herein are mine only and do not represent the official views of the Advisory Committee on the Federal Rules of Evidence. I wish to thank Professor Daniel Capra, the Committee's Reporter, for use of his excellent memoranda on Rule 702, as well as materials from Timothy Lau, PhD, Senior Research Associate, of the Federal Judicial Center. The Advisory Committee memoranda are available at <https://www.uscourts.gov/committees/evidence>.

1 509 U.S. 579, 597 (1993).

2 *Id.* at 596.

The state of affairs has prompted the United States Judicial Conference's Advisory Committee on the Federal Rules of Evidence to consider possible amendment to Rule 702 to reiterate the need for proper application of Rule 104(a)'s threshold to each requirement of Rule 702.

This Article highlights lingering confusion in the caselaw as to the proper standard for the trial court's discharge of its gatekeeping role for the admission of expert testimony. The Article urges correction of the faulty application of *Daubert's* admonition as to "shaky but admissible" evidence as a substitute for proper discharge of the trial court's gatekeeper function under Rule 104(a). The Article concludes with several suggestions for trial and appellate courts to consider for better decisionmaking in discharging their duty to apply Rule 104(a)'s preponderance standard to the elements of Rule 702.

I. THE *DAUBERT* STANDARD IN APPLICATION

In 1993, the Supreme Court decided *Daubert*, a personal injury case involving an antinausea drug, and revolutionized how trial courts are to consider the admission of scientific and technical expert evidence. In eschewing the *Frye*³ "general acceptance" test as inconsistent with the "liberal thrust" of the subsequent Federal Rules of Evidence,⁴ the Court simultaneously expanded and restricted the availability of expert testimony. It liberalized the availability of evidence because the *Frye* test became, under the language of Rule 702, but one of several factors for a court to consider when determining whether the proffered evidence is valid and reliable: whether the theory or technique can be (or has been) tested; whether it has been subjected to peer review and publication; its known or potential rate of error; the existence and maintenance of standards controlling its operation; and whether it has attracted "widespread acceptance within a relevant scientific community."⁵ At the same time, the Court tightened the admissibility threshold by charging trial judges to act as "gatekeepers" against the admission of unreliable expert opinion.⁶ In doing so, the Court reminded trial judges that, as with other questions of preliminary admissibility, a court "[f]aced with a proffer of expert scientific testimony . . . must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue."⁷ In a footnote, the Court noted that "[t]hese matters should be established by a preponderance of proof," pursuant to Rule 104(a).⁸

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

4 *Daubert*, 509 U.S. at 588 (citing *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)).

5 *Id.* at 580, 592-95.

6 *Id.* at 597.

7 *Id.* at 592.

8 *Id.* at 592 n.10 (citing *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987) (applying Rule 104(a)'s preponderance test to the threshold question of the existence of a conspiracy)). Rule 104(a) provides: "The court must decide any preliminary question

Rule 702 was amended in 2000.⁹ In addition to requiring that the expert be qualified to testify about scientific knowledge that will assist the trier of fact, the Rule added further foundational requirements, now found in sections (b), (c), and (d), that the testimony be based on sufficient facts or data, the testimony be the product of reliable principles and methods, and the expert have reliably applied the principles and methods to the facts of the case, respectively.¹⁰ In light of *Daubert's* reference to Rule 104(a), the Advisory Committee expressly stated that the trial judge determine these elements by a preponderance before allowing such testimony into evidence.¹¹ The extensive Advisory Committee note further explained the limits of the preponderance standard in this context. For example, competing and contradictory expert testimony can meet the standard, as proponents “do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*,” but only that “their opinions are reliable”—a lesser standard.¹² Moreover, the standard can be met even where competing experts rely on competing versions of the facts, as it is not the trial judge’s role to believe one version of the facts over another.

After *Daubert*, the Court has clarified that this gatekeeper function applies to all expert testimony, not just that based on science.¹³ Over the years, courts have supplemented the various *Daubert* factors for determining reliability. They include whether the opinions are litigation driven, or naturally flow from independent scientific research; whether the expert has accounted for obvious alternative explanations; whether the expert has employed the same level of rigor as required in the relevant field; and whether the field of expertise is known to reach reliable results.¹⁴

Ever since *Daubert*, the Court has expressed conflicting views on the ease with which trial judges will be able to discharge their gatekeeper role.¹⁵ For

about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege.” FED. R. EVID. 104(a).

9 FED. R. EVID. 702 advisory committee’s note to 2000 amendment.

10 The full Rule provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702.

11 FED. R. EVID. 702 advisory committee’s note to 2000 amendment.

12 *Id.* (emphasis added) (quoting *Brown v. Se. Pa. Transp. Auth. (In re Paoli R.R. Yard PCB Litig.)*, 35 F.3d 717, 744 (3d Cir. 1994)).

13 *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

14 See FED. R. EVID. 702 advisory committee’s note to 2000 amendment.

15 See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 598–601 (1993) (Rehnquist, C.J., concurring in part and dissenting in part, joined by Stevens, J.).

example, in *General Electric Co. v. Joiner*,¹⁶ the Court retrenched from its previous admonition against judging the strength of an expert's conclusions by recognizing that on occasion an expert may "unjustifiably extrapolate[] from an accepted premise to an unfounded conclusion"¹⁷ such that the trial judge may find that there is "simply too great an analytical gap between the data and the opinion proffered" to rely on the expert's *ipse dixit* to make the connection.¹⁸ Justice Breyer, after acknowledging that *Daubert* "ask[s] judges to make subtle and sophisticated determinations" about scientific methodology and its relation to the conclusions offered by an expert witness, nevertheless predicted that given the "offer of cooperative effort" from the scientific community (there, the *New England Journal of Medicine*) and the "various Rules-authorized methods for facilitating the [trial] courts' task" (such as appointing a Rule 706¹⁹ advisory expert), implementing *Daubert's* gatekeeping task "will not prove inordinately difficult."²⁰ Justice Stevens, in contrast, noted that "*Daubert* quite clearly forbids trial judges to assess the validity or strength of an expert's scientific conclusions, which is a matter for the jury."²¹ Justice Stevens saw a distinct difference between methodology and conclusions, relying on *Daubert's* statement that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."²²

Not only is it "not always a straightforward exercise to disaggregate method and conclusion,"²³ it is also not always easy to assess when the Rule's foundational requirements—namely, sufficiency of the basis of a proposed opinion and whether the opinion resulted from reliable application of valid principles and methods—falls short of the preponderance standard for threshold admissibility. While courts no doubt acknowledge and grapple with the issue before determining admissibility, some courts have defaulted to invoking the Supreme Court's caution that Rule 702 is not meant to prohibit "shaky but admissible" evidence and have relegated the issue to the jury's consideration on the grounds it can be subject to cross-examination and contrary proof. In doing so, some of these courts have inadvertently

16 522 U.S. 136 (1997).

17 FED. R. EVID. 702 advisory committee's note to 2000 amendment.

18 *Joiner*, 522 U.S. at 146.

19 FED. R. EVID. 706.

20 *Joiner*, 522 U.S. at 147, 150 (Breyer, J., concurring).

21 *Id.* at 154 (Stevens, J., concurring in part and dissenting in part).

22 *Id.* at 154 n.9 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)). Some commentators have suggested that this mantra "simply begs the central question" of admissibility under Rule 702. KENNETH R. FOSTER & PETER W. HUBER, *JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS* 16 (1997); see also *id.* at 15 ("This language is usually cited by those favoring looser standards of admissibility.").

23 *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005) (quoting *Bitler v. A.O. Smith Corp.*, 391 F.3d 1114, 1121 (10th Cir. 2004)) (but noting where the conclusion simply does not follow from the data, the district court is free to conclude that the analytical gap is impermissible).

applied Rule 104(b)'s standard for admissibility, in contravention of *Daubert*.²⁴ Some courts merely find that there is sufficient evidence, *if believed*, for a reasonable juror to find that the expert has a sufficient basis for his opinion or that he reliably applied the principles and methods he claims. Other courts conclude that the application of a valid methodology should be deemed unreliable only if it skews the methodology itself. Rule 104(a) and the *Daubert* line of cases require, however, that the trial judge *actually determine* whether it is more likely than not that the expert has met these threshold requirements of Rule 702.

In this respect, therefore, some courts appear to be abdicating their charge under the Federal Rules of Evidence and *Daubert* and its progeny to make the hard call on admissibility. The end result in such cases is to relegate to the jury the very decisions Rule 702 contemplates to be beyond jury consideration. In other cases, however, it is more difficult to tell what the courts are actually doing, as they do not articulate their reasoning in a way that demonstrates how they are applying the preponderance standard to the required elements of the Rule.

II. COURTS THAT SEEMINGLY MISSTATE AND/OR MISAPPLY THE RULE 104(a) STANDARD

Numerous cases have stated that questions as to sufficiency of basis or reliability of application raise questions of weight that are necessarily for a jury, and not questions of admissibility for the court. Some of these courts may very well have actually applied Rule 104(a)'s standard; or, they may have applied Rule 104(b)'s standard. It is simply difficult to tell, and the courts' misstatement of the legal standard confounds a clear determination.

Since *Joiner*, it has been settled that an appellate court reviews the trial judge's Rule 702 admissibility determination for an abuse of discretion—the same standard that governs most trial court evidentiary decisions. Thus, an admissibility ruling as to evidence will not be reversed unless “manifestly erroneous.”²⁵ Inherent in this highly deferential standard is a certain “play in the joints” that permits divergent results on the same evidence, depending on the judge's explanation for the exercise of discretion. Consequently, as the *Joiner* Court observed, “[a] court of appeals applying ‘abuse-of-discretion’

24 Rule 104(b) provides: “When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist. The court may admit the proposed evidence on the condition that the proof be introduced later.” FED. R. EVID. 104(b). In *Huddleston v. United States*, 485 U.S. 681, 690 (1988), the Court clarified that in determining whether a party has introduced sufficient evidence to meet Rule 104(b), “the trial court neither weighs credibility nor makes a finding that the [party] has proved the conditional fact by a preponderance of the evidence.” Rather, “[t]he court simply examines all the evidence in the case and decides whether the jury could reasonably find the conditional fact . . . by a preponderance of the evidence.” *Id.*

25 *Joiner*, 522 U.S. at 142 (quoting *Spring Co. v. Edgar*, 99 U.S. 645, 658 (1879)). “[E]mbedded findings of fact are reviewed for clear error” *Ungar v. Palestine Liberation Org.*, 599 F.3d 79, 83 (1st Cir. 2010).

review to such rulings may not categorically distinguish between rulings allowing expert testimony and rulings disallowing it.”²⁶ This is yet another reason trial and appellate courts would be best served to be as clear as possible in their reasoning and to avoid generalized misstatements that questions as to sufficiency of basis and reliable application of method go to weight and not admissibility.

What follows is a sampling of illustrative cases that have been identified to the Advisory Committee as evidence that courts are abdicating their gatekeeper role.²⁷ This selection is by no means intended to be complete, nor is it meant to suggest (except perhaps for the Ninth Circuit) a consistent circuit-wide problem. What it tends to show is that in many instances the extent of the problem is murky. A closer look at the facts of these cases suggests that some courts may be hewing closer to the Rule 702 standard than the decisions suggest.

A. *First Circuit*

Milward v. Acuity Specialty Products Group, Inc.,²⁸ has been cited as a prime example of the problem. The question in that case was the admissibility of testimony by Dr. Martyn Smith, a toxicologist, as to general causation—that exposure to benzene can cause acute promyelocytic leukemia, which the plaintiff had contracted.²⁹ After a four-day evidentiary hearing, the district court concluded that the expert’s testimony lacked sufficient demonstrated scientific reliability under Rule 702.³⁰ The First Circuit reversed.³¹ After citing the requirements of Rule 702 and *Joiner*’s acknowledgment that “conclusions and methodology are not entirely distinct from one another,” the court engaged in a lengthy analysis of Dr. Smith’s “weight of the evidence” methodology for arriving at his opinion.³² This methodology was drawn from the work of Sir Austin Bradford Hill, who concluded that an association between a disease and a feature of the environment should not be deemed causal without a proper weighing of several factors, including the strength, frequency, consistency, and specificity of the association; the temporal relationship; the dose-response curve; biological plausibility; coherence of the explanation with generally known factors of the disease; experimental data;

26 *Joiner*, 522 U.S. at 142.

27 The Advisory Committee’s investigation was prompted by an article by David E. Bernstein & Eric G. Lasker, *Defending Daubert: It’s Time to Amend Federal Rule of Evidence 702*, 57 WM. & MARY L. REV. 1 (2015), which identified many cases as evidencing erroneous application of Rule 702 and urged amendment of the Rule to underscore the need for the trial court to address each of the Rule’s requirements.

28 639 F.3d 11 (1st Cir. 2011).

29 *Id.* at 13.

30 *Id.*

31 *Id.* at 14.

32 *Id.* at 15–16 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

and analogous causal relationships.³³ The weight of the evidence approach involves the drawing of an “inference to the best explanation.”³⁴

The First Circuit found that the district court had abused its discretion in rejecting the sufficiency of some of the Hill criteria on which Dr. Smith relied,³⁵ stating that the alleged flaws “go to the weight of Dr. Smith’s opinion, not its admissibility.”³⁶ The court noted that “[t]here is an important difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert’s conclusion.”³⁷ Finding that the district court exceeded its gatekeeper role, the court stated that “[t]he soundness of the factual underpinnings of the expert’s analysis and the correctness of the expert’s conclusions based on that analysis are factual matters to be determined by the trier of fact.”³⁸ So, when the factual underpinning is “weak,” it is a matter “affecting the weight and credibility of the testimony,” which is for a jury’s determination.³⁹ It was sufficient for the court of appeals that Dr. Smith opined that, in his opinion, he weighed these flaws in his weight of the evidence methodology and nevertheless concluded there was general causation.

Putting aside any criticism of the “weight of the evidence” approach,⁴⁰ the problem with the court’s analysis is that it appears to require a preponderance standard for application of Rule 702(c) (reliable method) but not for Rule 702(b) (sufficiency of basis). This, even though the trial judge had found that the expert’s assumptions were “plausible” but not “based on sufficient facts and data to be accepted as a reliable scientific conclusion”—a Rule 104(a) determination.⁴¹ The court of appeals’s error may have resulted in part from the fact that it cited cases decided before the 2000 amendment to Rule 702, a problem not unique to this case.⁴²

33 *Id.* at 17 (citing Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC’Y MED. 295, 295–99 (1965)).

34 *Id.* at 17 (quoting *Bitler v. A.O. Smith Corp.*, 391 F.3d 1114, 1124 n.5 (10th Cir. 2004)).

35 For example, the district court had found that Dr. Smith’s conclusions lacked general acceptance, there was insufficient evidence to support Dr. Smith’s opinion that all subtypes of acute myeloid leukemia likely share a common etiology (finding the expert’s broad extrapolation from acute myeloid leukemia to acute promyelocytic leukemia unsupported), existing knowledge of DNA did not support biological plausibility, insufficient evidence to support the expert’s opinion on mechanism to cause chromosomal damage, the epidemiological evidence on which Dr. Smith relied was not statistically significant, and Dr. Smith had faulty calculations in his odds ratios. *See id.* at 21–23.

36 *Id.* at 22.

37 *Id.* (emphasis omitted).

38 *Id.* (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000)).

39 *Id.* (quoting *United States v. Vargas*, 471 F.3d 255, 264 (1st Cir. 2006)).

40 *See, e.g.*, *Bernstein & Lasker*, *supra* note 27, at 40–42 (arguing that the “weight of the evidence” methodology was rejected by *Joiner*).

41 *Milward*, 639 F.3d at 22 (quoting *Milward v. Acuity Specialty Prods. Grp., Inc.*, 664 F. Supp. 2d 137, 146 (D. Mass. 2009)).

42 Other First Circuit caselaw demonstrates a proper application of Rule 104(a), *see, e.g.*, *Pelletier v. Main St. Textiles, LP*, 470 F.3d 48 (1st Cir. 2006), while other cases do not,

B. *Eighth Circuit*

*United States v. Gipson*⁴³ involved the use of DNA evidence to link a baseball cap left at the scene of a bank robbery to the defendant. Part of the government's case rested on a forensic expert's use of AmpF/STR Profiler Plus and AmpF/STR Cofiler multiplex kits to apply the Sort Tandem Repeat (STR) profiling methodology to the DNA found on the cap so she could create the relevant DNA profiles of the dominant DNA within the mixture found on the cap.⁴⁴ Before trial, the defendant moved to suppress the expert's testimony as unreliable based on the application of the kits; the defendant did not challenge the reliability of the STR DNA methodology itself.⁴⁵ The government argued that the reliability of the use of the kits went to the weight, not the admissibility, of the challenged evidence.⁴⁶ The trial court denied the motion, and the court of appeals affirmed.⁴⁷ While the appellate court cited to *Daubert*, it never cited the then-amended Rule 702. In citing to cases predating the 2000 revisions, the court stated that "this court has drawn a distinction between, on the one hand, challenges to a scientific methodology, and, on the other hand, challenges to the *application* of that scientific methodology."⁴⁸ So, "when the *application* of a scientific methodology is challenged as unreliable under *Daubert* and the methodology itself is otherwise sufficiently reliable," the court said, "outright exclusion of the evidence in question is warranted only if the methodology 'was so altered [by a deficient application] as to skew the methodology itself.'⁴⁹ The problem is that this construction ignores Rule 702(d), which requires that the trial court find by a preponderance that the expert has reliably applied the methodology to the facts of the case, and effectively creates a rebuttable presumption in favor of admissibility. It may be that the court nevertheless found by a preponderance that the application of the kits to the methodology was reliable, but that is not clear from the opinion, and the statement of law is incorrect.

The difficulty of conducting a proper Rule 104(a) analysis under Rule 702 is illustrated by *Kuhn v. Wyeth, Inc.*⁵⁰ There, the parties disputed whether the use of the defendant's hormone replacement drug, Prempro, caused the breast cancers of two plaintiffs, both of whom used the drug for three years

see, e.g., *United States v. Shea*, 211 F.3d 658, 668 (1st Cir. 2000) (noting that "any flaws in [an expert's] application of an otherwise reliable methodology went to weight and credibility and not to admissibility").

43 383 F.3d 689 (8th Cir. 2004).

44 *See id.* at 694.

45 *Id.*

46 *Id.* at 695.

47 *Id.* at 695, 670.

48 *Id.* at 696.

49 *Id.* at 697 (alteration in original) (quoting *United States v. Beasley*, 102 F.3d 1440, 1448 (8th Cir. 1996)).

50 686 F.3d 618 (8th Cir. 2012).

or less.⁵¹ The plaintiffs proffered Donald Austin, MD, who opined that this short-term use of the drug increased their cancer risk.⁵² Wyeth challenged his opinions, and the court held a lengthy *Daubert* hearing, ultimately excluding his testimony because the expert failed to discredit a key Women's Health Initiative (WHI) study that found no risk from short-term drug use and because he failed to base his opinions on epidemiological studies that "reliably support[ed] his position."⁵³ The court of appeals reversed.⁵⁴ As to the WHI study, the court found, quite properly, that the trial court erroneously put the burden on the expert to exclude the study, when Rule 702 requires that the expert demonstrate he "arrived at his contrary opinion in a scientifically sound and methodological fashion."⁵⁵ Dr. Austin had provided his opinion that the WHI study did not preclude his opinion on short-term risk because it was designed to measure heart disease, involved a study population at a much lower risk of cancer, and involved participants who had a larger gap time between menopause and beginning hormone therapy than women who began their hormone therapy on their own.⁵⁶ The study found women using hormone therapy for more than five years to have a statistically significantly increased risk of breast cancer, which Dr. Austin found supportive of his opinion on short-term risk.⁵⁷ As to this aspect of the case, the court of appeals properly applied Rule 104(a)'s preponderance standard to the methodology the expert used.

The court of appeals also reversed the district court on the sufficiency of basis as well. This aspect of the court's ruling is more suspect. The record revealed that the selection of studies Dr. Austin relied upon was made by plaintiffs' counsel, a fact that no doubt influenced the trial court.⁵⁸ And, according to the court, Dr. Austin had ignored "a wealth of studies showing no increased risk of breast cancer from short-term Prempro use," which led to an accusation he had "cherry picked" the handful of studies he relied upon.⁵⁹ Indeed, the record showed, the expert "had never really thought about the short-term use issue before Plaintiffs' counsel presented it to him shortly before the recent *Daubert* challenge."⁶⁰ Moreover, during the *Daubert* hearing, Dr. Austin conceded that two studies he had listed on his declaration as supportive of his opinion on causation were not and should not have been included.⁶¹ Apart from the WHI study, this left the "Million Women Study," the "French Teachers Study," and an American Cancer Society

51 *Id.* at 620.

52 *Id.*

53 *Id.* at 624 (alteration in original) (quoting *Kuhn v. Wyeth, Inc. (In re Prempro Prods. Liab. Litig.)*, 765 F. Supp. 2d 1113, 1126 (W.D. Ark. 2011)).

54 *Id.* at 633.

55 *Id.* at 626.

56 *Id.* at 627.

57 *See id.*

58 *See id.* at 628.

59 *Id.* at 633.

60 *Id.* (Loken, J., dissenting).

61 *Id.* at 624 (majority opinion).

study—all observational studies—as the basis for his opinion that short-term use causes breast cancer, even though he conceded that observational studies were “not as good for demonstrating cause and effect.”⁶² The trial court had found too great an analytical gap between the underlying studies and Dr. Austin’s opinion.⁶³ But the court of appeals found that Dr. Austin’s studies provided “adequate foundation”⁶⁴ for his opinion, citing *Daubert’s* admonition that “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”⁶⁵ Although the trial court found the American Cancer Society study (which found no risk below two years of use, but a significant increase at two and three years)⁶⁶ unreliable because it failed to account for prior use of hormone therapy, the appellate court was satisfied that the study purported to exclude women with unknown duration of use. As to the Million Women Study, an English study, the trial court considered it unreliable because it analyzed the use of Prempro for “five years or less”⁶⁷ without breaking out three years or less, involved other formulations of estrogen, and did not measure use after enrollment—a fact the judge found “irreconcilable with ‘his position that when looking at short-term use, one must be quite precise.’”⁶⁸ But the court of appeals found the lack of material difference in the other formulations of estrogen and Dr. Austin’s decision to add 1.2 years to those participants with less than one year of use to be adequate responses.⁶⁹ Finally, the trial court had found the French Teachers Study unreliable because it admittedly provided no analysis of Prempro at three years or less and did not separate Prempro use from other formulations.⁷⁰ Again, the court of appeals determined that the differences in formulations of estrogen failed to render the study unreliable.⁷¹

These conclusions by the court of appeals are hard to explain. To say that an underestimate of 1.2 years in the Million Women Study “do[es] not create so great an analytical gap between the data and the opinion as to render the opinion inadmissible”⁷² when the issue in the case involves causation for use of three years or less seems to be an abdication of the gatekeeping function and an application of Rule 104(b). Moreover, the trial court

62 *Id.* at 624, 627. He did contend that observational studies were “much better at estimating the size of the risk.” *Id.* at 627.

63 *Id.* at 628.

64 *Id.*

65 *Id.* at 625 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993)) (citing amended Rule 702 as well).

66 *Id.* at 628.

67 *Id.* at 631 n.17.

68 *Id.* at 631 (quoting *Kuhn v. Wyeth, Inc.* (*In re Prempro Prods. Liab. Litig.*), 765 F. Supp. 2d 1113, 1123 (W.D. Ark. 2011)).

69 *See id.* at 629.

70 *Id.* at 631.

71 *Id.*

72 *Id.* at 632.

had found that, based on Dr. Austin's prior testimony, the studies failed to meet his own previously set criteria of accurate characterization of exposure to the drug, identification of the specific drug formulation, and analysis of Prempro separately.⁷³ For the court of appeals, this was merely a reason to "call his credibility into question."⁷⁴ The court even rejected the fairly obvious cherry picking that occurred, ostensibly at the behest of plaintiffs' counsel, with the statement that while "[t]here may be several studies supporting Wyeth's contrary position, . . . it is not the province of the court to choose between the competing theories."⁷⁵ These were not theories, of course, but rather factual bases for the opinions. As the dissent suggested, it surely seemed that in the end the district court properly exercised its gatekeeping function by concluding that the proffered opinion simply lacked a sufficient, reliable basis.⁷⁶

C. Fourth Circuit

*Bresler v. Wilmington Trust Co.*⁷⁷ was a breach of contract case involving life insurance held in a trust for tax purposes. Plaintiff beneficiaries contended that the defendants breached an agreement to lend money to maintain and fund certain investments related to the life insurance policies.⁷⁸ Defendants challenged the plaintiffs' accounting expert's damages calculations on the grounds they included certain cost-of-insurance values, used an "invalid interest spread," and improperly calculated the present value of the future net trust shortfall.⁷⁹ Defendants contended that the expert's calculations were "riddled with mistakes" and "wholly unreliable."⁸⁰ Acknowledging that these were challenges made under Rule 702 and *Daubert* to the factual sufficiency of the method used, the court affirmed the district court's refusal to exclude the opinion testimony.⁸¹ According to the court, "'questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility' of the witness' assessment, 'not its admissibility.'"⁸² Without explanation, the court concluded that the defendants' challenge amounted to a "disagreement" with the values the expert chose for certain variables in his opinion and consequently "'affect[ed] the weight and

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 633. Despite this statement, a review of the appellate briefs suggests that one plaintiff (Davidson) actually attempted to explain away the contrary data from the other studies cited by Wyeth. See Appellant's Brief at 42–45, *Davidson v. Wyeth*, 686 F.3d 618 (8th Cir. 2012) (No. 11-1815).

⁷⁶ *Kuhn v. Wyeth, Inc.*, 686 F.3d at 633–34 (Loken, J., dissenting).

⁷⁷ 855 F.3d 178 (4th Cir. 2017).

⁷⁸ *Id.* at 203.

⁷⁹ *Id.* at 195.

⁸⁰ *Id.* at 188.

⁸¹ *Id.* at 195.

⁸² *Id.* (alteration in original) (quoting *Structural Polymer Grp., Ltd. v. Zoltek Corp.*, 543 F.3d 987, 997–98 (8th Cir. 2008)).

credibility’ of [the expert’s] assessment, not its admissibility.”⁸³ As a general rule, the Fourth Circuit’s statement effectively vitiated the application of Rule 104(a) to Rule 702(b). Here, too, it may be that the court was effectively saying that there *was* a showing by a preponderance that the expert’s opinion had sufficient basis under Rule 702(b), but in light of the claim that the bases of the opinions were “riddled with mistakes” and “wholly unreliable,” and without any analysis, one cannot know for sure.⁸⁴

D. Ninth Circuit

Ninth Circuit caselaw appears to interpret *Daubert* as liberalizing the admission of expert testimony, which may explain decisions from that circuit that set it apart from most others.⁸⁵ *City of Pomona v. SQM North America Corp.*⁸⁶ is illustrative. The City of Pomona sued the importer of natural sodium nitrate from the Atacama Desert in Chile between 1927 and the 1950s, contending that perchlorate impurities in the nitrate, which had been used in fertilizer, contaminated its groundwater.⁸⁷ Central to the city’s claim was Dr. Neil Sturchio, the city’s causation expert, who opined that his four-step “stable isotope analysis” led him to conclude that the perchlorate found in the city’s water had the same distinctive isotopic composition as the perchlorate from the Atacama Desert.⁸⁸ Upon the defendant’s motion in limine, the trial judge held a *Daubert* hearing and excluded the expert’s opinions as unreliable on several grounds.⁸⁹ The Ninth Circuit reversed, citing the proposition that “[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion.”⁹⁰

83 *Id.* at 195–96 (quoting *Zoltek Corp.*, 543 F.3d at 997–98).

84 That this case may be an outlier is demonstrated by *Nease v. Ford Motor Co.*, 848 F.3d 219, 230–31 (4th Cir. 2017), where the court reversed the district court for concluding that criticisms of the expert’s opinion testimony went to its weight and not its admissibility.

85 *See, e.g., In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1112–13 (N.D. Cal. 2018) (“The Ninth Circuit has placed great emphasis on *Daubert*’s admonition that a district court should conduct this analysis ‘with a “liberal thrust” favoring admission,’” which “has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits.” (quoting *Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014))).

86 750 F.3d 1036 (9th Cir. 2014).

87 *Id.* at 1041.

88 *Id.* at 1042–43.

89 *Id.* at 1043.

90 *Id.* at 1044 (quoting *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010)). The court also cited its own standard, articulated in 2013, that “[t]he judge is ‘supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable.’” *Id.* (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013)). While true, this holding ignores the wide gap between the two standards where otherwise qualified experts rely on faulty data or misapply critical procedures.

To be sure, the Ninth Circuit properly noted that a lack of general acceptance was not grounds alone to exclude an expert's methodology, especially if there is a "recognized minority of scientists in the [] field" who support it.⁹¹ Likewise, that the expert did not retest his results himself was not a basis to reject his evidence, where other independent laboratories have tested the methodology.⁹² But the court's blanket conclusion that challenges to the expert's deviation from the protocols merely raised questions as to the weight of the evidence and presented a question for the fact finder, not the trial court, appears facially wrong.

The Ninth Circuit properly recited the 2000 version of Rule 702 and its Advisory Committee note to the amendments,⁹³ but then it rested its key statements on *United States v. Chischilly*,⁹⁴ a 1994 opinion that predated *Daubert* and, more importantly, the 2000 changes to Rule 702, for the proposition that an argument as to "adherence to protocol . . . typically is an issue for the jury."⁹⁵ The court specifically rejected *In re Paoli Railroad Yard PCB Litigation*,⁹⁶ which held that "any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible."⁹⁷ Instead, and again citing *Chischilly*, the court stated that in the Ninth Circuit expert evidence "is inadmissible where the analysis 'is the result of a faulty methodology or theory as opposed to imperfect execution of laboratory techniques whose theoretical foundation is sufficiently accepted in the scientific community to pass muster under *Daubert*.'"⁹⁸ According to the court, a "more measured approach" to an expert's adherence to methodological protocol is more "consistent with the spirit of *Daubert* and the Federal Rules of Evidence" because they place a "strong emphasis on the role of the fact finder in assessing and weighing the evidence."⁹⁹

The Ninth Circuit appears to set its own standard for assessing admissibility of expert opinion apart from Rule 702. Notably, in rejecting *In re Paoli*, the Ninth Circuit disregarded the 2000 Advisory Committee note's favorable citation to the case for the proposition that under Rule 702(d) the methodology must be applied accurately to every step.¹⁰⁰ What confounds the analysis is that the Ninth Circuit ultimately may have been correct on the result, despite these apparent misstatements of the law, when one examines the court's statements as to the factual record. The court noted the district

91 *Id.* at 1045 (alternation in original) (quoting *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1141 (9th Cir. 1997)).

92 *Id.* at 1046.

93 *Id.*

94 30 F.3d 1144 (9th Cir. 1994).

95 *City of Pomona*, 750 F.3d at 1047.

96 *Brown v. Se. Pa. Transp. Auth.* (*In re Paoli R.R. Yard PCB Litig.*), 35 F.3d 717 (3d Cir. 1994).

97 *City of Pomona*, 750 F.3d at 1047 (quoting *In re Paoli*, 35 F.3d at 745).

98 *Id.* at 1047–48 (quoting *Chischilly*, 30 F.3d at 1154).

99 *Id.* at 1048.

100 It is ironic that the court of appeals faulted the district court for "not apply[ing] the correct rule of law." *Id.* at 1048.

court's lack of explanation as to why the expert's failure to adhere to protocols was significant enough to warrant exclusion, and the expert did testify that he followed the protocols.¹⁰¹ In this light, if the failure to adhere to protocols was relatively minor and did not undermine the reliability of the method or its application, the result comports with current law. For questions of weight frequently arise, even under a proper Rule 104(a) analysis as to Rule 702. But such questions do not automatically render it a jury question. To suggest otherwise, as this case does, misreads Rule 702 and ignores the proper standard. The issue is whether the deviations from the proper method are enough to render the principles and methods not reliably applied—and that's a determination that Rule 702(d) requires the trial judge to make.¹⁰²

E. Eleventh Circuit

*Quiet Technology DC-8, Inc. v. Hurel-Dubois UK Ltd.*¹⁰³ demonstrates the difficulty in asking courts of general jurisdiction to delve into sophisticated scientific questions that arise in cases dependent on technical experts. In this case, Quiet, which manufactured noise-reducing “hush kits” to retrofit DC-8 jet engines, contracted with Hurel to make a compatible thrust reverser, a necessary component for stopping upon landing. Quiet contended that the thrust reversers were defective because their linkages blocked the engine air flow and thereby significantly impaired the efficiency of performance. Hurel blamed the problem on the design of Quiet's hush kit.¹⁰⁴ The case focused on a battle of experts, whose analyses attempted to explain the phenomenon observed.

Hurel proffered Joel Frank, an expert in aerodynamics, to testify that using a commercial computer software to measure fluid dynamics (CFD)—the airflow around and through the jet engine—only 3.08% of the loss in performance was attributable to Hurel's reverser linkages.¹⁰⁵ Quiet did not challenge the reliability of CFD software generally, but it did challenge Frank's application of it under Rule 702. Quiet focused on the “boundary conditions” the expert had selected, which “define where the [computer] model begins and where it ends.”¹⁰⁶ More specifically, in uniform flow profile cases (where a constant uniform pressure was applied at the leading edge

101 *Id.* Had the trial court articulated the reasons it determined the expert's failure to adhere to protocols rendered the expert's entire analysis unreliable, it is entirely possible that, under an abuse of discretion review, the decision to exclude the witness would have been affirmed.

102 *See, e.g.,* *Dow Chem. Co. v. Seegott Holdings, Inc. (In re Urethane Antitrust Litig.)*, 768 F.3d 1245, 1261 (10th Cir. 2014) (finding that the district court reasonably concluded that the statistical expert's foundation was reliable because there was “no need to consider every measurable factor—just the ‘major’ ones”).

103 326 F.3d 1333 (11th Cir. 2003).

104 *Id.* at 1336–37.

105 *Id.* at 1339.

106 *Id.* at 1338.

of the ejector, to serve as a baseline), the expert placed the inlet boundary more than a meter ahead of the leading edge of the ejector; while for in-flight profile cases (using pressure measurements Quiet had taken during its in-flight testing), he placed the inlet boundary condition at the “highlight of the ejector’s leading edge.”¹⁰⁷ Relatedly, Quiet challenged the expert’s use of the formula for calculating the intake pressures in his uniform profile cases. Quiet contended that the expert had “put the wrong information into the . . . software” or, as the court of appeals characterized it, “garbage in, garbage out.”¹⁰⁸ The trial court held a *Daubert* hearing and denied the motion.¹⁰⁹ A jury returned a verdict for Hurel, and the court of appeals affirmed.¹¹⁰

Surely animating the Eleventh Circuit’s analysis, under an abuse of discretion standard, was the parties’ extension of expert discovery up until close to trial, and the timing of the objection forced the court to conduct its *Daubert* hearing on the sixth day of trial. Moreover, the substance of the challenge was literally rocket science: Quiet contested the application of the expert’s fan pressure ratio, using “ $PT_{\text{Intake}} = \text{FPR}(P_{\text{amb}})$,” where PT_{Intake} is the intake pressure, FPR is the fan pressure ratio, and P_{amb} is the ambient pressure.”¹¹¹ As the Eleventh Circuit explained:

Thus, the intake pressure equaled the fan pressure ratio multiplied by the standard ambient pressure for the particular altitude being tested. For example, for the 35,000 feet altitude calculation, the ambient pressure—which is a known, unchanging figure—was 23,842 pascals which, when multiplied by a power setting of 1.9 FPR, yields a PT_{Intake} of 45,300 pascals. To arrive at the FPR, Frank divided the total pressure at the intake ($P_{t2.5}$) by the ambient pressure. However, Quiet says that he should have derived the FPR by dividing the total intake pressure ($P_{t2.5}$) by the exit pressure (P_{t2}). Quiet avers that as a result of this error, the $P_{t_{\text{Intake}}}$ derived by Frank was “substantially less than the actual varying intake pressures at the fan exit and substantially greater than the actual varying pressures at the ambient air intake gap. . . . [B]y using the wrong formula and the fictitious uniform flow, Frank did not even come close to duplicating the actual ejector intake pressures.”¹¹²

It is not surprising, therefore, that the Eleventh Circuit affirmed the trial judge’s decision. Before doing so, the court engaged in an extensive analysis of the technical testimony, eventually concluding that the ultimate issue was whether the expert’s selection of variables for the formula was correct. Citing the Supreme Court’s admonition that “[n]ormally, failure to include variables will affect the analysis’ probativeness, not its admissibility,” the court

107 *Id.*

108 *Id.* at 1344.

109 *Id.* at 1352.

110 *Id.*

111 *Id.* at 1344 n.11.

112 *Id.*

rejected the challenges.¹¹³ The court emphasized that Quiet had ample opportunity to cross-examine Frank as to his application of the methodology, noting that “[t]he identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination.”¹¹⁴ Thus, the court held that the trial judge did not abuse his discretion in allowing the testimony, and that ultimately it was for the jury to appropriately weigh the alleged defects, which “go to the weight, not the admissibility.”¹¹⁵

Given the highly complex nature of the testimony, it is difficult to be too critical of the Eleventh Circuit. That said, there are two problems with the court’s opinion. First, the court appears to have abdicated its role under Rule 702(d) to ensure, by a preponderance, that the methodology (which went largely unchallenged) was *applied* reliably. Instead, the court left that issue to a jury. As one can tell from the excerpt above, even an experienced trial judge would have difficulty working through the science. Could a jury? We do not know, but that is the point of Rule 702: to ensure that the methodology is not only reliable, but that it is reliably applied in the particular instance, with the underlying assumption that the jury is not able to handle these matters. However, it is entirely possible that the court of appeals did not mean to issue a categorical statement that arguments as to an expert’s application of a recognized methodology go to the weight of such testimony. Rather, its statement that the alleged flaws “are of a character that impugn the accuracy of [Frank’s] results, not the general scientific validity of his methods”¹¹⁶ may have been a conclusion that Frank met Rule 104(a)’s threshold and that the criticisms were sufficiently minor so as to go to weight.¹¹⁷ The opinion also reflects the high level of deference accorded a trial court under the abuse of discretion standard of review.

Second, it appears that the Eleventh Circuit was incorrect as a technical matter.¹¹⁸ While it stated that Quiet “does not contest the [expert’s] formulation that $PT_{\text{Intake}} = FPR(P_{\text{amb}})$,”¹¹⁹ the court’s footnote one page earlier acknowledged that Quiet had in fact argued that Frank should have “derived the FPR by dividing the total intake pressure ($P_{t2.5}$) by the exit pressure (P_{t2})” such that $PT_{\text{Intake}} = FPR(P_{\text{exit}})$.¹²⁰ This fundamental contradiction went unrecognized in the court’s opinion. In this light, the court’s citation to the

113 *Id.* at 1346 (alteration in original) (quoting *Bazemore v. Friday*, 478 U.S. 385, 400 (1986) (Brennan, J., concurring in part)).

114 *Id.* at 1345.

115 *Id.*

116 *Id.*

117 For example, the court noted Hurel’s contention that the criticism applied only in the calculations for the uniform profile cases, not the flight profile cases, and that even if Quiet were correct, Frank’s analysis was “not completely invalid” but instead required (at most) a “re-matching” of data. *Id.* at 1344 n.12.

118 Dr. Timothy Lau is credited with this observation. Dr. Lau, a lawyer, also holds a doctorate in materials science and engineering from the Massachusetts Institute of Technology and serves as a Senior Research Associate at the Federal Judicial Center.

119 *Quiet Tech.*, 326 F.3d at 1345.

120 *Id.* at 1344 n.11.

Supreme Court's statement that "[n]ormally, failure to include variables will affect the analysis' probativeness, not its admissibility"¹²¹ seems misplaced, as the claim was use of the *wrong* variable. In the end, the case puts to the test Justice Breyer's prediction that implementing *Daubert's* gatekeeping task "will not prove inordinately difficult."¹²²

F. Sixth Circuit

*McLean v. 988011 Ontario, Ltd.*¹²³ was a wrongful death lawsuit involving the crash of a private airplane brought against a refurbisher and an inspector. The pilot had purchased the used Piper Cherokee the month before the crash and had the defendants paint it and replace horizontal stabilizer tips, dorsal fin fairings, and other miscellaneous items. At the time of the crash at 1:04 a.m., the pilot had only 110 flight hours of experience, was in instrument meteorological conditions even though he was only trained for visual flight rules, and had just received a traffic advisory from air traffic control.¹²⁴ Plaintiffs offered two expert witnesses who contradicted each other as to the cause of the crash, but both contended it was ultimately a result of "flutter"—a "destructive harmonic event that virtually destroys the integrity of the control" of an aircraft.¹²⁵ The trial court granted summary judgment to the defendants on the grounds that the experts contradicted each other, relied on circumstantial evidence whose factual basis was undermined on key points by the defendants, and provided an explanation no more plausible than the defendants' explanation of pilot error.¹²⁶ The Sixth Circuit reversed.¹²⁷ Acknowledging that an expert's opinion must be supported by "'good grounds,' based on what is known,"¹²⁸ the court nevertheless stated that "mere 'weaknesses in the factual basis of an expert witness' opinion . . . bear on the weight of the evidence rather than on its admissibility."¹²⁹

The defects the defendants noted appear to be more than "mere weaknesses," however. For example, one expert, Rick Wilken, attributed the crash to a horizontal stabilizer that had been improperly balanced and separated in flight, a sloppy paint job, the lack of calibration, the use of replacement parts not from the manufacturer, and improper tensioning of the control

121 *Id.* at 1346 (alteration in original) (quoting *Bazemore v. Friday*, 478 U.S. 385, 400 (1986) (Brennan, J., concurring in part)).

122 *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 150 (1997) (Breyer, J., concurring).

123 224 F.3d 797 (6th Cir. 2000).

124 *Id.* at 799.

125 *Id.* at 802. One expert blamed faulty repairs; the other cited a loose balance weight on the tail section. *Id.*

126 *Id.* at 799.

127 *Id.* at 800.

128 *Id.* at 801 (quoting *Pomella v. Regency Coach Lines, Ltd.*, 899 F. Supp. 335, 342 (E.D. Mich. 1995)).

129 *Id.* (alteration in original) (quoting *United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir. 1993)).

cables.¹³⁰ However, Wilken did not know whether the control cables had been adjusted, and defendants' paperwork did not indicate that anyone "had touched the cables," although one employee's testimony "appears to indicate that the cables were detached and reattached" as part of the stabilizer-rebalancing procedure.¹³¹ Plaintiffs' other expert, Robert Donham, was a "flutter" expert. He blamed the crash on a loose balance weight on the top of the plane's rudder. However, he admitted he did not know specifically what the defendant did or did not do wrong in removing and reinstalling the weight, conceding, "I have no idea what happened to the unit."¹³² Moreover, the National Transportation Safety Board report of the crash did not show the weight as being found upstream of the crash, as Donham's theory assumed.¹³³ The court of appeals found both expert theories "plausible" and "supported by what evidence is available."¹³⁴ In other words, the court appeared to accept that the dearth of available evidence hampered plaintiffs' ability to demonstrate causation with any more precision. Plausibility, however, is plainly lower than a preponderance.

It would have been far better had the Sixth Circuit described how the available evidence was a sufficient basis for the expert's opinion under Rules 702(b) and 104(a). In the absence of such explication and given the lack of factual support for the opinions of the experts, relegating the decision to a jury under the notion that obvious weaknesses go to the weight, not admissibility, of the alleged flutter theory as the cause of the crash appears to invite speculation. This is particularly so given the uncontested facts surrounding the accident and the pilot's inexperience and lack of training for instrument meteorological weather conditions.

G. District Courts

Several district court opinions also address the sufficiency/weight/admissibility question. The following are representative.

*Bouchard v. American Home Products Corp.*¹³⁵ was a personal injury action involving the diet drug Redux. The plaintiff contended that ingesting the drug caused cardiac, brain, and pulmonary injury. Among the pretrial motions were motions to exclude expert testimony of experts by both parties. In one motion, the plaintiff moved to exclude the defendant's vocational expert, a licensed psychologist, who proposed to testify that the plaintiff could still perform sedentary work and lost only twenty percent of her ability to perform household services. Plaintiff contended that the expert lacked a sufficient basis for his opinion because he failed to evaluate all available information before making his decision and relied in part on the plaintiff's

130 *Id.* at 801–02.

131 *Id.* at 802.

132 *Id.* at 803–04.

133 *Id.* at 804.

134 *Id.* at 805.

135 No. 3:98CV7541, 2002 WL 32597992 (N.D. Ohio May 24, 2002).

self-assessment of her lifting requirements at work.¹³⁶ Though the opinion does not explain the nature of the alleged deficiencies, the court agreed with the defendant that such challenges did not warrant exclusion, noting that “weaknesses in the factual basis of an expert witness’ opinion . . . bear on the weight of the evidence rather than on its admissibility.”¹³⁷ According to the court, the failure to “examine sufficient evidence” was a subject “fit . . . for cross-examination, not a grounds for wholesale rejection of the expert opinion.”¹³⁸

Facially, the court’s opinion appears to have ignored Rule 702(b)’s requirement that there be a preponderance of evidence to support the basis for the expert’s opinion. However, other aspects of the court’s opinion suggest otherwise. For example, the court rejected the plaintiff’s contention that an expert could not rely on the plaintiff’s self-assessment of work obligations without independently verifying it, finding that a plaintiff’s self-assessment is prima facie evidence sufficient for an expert’s reliance. Moreover, the expert had reviewed four of the five years since plaintiff had been diagnosed, which the court may have found sufficient for admissibility under Rule 702(b). These facts may explain the court’s practical recognition that had the plaintiff felt the alleged flaws would have required the expert “to substantially change his opinion,” the plaintiff would have cross-examined him in his deposition.¹³⁹ In addition, although not expressly recognizing the Rule 104(a) requirement, the court provided a thorough and complete recitation of the legal standards for the admission of expert opinion and, in a careful analysis granting the plaintiff’s motion to exclude another witness (the defendant’s economist), found that his testimony violated the rule that it “must be accompanied by a sufficient factual foundation before it can be submitted to the jury.”¹⁴⁰

In many ways, *United States v. McCluskey*¹⁴¹ encapsulates the conflicting approaches to considering threshold sufficiency under Rule 702 reflected in the caselaw. The defendant moved to preclude the government’s expert from testifying that polymerase chain reaction/short tandem repeat (PCR/STR) DNA analysis tied the defendant to a firearm used as a murder weapon.¹⁴² The government argued that PCR/STR DNA analysis has been widely held to be a reliable methodology and that the defendant’s challenges to its application went “primarily to the weight . . . not [to] its admissibility.”¹⁴³ The defendant contended that neither the methodology nor applica-

136 *Id.* at *7.

137 *Id.* (citing *McLean*, 224 F.3d at 801).

138 *Id.*

139 *Id.*

140 *Id.* at *10 (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 754 (3d Cir. 2000)). The court ultimately rejected the testimony on a lack of “fit” with the evidence, because the expert had an “almost complete disregard for the . . . facts of [the] case.” *Id.*

141 954 F. Supp. 2d 1224 (D.N.M. 2013).

142 *Id.* at 1228.

143 *Id.* at 1244.

tion was reliable and that “no distinction should be made between methodology and application” in the court’s analytical approach.¹⁴⁴ According to the defendant, the government must prove that “each step in the procedure and each item used in the procedure meet the *Daubert* test for scientific reliability.”¹⁴⁵ The court independently determined that the PCR/STR methodology was reliable and admissible under Rule 702 and *Daubert* and concluded that the defendant’s challenges to the application of that methodology “go primarily to the weight of the DNA evidence, not its admissibility.”¹⁴⁶

What is remarkable about the case is the trial court’s extensive analysis. It contains an erudite discussion of the policy and principles underlying Rule 702 and *Daubert*. In painstaking detail, the court described all the proper applicable standards, even acknowledging that the government, as proponent, bore the burden under Rule 104(a) of proving admissibility under Rule 702 by a preponderance of the evidence.¹⁴⁷ The court also held an evidentiary hearing, accepted hundreds of pages of briefing, and admitted about 3500 pages of exhibits.¹⁴⁸ The opinion reviews scores of cases nationwide (many of which are described in this Article) to determine the proper standard for analyzing the application of the PCR/STR methodology to the defendant’s facts. The court eventually sided with those courts that hold that unless the challenges to the application of the methodology raise a “major flaw which undermines the entire analysis,” they constitute questions of weight for the jury.¹⁴⁹

For all that the *McCluskey* court did right (and it is a lot), it failed to analyze and apply Rule 702(d), which requires that the court apply the Rule 104(a) standard to the question of reliable application of the methodology to the facts of the case. In adopting the rule that challenges to application should be left to the jury “unless the alleged ‘error negates the basis for the reliability of the principle itself,’” the court relied upon cases predating the 2000 amendments to the Rules, particularly those in the Third and Eighth Circuits.¹⁵⁰ The court also interpreted Tenth Circuit cases to hold that *In re Paoli*’s admonition that “any step that renders the analysis unreliable . . . renders the expert’s testimony inadmissible”¹⁵¹ was merely a reference to *Joiner*’s invitation to ensure there is not “too great an analytical gap” between the

144 *Id.*

145 *Id.* Elsewhere, the court noted that the defendant argued that the methods employed must be “independently review[ed]” at “each major step” under *Daubert*. *Id.* (emphasis omitted).

146 *Id.*

147 *Id.* at 1233–36.

148 *Id.* at 1228–29.

149 *Id.* at 1248.

150 *Id.* at 1250 (quoting *United States v. Martinez*, 3 F.3d 1191, 1198 (8th Cir. 1993)).

151 *Id.* at 1245 (quoting *Brown v. Se. Pa. Transp. Auth. (In re Paoli R.R. Yard PCB Litig.)*, 35 F.3d 717, 745 (3d Cir. 1994)). The “any step” requirement is specifically quoted in Rule 702’s 2000 Advisory Committee note.

methodology and result.¹⁵² This conclusion seems to be a strained reading of *In re Paoli*, which went on to say that “[t]his is true whether the step completely changes a reliable methodology or merely misapplies that methodology.”¹⁵³ The *McCluskey* court arrived at this conclusion by repeatedly characterizing *Daubert* as *liberalizing* the admissibility standard and citing the opinion’s reference to the “liberal thrust” of the Federal Rules and their “general approach of relaxing the traditional barriers to ‘opinion’ testimony.”¹⁵⁴ While the Supreme Court indeed said this, such statements do not override the express terms of the 2000 version of Rule 702(d).

III. SUGGESTIONS FOR FUTURE CASES

Based on decisions like those highlighted in this Article, the Advisory Committee on the Federal Rules of Evidence has spent the last two years debating whether Rule 702 should be amended to underscore the need to apply Rule 104(a) to ensure that the gatekeeper function contemplated by the Rules and *Daubert* and its progeny is performed. Central to the Committee’s discussion is adding the preponderance requirement to the text of Rule 702. The argument in favor construes the cases as evidence that a significant number of courts are simply misapplying Rule 702 and misstating the law.¹⁵⁵ The argument against the amendment is that Rule 104(a) is a rule of general application and that Rule 702 should not be singled out for special treatment. Moreover, the Supreme Court has already made the point in *Daubert*, and the 2000 Advisory Committee note repeats it. Therefore, some say, the amendment would do no more than reinforce what has already been said. If courts are currently ignoring the Supreme Court and the 2000 amendments, is it likely they would follow a new amendment?

No doubt, in some cases the courts are misstating and misapplying Rule 702. Correction by the courts of appeals will go a long way to remedying the most obvious outliers. But it is unlikely that in the main courts are erring as egregiously as the proponents of a rule change suggest.¹⁵⁶ True, courts could be more careful in how they state that the challenges “go to weight, not admissibility.” But as demonstrated above, in many cases the courts may very well be applying the proper Rule 104(a) standard; they are just not explicating it. Confounding any ultimate determination are the oftentimes complex and highly technical nature of the disputes, *Daubert*’s description of the Rule 702 inquiry as “a flexible one”¹⁵⁷ that accords the trial judge “considerable

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

153 *In re Paoli*, 35 F.3d at 745 (emphasis omitted).

154 *McCluskey*, 954 F. Supp. 2d at 1238 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993)); see also *id.* at 1238, 1246, 1251, 1255.

155 See Bernstein & Lasker, *supra* note 27, at 19–25.

156 See 3 STEPHEN A. SALTZBURG, ET AL., FEDERAL RULES OF EVIDENCE MANUAL § 702.02[10], at 702-57 (12th ed. 2019) (concluding that the problem is “not . . . as great” as intimated).

157 *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (quoting *Daubert*, 509 U.S. at 594).

leeway,”¹⁵⁸ and the highly deferential abuse of discretion standard of review. Whether or not Rule 702 is amended, however, trial and appellate courts would be best served to adopt better practices in analyzing challenges to the admissibility of expert witnesses under Rule 702.

First, courts should cite the standard of admissibility they are employing. Specifically, citation to Rule 104(a) and its preponderance standard will educate the reader (and reviewing court) as to the threshold used and reinforce the proper admissibility framework. In virtually every other context, a judicial opinion always begins with a recitation of the proper standard of review. In the vast majority of cases under question, while Rule 702 and relevant cases are cited, there is no acknowledgment that the gatekeeper function requires application of Rule 104(a)’s preponderance test, much less for *each* of the elements of the Rule. Instead, courts tend to defer to statements from caselaw, even if it is outdated.

Second, a surprising number of cases start and end with *Daubert* and its progeny and fail to mention Rule 702.¹⁵⁹ Of course, Rule 702 was amended in 2000, and the elements of Rule 702, not the caselaw, are the starting point for the requirements for admissibility.¹⁶⁰ In this respect, labeling expert challenges “*Daubert*” motions is a misnomer. Moreover, statements as to the “liberal thrust” of Rule 702 and “flexible” standard trial judges should apply must be contextualized. Expansion of the gatekeeper inquiry beyond *Frye*’s general acceptance test is necessarily cabined by the elements of Rule 702. And the flexibility accorded trial judges relates to which *Daubert* factors, in the totality of circumstances, the court chooses to examine in applying Rule 702’s required elements; the court cannot pick and choose among the Rule 702 elements. Such generalizations should not be used as a basis to evade the Rule. Rather, courts should cite the current Rule 702 and its elements for admissibility. Caselaw may be indispensable for interpreting those elements, but the foundation for the test is Rule 702.

Third, courts should read cases predating the 2000 amendments to Rule 702 with caution. Rule 702 has changed, and thus so have the admissibility requirements. *City of Pomona* illustrates this problem.

Fourth, courts should identify what evidence either meets or fails the preponderance standard for threshold admissibility, and why. In several cases, such as *Bouchard*, statements that the weaknesses of the evidence went to the weight and not admissibility may have merely reflected the court’s con-

158 *Id.* at 152.

159 This point was made by Bernstein & Lasker, *supra* note 27, at 8.

160 See *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) (“Because the Federal Rules of Evidence are a legislative enactment, we turn to the ‘traditional tools of statutory construction’ in order to construe their provisions. We begin with the language of the Rule itself.” (quoting *INS v. Cardonza-Fonseca*, 480 U.S. 421, 446 (1987))); *United States v. Parra*, 402 F.3d 752, 758 (7th Cir. 2005) (acknowledging that “Rule 702 has superseded *Daubert*”); *United States v. Mamah*, 332 F.3d 475, 477 (7th Cir. 2003) (“We begin our analysis by looking at the actual text of Rule 702, which was amended in 2000 in response to *Daubert* and *Kumho Tire* . . .”).

clusion that there was a preponderance of evidence to support the opinion. One does not always know for sure, as it was never articulated. *Daubert's* famous line about “shaky *but admissible* evidence”¹⁶¹ should not be misused to avoid a proper analysis or, worse, relegate gatekeeper questions to a factfinder. The trial court must first find whether the opinion testimony is admissible.

Fifth, courts should require that challenges be raised timely, so that thoughtful analysis can be conducted. Trial courts are exceedingly busy, and *Daubert* motions tend to be very time consuming.¹⁶² Many Rule 702 challenges involve highly technical questions, and the parties' disagreement often stems from the complexity. Planning should begin with the Rule 26(f) scheduling conference, allowing ample time for the court to understand and contemplate the issues. In this respect, criminal cases raise even more of a challenge.¹⁶³ For the seasoned trial judge, last-minute challenges may be resolved during trial for efficiency's sake,¹⁶⁴ but making appropriate findings on the record at this late stage may be more difficult.

Sixth, there will be challenges to the weight of an opinion's basis even under a proper Rule 104(a) analysis. This does not automatically render the question one for a jury, as some of the cases suggest. Rather, the trial judge, as gatekeeper, must determine whether such challenges are so significant that the factual basis for the opinion fails to reach the preponderance standard or, instead, whether the alleged defects are sufficiently minor, such that they do not undermine the remaining basis. In the latter instance, the alleged flaws do not impugn the reliability or validity of the method or results. For example, an expert who allegedly failed to include a handful of patients in a study of over 100 patients, or an expert whose opinion is supported by a dozen studies but is contrary to a study that would not undermine her ultimate conclusion would likely pass the Rule 104(a) bar.¹⁶⁵ Of

161 *Daubert*, 509 U.S. at 596 (emphasis added).

162 *Symposium on Forensic Expert Testimony, Daubert, and Rule 702*, 86 *FORDHAM L. REV.* 1463, 1535 (2018) (U.S. District Judge Patti Saris noting necessity of reaching *Daubert* motions early in the litigation, “so that you can think about it more slowly” because it is “complicated” and “hard”).

163 *FED. R. CIV. P.* 26(f); see Paul W. Grimm, *Challenges Facing Judges Regarding Expert Evidence in Criminal Cases*, 86 *FORDHAM L. REV.* 1601, 1611–13 (2018).

164 See, for example, *United States v. McCluskey*, 954 F. Supp. 2d 1224, 1234 (D.N.M. 2013) (citing *United States v. Nichols*, 169 F.3d 1255, 1264 (10th Cir. 1999)), for the proposition that, if the expert's testimony is admissible, the jury is entitled to hear the same criticisms raised during the *Daubert* challenge, and to avoid duplication it may be presented once before the jury.

165 How to deal with competing scientific studies is an area that continues to confound courts. Rule 702(b) requires that “the testimony [be] based on sufficient facts or data.” *FED. R. EVID.* 702. The 2000 Advisory Committee note reminds that in determining reliability, a trial judge should consider “[w]hether the expert has adequately accounted for obvious alternative explanations.” *FED. R. EVID.* 702 advisory committee's note to 2000 amendment. Here, too, the inquiry is one of degree. The Advisory Committee note provides some guidance in the context of causation: “[T]he possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been consid-

course, where there is a legitimate question of fact on which the admissibility of the expert opinion turns, Rule 104(a) does not allow the trial court to make that call, and the jury must decide.¹⁶⁶

In the end, just as the Supreme Court has reiterated that the nature of the task of gatekeeping is by design flexible, there will be no silver bullet to ensuring a proper application of Rule 702. But the leeway accorded trial courts in deciding *how* to determine reliability cannot serve as a substitute for the application of the proper threshold standards for determining admissibility. Hopefully, these suggestions will assist trial and appellate courts in making the best decisions possible.

CONCLUSION

As trial judges can attest, discharging their gatekeeper role under Rule 702 can frequently be exceedingly difficult, especially when it is case dispositive. While judges are accorded wide latitude in how they go about making that determination and are reviewed for an abuse of discretion, they are nevertheless bound by Rule 104(a)'s requirement that there be a preponderance of evidence supporting each of the requirements of Rule 702(a) through (d). Decisionmaking on the admissibility of expert testimony would be better served if trial judges acknowledged the Rule 104(a) standard and articulated how the expert's opinion fared under each element of Rule 702. This would also assist the appellate courts, which, in conducting their deferential review, should avoid blanket statements suggesting that any alleged flaws affect the weight of the evidence, not its admissibility.

ered and reasonably ruled out by the expert." *Id.* (citing *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996)). Thus, where the studies relied upon provide sufficient basis for the expert's opinion, Rule 104(a) is met as long as the conflicting studies can be adequately explained or raise issues that are insufficient to undermine the Rule 104(a) preponderance requirement. In many cases, this may be what courts mean when they say that the criticisms "go to the weight, not the admissibility, of the evidence." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1345 (11th Cir. 2003); *see also* Margaret A. Berger, *The Admissibility of Expert Testimony*, in *REFERENCE MANUAL ON SCIENTIFIC EVIDENCE* 11, 19 (3d ed. 2011) (discussing problems in experts' reliance on some, but not all, scientific studies in a field).

166 *See* FED. R. EVID. 702 advisory committee's note to 2000 amendment ("The emphasis in the amendment on 'sufficient facts or data' is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other."). To preserve the issue, the jury could be instructed that if they find the fact as proffered, they may consider the expert's opinion.