

THE *DAUBERT* TRIAL TOOLBOX—NATIONAL EDITION Updated March 2024

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I. FEDERAL RULE OF EVIDENCE 702

A. THE TEXT OF THE RULE

“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 the proponent demonstrates to the court that it is more likely than not that:

(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’s opinion reflects a reliable application of the principles and methods to the facts of the case.”

II. THE STORY BEHIND DAUBERT

1. Between 1956 and 1983, over 33 million women took Bendectin as an anti-nausea medication during pregnancy. In the late 1970’s and throughout the 1980’s, thousands of lawsuits were filed all over the country claiming that Bendectin caused birth defects (specifically limb deformities). It was a true mass tort. Prominent attorneys like Melvin Belli, Jim Butler, Allen Eaton, and Barry Nace spearheaded the litigation. In June 1983, Barry Nace

obtained a \$750,000.00 verdict for Mary Oxendine, who was born with a shortened right forearm and only three fingers on her right hand after her mother had taken Bendectin while pregnant. 13 days after the verdict, Merrell Dow Pharmaceuticals, Inc. took Bendectin off the market. Merrell cited an increase in insurance rates and maintained that the drug is perfectly safe.

2. Despite the verdict, an issue that continued to loom over the entire litigation was – did Bendectin actually cause birth defects? And the central issue in each case was – did Bendectin cause *this* plaintiff’s birth defects? At the time, there was no scientific understanding of the causal mechanism by which Bendectin (allegedly) caused birth defects, and no epidemiological study had ever concluded Bendectin caused birth defects. Courts across the country struggled with the issue of whether, *and on what basis*, an expert could testify that Bendectin, not only caused birth defects, but caused the birth defects experienced by a particular plaintiff.

3. The question was, and is, essentially epistemological. That is—how does the expert “know” what the expert claims to “know”? What basis does the expert have for saying it? And the important question for courts in determining whether an expert’s opinion is admissible is: What counts as a *sufficient* basis—as a legally adequate foundation—as “good grounds”—for an expert’s opinion?

III. THE DAUBERT TRILOGY

A. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) – Reliability and Relevancy

1. In response to a motion for summary judgment at the trial court level (this is now 1989), the Daubert plaintiffs produced eight experts who based their causation opinions on: (1) *in vivo* animal studies – which showed giving Bendectin to pregnant rabbits causes birth defects; (2) *in vitro* studies – which showed Bendectin causes malformations to animal cells in a test tube; (3) chemical structure analyses – which showed that Bendectin’s molecular structure is extremely similar to that of other known teratogens; and (4) a re-analysis of prior epidemiological studies – which showed (according to the experts) there was indeed a statistically significant relationship between Bendectin and birth defects.

2. The district court acknowledged that, “there are two schools of thought governing expert testimony in these Bendectin cases.” Daubert v. Merrell Dow Pharmaceuticals, Inc., 727 F. Supp. 570, 572 (S.D.CA. 1989). The majority view (already supported by the First, Fifth, Sixth and D.C. Circuits) was that: “Absent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological evidence. . . . ‘[F]ailure to present statistically significant epidemiological proof’ is ‘fatal’ to the case.” Id. (quoting Brock v. Merrell Dow Pharmaceuticals, 874 F.2d 307 (5th Cir.1989)).

3. The minority view on the other hand did not require epidemiological evidence to prove causation. It permitted experts to weigh all of the available evidence in reaching a conclusion and gave “deference to the expert’s opinion,” viewing the “varying conclusions as involving a classic battle of the experts.” Id. at 573 (citing Oxendine v. Merrell Dow Pharmaceuticals, Inc., 506 A.2d 1100 (D.C.App.1986)). The district court sided with the majority view and granted the motion for summary judgment.

4. The Ninth Circuit (applying Frye) affirmed and held that a “reanalysis of epidemiological studies is

generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field.” Daubert v. Merrell Pharmaceuticals, Inc., 951 F.2d 1128, 1133 (9th Cir. 1991).

5. The Supreme Court reversed (a win for the Plaintiffs) and held that Frye “should not be applied in federal trials” because “a rigid ‘general acceptance’ requirement would be at odds with the ‘liberal thrust’ of the Federal Rules and their ‘general approach of relaxing the traditional barriers to opinion testimony.’” Daubert, 509 U.S. at 588.

6. Rather than adopting a bright-line rule of requiring expert testimony to be based upon “generally accepted” methods for establishing causation (i.e., statistically significant epidemiological evidence), the Court assigned trial courts the role of “gatekeeper” with “the task of ensuring that an expert’s testimony both rests on a **reliable foundation** and is **relevant** to the task at hand.” Id. at 597 (emphasis added)..

B. RELIABILITY MEANS “EVIDENTIARY RELIABILITY” – I.E., “TRUSTWORTHINESS”

1. It is critical to remember that Daubert was a case about scientific knowledge as opposed to the other types of knowledge expressly listed in F.R.E. 702 (“technical, or other specialized knowledge”). The Court made clear: “Our discussion is limited to the scientific context because that is the nature of the expertise offered here.” Id. at 590, n.8.

2. “[I]n order to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” Id. at 590.

3. In Daubert, the Court dropped a very important footnote (n.9) to specify what it meant by reliability: “We note that scientists typically distinguish between ‘validity’ (does the principle support what it purports to show?) and ‘reliability’

(does application of the principle produce consistent results?). Although ‘the difference between accuracy, validity, and reliability may be such that each is distinct from the other by no more than a hen's kick,’ **our reference here is to evidentiary reliability – that is, trustworthiness.**” *Id.* at 590, n.9.

4. We are all familiar with the notion that evidence must be trustworthy before it can be admitted into evidence. That is exactly what makes hearsay inadmissible – because something someone said out of court is not reliable evidence. We don’t know if it’s true. It can’t be trusted. It can’t be *relied upon*. In footnote 9 the Court goes on to compare its *Daubert* standard of evidentiary reliability to the theory behind exceptions to hearsay: “[H]earsay exceptions will be recognized only ‘under circumstances supposed to furnish guarantees of trustworthiness.’” *Id.* at n.9 (quoting the Advisory Committee’s Notes on Art. VIII of Rules of Evidence).

5. At the end of footnote 9, the Court states: “In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*.” *Id.* at n.9 (emphasis in original). The Court spends much of the rest of the opinion trying to set up a structure for evaluating scientific validity. That is where the Court lists out its factors and tries to describe what makes for good science.

6. So while the *Daubert* factors are important in the context of scientific testimony, they are just one application of the overarching requirement of *Daubert* – that expert testimony is reliable evidence, that it wasn’t just pulled out of a hat, that it is trustworthy.

7. The trustworthiness of an expert’s opinion is what *Daubert* is all about. The expert forms an opinion, and the trial court (as gatekeeper) gets to say, in essence – yea, but how do you know that? – what basis do you have for saying that? – please explain your reasoning. In other words, under *Daubert*, experts must show their work.

C. Relevancy Means the Testimony is Sufficiently Tied to the Facts of the Case

1. “Rule 702 further requires that the evidence or testimony ‘assist the trier of fact to understand the evidence or to determine a fact in issue.’ This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *Daubert*, 509 U.S. at 591.

2. “The consideration has been aptly described by Judge Becker as one of ‘fit.’ ‘Fit’ is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Id.*

3. “The study of the phases of the moon, for example, may provide valid scientific ‘knowledge’ about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent creditable grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night.” *Id.*

D. Daubert’s “General Observations” of Factors Bearing on the Inquiry

1. “Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate.” *Daubert*, 509 U.S. at 593.

- a. “a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested.” *Id.*
- b. “whether the theory or technique has been subjected to peer review and publication.” *Id.*
- c. “in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error.” *Id.* at 594.
- d. “‘general acceptance’ can yet have a bearing on the inquiry.” *Id.*

E. Vigorous Cross Examination

1. “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” Daubert, 509 U.S. at 596.

2. “Additionally, in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment . . . and likewise to grant summary judgment.” Id.

3. “These conventional devices, rather than wholesale exclusion under an uncompromising ‘general acceptance’ test, are the appropriate safeguards where the basis of scientific testimony meets the standards of *Rule 702*.” Id.

F. General Electric Co. v. Joiner, 522 U.S. 136 (1997) – Analytical Gaps and Abuse of Discretion

1. The Court affirmed a district court’s exclusion of an expert who testified that exposure to a chemical, PCB, “promoted” plaintiff’s lung cancer. The expert’s opinions were based upon mice studies and four readily distinguishable epidemiological studies, and plaintiff was a smoker with a family history of lung cancer.

2. Although in Daubert, Justice Blackmun said the focus “must be solely on the principles and methodology and not the conclusions they generate,” in Joiner Justice Rehnquist stated: “conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Joiner, 522 U.S. at 146.

3. The Joiner Court made clear that the “admissibility of expert testimony . . . is reviewable under the abuse of discretion standard.” Id. at 143.

G. Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999) – Expanding on the Factors Set Forth in Daubert

1. The Court held the Daubert gatekeeping obligation “applies to all expert testimony.” Id. at 147.

2. “Daubert makes clear that the factors it mentions do **not** constitute a ‘definitive checklist or test.’” Id. at 150 (emphasis in original).

3. In Kumho, the Court affirmed the district court’s exclusion of an expert who testified that a tire blow-out (which resulted in a car wreck) was caused by a defect in the tire rather than due to abuse or the tire being underinflated. The exclusion was based, in part, on the fact that the expert repeatedly relied “on the ‘subjectiveness’ of his mode of analysis in response to questions seeking specific information” about his method for determining the defect. Kumho, 526 U.S. at 155.

4. Additionally, and this was a big red flag, the expert determined the tire to be defective (and issued a report to that effect) after simply looking at photographs and only inspected the tire itself the morning of his deposition. Kumho, 526 U.S. at 155.

5. The trial court must “make certain that [the] expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of **intellectual rigor that characterizes the practice of an expert in the relevant field.**” Id. at 152 (emphasis added).

6. “[T]he factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony. The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in Daubert, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.” Id. at 155.

7. The Court went on to state, “no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience. *Id.* at 156. But, “it will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable.” *Id.* at 151.

8. “The trial court must have the same kind of latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether that expert's relevant testimony is reliable.” *Id.* at 152 (emphasis in original).

9. “Thus, whether *Daubert's* specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine.” *Id.* at 153.

H. Takeaways From the Daubert Trilogy

1. Expert testimony must be relevant and reliable.

2. *Kumho* makes clear that the factors listed in *Daubert* are not controlling and the trial courts have a significant amount of discretion and flexibility in determining whether the expert's testimony has evidentiary reliability (i.e., trustworthiness).

3. The purpose of a *Daubert* analysis is, “to analyze not what the experts say, but what basis they have for saying it.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (“*Daubert II*” on remand). See also *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) (quoting same from *Daubert II*).

4. Judges have extreme leeway in their *Daubert* decisions under the abuse of discretion standard.

5. Reliability means trustworthiness. Judges get to ask the experts – yea, but how do you know that? – please explain your reasoning. It is not the answer that is important, but how the expert came up with the answer. *Daubert* is just like 7th grade math class.

Your experts get no credit unless they show their work.

IV. GENERAL DAUBERT JURISPRUDENCE

A. “Distilled” to Three Requirements

“We have distilled from *Daubert*, *Kumho*, and Rule 702 these three requirements: First, ‘the expert must be qualified to testify competently regarding the matter he or she intends to address’; second, the expert's ‘methodology ... must be reliable as determined by a *Daubert* inquiry’; and third, the expert's ‘testimony must assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue.’” *Adams v. Lab. Corp. of America*, 760 F.3d 1322, 1328 (11th Cir., July 29, 2014) (quoting *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010)).

B. The Goals of Daubert

1. The “object” of *Daubert* is “to make sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work. If they do, their evidence (provided of course that it is relevant to some issue in the case) is admissible even if the particular methods they have used in arriving at their opinion are not yet accepted as canonical in their branch of the scientific community. If they do not, their evidence is inadmissible no matter how imposing their credentials.” *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318-19 (7th Cir. 1996) (J. Posner) (affirming exclusion of expert who testified that wearing a nicotine patch for three days was the cause of a heart attack without providing reasoning or evidence for such short-term consequences).

2. “*Daubert* attempts to strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading “junk science” on the other. *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 176-77 (6th Cir. 2009) (citing *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002)).

3. “Judges in jury trials should not exclude expert testimony simply because they disagree with

the conclusions of the expert. The Daubert duty is to judge the reasoning used in forming an expert conclusion.” Kennedy v. Collagen Corp., 161 F.3d 1226, 1230 (9th Cir. 1998).

C. Burden of Proof is on the Proponent of the Evidence

1. “[T]he proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable.” Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312 (11th Cir. 1999) (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3rd Cir. 1994)); see also Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir.1998).

2. “Daubert does not require that a party who proffers expert testimony carry the burden of proving to the judge the expert’s assessment of the situation is correct; rather, to satisfy Daubert’s objective, the proponent must show that the expert’s conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.” Lawes v. CSA Architects and Engineers LLP, 963 F.3d 72, 99 (1st Cir. 2020).

D. Daubert Does Not Supplant the Adversary System

1. “The Advisory Committee Notes state that, **after Daubert, ‘the rejection of expert testimony is the exception rather than the rule.’** Fed. R. Evid. 702 Advisory Committee’s Note to 2000 Amendments. Indeed, even when ‘a trial court, applying this amendment, rules that an expert’s testimony is reliable, this **does not necessarily mean that contradictory expert testimony is unreliable. The amendment is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise.**’ . . . Courts must remain chary **not to improperly use the admissibility criteria to supplant a plaintiff’s right to a jury trial:** ‘Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.’” Moore v. Intuitive Surgical, Inc., 995 F.3d 839, 850 (11th Cir. 2021).

2. “We have repeatedly stressed Daubert’s teaching that the gatekeeping function under Rule 702 ‘is not intended to supplant the adversary system or the role of the jury: vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking **shaky but admissible evidence.**” Adams v. Lab. Corp. of America, 760 F.3d 1322, 1334 (quoting United States v. Alabama Power Co., 730 F.3d 1278, 1282 (11th Cir. 2013)).

3. Daubert did not work a “seachange over federal evidence law,” and “the trial court’s role as gatekeeper is not intended to serve as a replacement for the adversary system.” United States v. 14.38 Acres of Land Situated in Leflore County, Mississippi, 80 F.3d 1074, 1078 (5th Cir. 1996).

E. Very High Abuse of Discretion Standard

1. “Because the task of evaluating the reliability of expert testimony is uniquely entrusted to the district court under Daubert, we give the district court considerable leeway in the execution of its duty.” Smith v. U.S., 2023 WL 5011730, at *4 (11th Cir. Aug. 7, 2023) (finding court did not abuse its discretion for excluding expert for failure to consider alternative explanations for plaintiff’s angioedema reaction) (quoting Rink v. Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005)).

2. “The flexibility of the Daubert analysis and the deferential review of district court decisions in this realm derive from the same general policy: allowing district courts, which are much more intimately familiar with the individual facts and needs of a particular case, to manage their dockets and counsels’ time to provide the most efficient and just resolution of issues.” United States v. Ware, 69 F.4th 830, 846 (11th Cir. 2023)

3. “If the court correctly applied the Rule 702 Daubert framework, we review its decision to admit or exclude expert testimony for abuse of discretion. Under that standard, so long as the district court adhered to Daubert’s requirements, we shall not disturb the district court’s findings unless they are

manifestly erroneous.” *Kirk v. Clark Equip. Co.*, 991 F.3d 865, 872 (7th Cir. 2021) (District court did not abuse its discretion in excluding the expert’s testimony since it was unreliable regarding defective condition and causation in a products liability action where plaintiff was injured by a skid-steer loader).

4. “[I]n the last five years, there have been 54 reported decisions of this court (13 published opinions and 41 unpublished opinions) reviewing district court evidentiary rulings under *Daubert*, and the district court was reversed in only three of those cases.” *U.S. v. Alabama Power Co.*, 730 F.3d 1278, 1289 (11th Cir. 2013) (J. Hodge dissenting).

5. “We are to review the district court’s decision on how to determine reliability with the same abuse of discretion standard that we use to review its ultimate conclusion. . . . [G]iven the heavy thumb—really a thumb and a finger or two—that is put on the district court’s side of the scale, we conclude that it was not an abuse of discretion to admit the expert opinions” *U.S. v. Brown*, 415 F.3d 1257, 1268 (11th Cir. 2005) (affirming admissibility of chemist and biochemist who conducted visual comparisons of molecular models of chemicals and based opinions on knowledge and experience).

6. “The deference we show trial courts on evidentiary rulings is especially pronounced in the *Daubert* context, where the abuse of discretion standard places a ‘heavy thumb’ — ‘really a thumb and a finger or two — ‘on the district court’s side of the scale.’ *Brown*, 415 F.3d at 1268. That’s done for a number of reasons. The district court occupies the best position to rule on *Daubert* issues given its familiarity ‘with the procedural and factual details’ of the trial, which it presides over and is immersed in. *Id.* at 1266. The rules that control the admission of expert testimony ‘must be applied in case-specific evidentiary circumstances that often defy generalization.’ *Id.* And deference maintains the importance of the trial and discourages appeals of rulings about expert witness testimony.” *United States v. Pon*, 963 F.3d 1207, 1219 (11th Cir. 2020).

F. Reversed for Abuse of Discretion

1. In *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227 (9th Cir. 2017), the Ninth Circuit reversed holding that the district court abused its discretion by excluding the expert testimony. The district court reasoned that the expert was unreliable because they never conducted independent research on the relationship between drugs and the lack of epidemiological studies showing general and specific causation. *Id.* at 1232. The Ninth Circuit reasoned that the district court “overemphasized the fact that (1) the experts did not develop their opinions based on independent research and (2) the experts did not cite epidemiological studies. *Id.* at 1233. Moreover, the district court failed to consider the “expert’s overall methodology.” *Id.* at 1233. The expert based his opinions on “medical records, his education, training and experience, knowledge of the pertinent medical literature and [his] knowledge of the epidemiology, diagnosis and natural history of HSTCL.” *Id.* at 1234.

2. In *Anderson v. Raymond Corporation*, 61 F.4th 505, 507 (7th Cir. 2023). the plaintiff’s leg was amputated after being run over by a forklift. The Seventh Circuit found that the district court abused its discretion in excluding the expert’s testimony. *Id.* The plaintiff’s expert testified that the manufacturer could have made a number of design changes that would have prevented the accident. *Id.* The district court excluded this testimony reasoning that it did not pass the *Daubert* tests or Rule 702. *Id.* at 508. The appellate court reasoned that the district court’s one sentence explanation was inadequate, and the expert’s testimony should have been admitted because: (1) his extensive training and experience in failure analysis; (2) his experience in investigating machine accidents and accident reconstruction; and (3) he has a license to operate a fork-lift. Furthermore, the court found that he was reliable and the fact that he did not conduct his own independent tests had no bearing on the reliability of his methodology. *Id.* at 508-09.

3. *MacDougall v. Am. Honda Motor Co., Inc.*, 2021 WL 6101256 (9th Cir. Dec. 21, 2021). The Ninth Circuit reversed and remanded finding that the district court abused its discretion by excluding the expert witness

and subsequently granting summary judgment in favor of Honda. *Id.* at *1. The district court reasoned that since the expert failed to consider actual market prices, he was unreliable. *Id.* The appellate court reasoned that “[t]he test under Daubert is not the correctness of the expert’s conclusions but the soundness of his methodology.” *Id.* Thus, the experts’ conclusions go to the weight of his testimony, i.e., his credibility, and not whether he is reliable.

4. *Martinez v. U.S.*, 33 F.4th 20 (1st Cir. 2022). The trial court abused its discretion when it excluded the plaintiff’s expert witness on the grounds that the expert report was deficient since it did not contain all of the requirements under Fed. R. Evid. 702. The appellate court reversed, reasoning that: 1) the report mentioned two types of standards of care; 2) his testimony was relevant; 3) he addressed causation; and 4) it had an accepted methodology.

H. Daubert Hearings

1. “Daubert hearings are not required.” *Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty.*, 402 F.3d 1092, 1113 (11th Cir. 2005) (quoting *Hansen*, 262 F.3d at 1234).

2. “[A] Daubert hearing may be helpful in complicated cases involving multiple expert witnesses.” *U.S. v. Ware*, 69 F.4th 830, 846 (11th Cir. 2023) (internal quotation marks omitted).

3. “A district court should conduct a *Daubert* inquiry when the opposing party’s motion for a hearing is supported by conflicting medical literature and expert testimony.” *Id.* “On the other hand, some expert testimony will be so clearly admissible that a district court need not conduct a Daubert hearing in every case.” *Id.* (internal quotation marks omitted).

I. Important Advisory Committee Notes to F.R.E. 702

1. **Expert Can Be a Teacher.** “The rule accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts.”

2. **“Skilled” Witnesses.** “Thus within the scope of the rule are not only experts in the strictest sense

of the word, e.g., physicians, physicists, and architects, but also the large group sometimes called “skilled” witnesses, such as bankers or landowners testifying to land values.”

3. **Experience Alone.** “[T]he text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.”

4. **Good Grounds.** “Some types of expert testimony will be more objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication, than others. Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise. The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted.”

5. **Opinions of Other Experts.** “The amendment requires that expert testimony be based on sufficient underlying ‘facts or data.’ The term ‘data’ is intended to encompass the reliable opinions of other experts.”

6. **Exclusion is the Exception.** “A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.”

V. QUALIFICATIONS

A. Principles of Law

1. The proponent must show “the expert is qualified to testify competently regarding the matters he intends to address.” *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1309 (11th Cir. 1999).

2. “[A] witness is not an expert simply because he claims to be. The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” *Rose v. Truck Centers, Inc.*, 388 Fed. Appx. 528, 533 (6th Cir. 2010) (internal quotes and citations omitted).

3. “Although an expert's qualifications go primarily to the first prong of Daubert's inquiry, ‘an expert's overwhelming qualifications may bear on the reliability of his proffered testimony’ even if ‘they are by no means a guarantor of reliability.’” Tampa Bay Water v. HDR Engineering, Inc., 731 F.3d 1171, 1185 (11th Cir. 2013) (quoting Quiet Technology DC-8, Inc. v. Hurl-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003)).

4. “If the expert meets liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility.” Kannankeril v. Terminix Intern., Inc., 128 F.3d 802, 808 (3d Cir. 1997) (citing In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 741 (3d Cir. 1994)).

5. “[The expert’s] background and practical experience qualify as ‘specialized knowledge’ gained through ‘experience, training, or education.’” McCulloch v. H.B. Fuller, Co., 61 F.3d 1038 (2nd Cir. 1995) (affirming admissibility of expert consultant on fume dispersal).

6. “Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that ‘a broad range of knowledge, skills, and training qualify an expert.’” Schneider v. Fried, 320 F.3d 396, 404 (3rd Cir. 2003) (reversing exclusion of cardiologist’s standard of care opinion because expert had sufficient experience to testify to such matters) (citations omitted).

7. “[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 782 (3rd Cir. 1996).

8. “If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court’s gatekeeping function requires more than simply ‘taking the expert’s word for it.’” U.S. v.

Frazier, 387 F.3d 1244, 1261 (11th Cir. 2004) (quoting Advisory Committee Notes on Fed. R. Evid. 702, 2000 Amendments).

9. “The distinction between scientific and non-scientific expert testimony is a critical one. By way of illustration, if one wanted to explain to a jury how a bumblebee is able to fly, an aeronautical engineer might be a helpful witness. Since flight principles have some universality, the expert could apply general principles to the case of the bumblebee. Conceivably, even if he had never seen a bumblebee, he still would be qualified to testify, as long as he was familiar with its component parts.

On the other hand, if one wanted to prove that bumblebees always take off into the wind, a beekeeper with no scientific training at all would be an acceptable expert witness if a proper foundation were laid for his conclusions. The foundation would not relate to his formal training, but to his firsthand observations. In other words, the beekeeper does not know any more about flight principles than the jurors, but he has seen a lot more bumblebees than they have.” Rose v. Truck Centers, Inc., 388 Fed. Appx. 528, 533 (6th Cir. 2010) (quoting Berry v. City of Detroit, 25 F.3d 1342, 1349-50 (6th Cir. 1994)).

B. Areas of Questioning to Test Qualifications

1. For each opinion and sub-opinion, find out how the expert gained the knowledge to provide those opinions – how does the expert know what the expert claims to know?

- i. Learned in school/college/post-graduate work?
- ii. Learned from “on the job” training?
- iii. Based on experience or academic knowledge?
- iv. Conducted own research independent of litigation?
- v. Relied on other sources and authorities for information related to this case?

2. How does the expert’s professional work/experience relate to the opinions being offered? Does expert regularly perform this kind of work in professional life? What are the differences between

the expert's work/experience and the work performed in this case? What percentage of the expert's work relates to the specific issues in the case? How recently has expert engaged in professional work on issues specific to the case?

3. Has the expert been published? On anything related to the case? Was the expert the primary contributor to the work or was name simply attributed to the work?

4. Do opinions exceed scope of expertise? Are opinions based on, even in part, knowledge or principles derived from fields of study not within the scope of expertise?

5. Opinions based on any bedrock assumptions that come from other disciplines? Will expert admit he is not an expert in those areas? No training in those areas? No experience in those areas? If issue came up in professional life, would expert defer to expert in another field? Would expert defer to another expert regarding any issues in this case?

6. Would expert feel comfortable lecturing on topic about which she is opining? Has expert lectured/taught on subject matter contained within opinions? When? Where? To whom?

7. Membership in associations? Current? Paid dues? Does CV list anything misleading or outdated items? Subject to disciplinary actions within the field?

8. Involvement in litigation in the past?

9. Does knowledge in this field change rapidly? What does expert do to keep abreast of changes?

10. Is there any other information or experiences that you did not have, but which would have helped you in forming your opinion?

VI. RELIABILITY

A. Factors Indicating Reliability

1. **Can Be (Has Been) Tested.** (*Daubert*)

2. **Subjected to Peer Review.** (*Daubert*)

3. **Known or Potential Error Rate.** (*Daubert*)

4. **General Acceptance.** (*Daubert*)

5. **Analytical Gaps.** "Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion." Advisory Committee

Notes on Fed. R. Evid. 702, 2000 Amendments (citing *Joiner*, 522 U.S. at 146).

6. **Research Independent of Litigation.** Whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharma. Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("Daubert II"). "A district court can also analyze more rigorously the admissibility of an expert's testimony if the expert's opinion was prepared solely for litigation." *Lawrence v. Raymond Corp.*, 501 Fed.Appx. 515, 518 (6th Cir. 2012) (citing *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434 (6th Cir. 2007)).

7. **Intellectual Rigor.** "The *sine qua non*, however, is whether in his courtroom presentation the expert used 'the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Roman v. Western Manufacturing, Inc.*, 691 F.3d 686, 693 (5th Cir. 2012) (citing *Kumho*, 526 U.S. at 152); see also, *Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997) (J. Posner) ("[Daubert] requires the district judge satisfy himself that the expert is being as careful as he would in his regular professional work outside his paid litigation consulting.").

8. **Consideration of Alternative Explanations.** See *Claar v. Burlington N.R.R.*, 29 F.3d 499 (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiff's condition); *Smith v. U.S.*, 2023 WL 5011730, at *4 (11th Cir. Aug. 7, 2023) (finding court did not abuse its discretion for excluding expert for failure to consider alternative explanations for plaintiff's angioedema reaction). Compare *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996) (the possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert).

9. **Practical Experience.** "Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other

knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.” Advisory Committee Notes on Fed. R. Evid. 702, 2000 Amendments (citing United States v. Jones, 107 F.3d 1147 (6th Cir. 1997) (no abuse of discretion in admitting the testimony of a handwriting examiner who had years of practical experience and extensive training, and who explained his methodology in detail)).

B. Evidentiary Reliability/Good Grounds/Trustworthiness

1. **Trustworthiness.** “Federal Rule of Evidence 702 requires an expert witness to testify as to ‘scientific, technical, or other specialized knowledge.’ As the Supreme Court in Daubert noted, this requirement establishes a standard of ‘evidentiary reliability’ or ‘trustworthiness.’” Rose v. Truck Centers, Inc., 388 Fed. Appx. 528, 534 (6th Cir. 2010) (citing Daubert, 509 U.S. at 590, n.9).

2. **Some Speculation is Necessary.** “A certain amount of speculation is necessary, an even greater amount is permissible (and goes to the weight of the testimony), but too much is fatal to admission.” Group Health Plan, Inc. v. Philip Morris, USA, Inc., 344 F.3d 753, 760 (8th Cir. 2003).

3. **Reviewer Bias.** “Hindsight bias is a common-sense concept—everyone knows that ‘hindsight is 20/20.’ And common-sense concepts are especially appropriate for consideration by a jury.” Adams v. Lab. Corp. of America, 760 F.3d 1322, 1335 (11th Cir. July 29, 2014) (reversing exclusion of cytotechnologists who reviewed slides using a widely accepted methodology; the court did not take kindly to the industry guidelines which intended to affect admissibility in litigation).

4. **Red Flags.** “Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and

subjectivity.” Newell Rubbermaid, Inc. v. Raymond Corp., 676 F.3d 521, 527 (6th Cir. 2012) (citing Best v. Lowe’s Home Centers, Inc., 563 F.3d 171, 177 (6th Cir. 2009)).

5. **Attacks on the Expert.** “Disputes as to the strength of [an expert’s] credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.” Kennedy v. Collagen Corp., 161 F.3d 1226, 1230 (9th Cir. 1998) (quoting McCulloch v. H.B. Fuller Co., 61 F.3d 1038, 1044 (2d Cir. 1995)).

6. **Inadequacies in a Study.** “Indeed, ‘in most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility.’” Rosenfeld v. Oceania Cruises, Inc., 654 F.3d 1190, 1193 (11th Cir. 2011) (quoting Hemmings v. Tidyman’s Inc., 285 F.3d 1174, 1188 (9th Cir.2002)).

7. **Flaws in Analysis.** “[T]he alleged flaws in [the expert’s] analysis are of a character that impugn the accuracy of his results, not the general scientific validity of his methods.” Quiet Technology DC-8, Inc. v. Hurl-Dubois UK Ltd., 326 F.3d 1333, 1345 (11th Cir. 2003). “Quiet says that ‘Frank’s failure to include all available flight test parameters in his model is fatal to any meaningful correlation of flight test results with computer results....’ Yet the Supreme Court has explicitly rejected the same argument in a different substantive context, holding that ‘[n]ormally, failure to include variables will affect the analysis’ probativeness, not its admissibility.” Id. at 1346 (quoting Bazemore v. Friday, 478 U.S. 385, 400 (1986)).

8. **Post Hoc Ergo Propter Hoc.** “Expert opinions based upon nothing more than the logical fallacy of post hoc ergo propter hoc typically do not pass muster under Daubert.” Rolen v. Hansen Beverage Co., 193 Fed.Appx. 468, 473 (6th Cir. 2006) (citing McClain v. Metabolife Intern., Inc., 401 F.3d 1233, 1242-43 (11th Cir. 2005)).

9. **Temporal Relationship Sometimes Okay.** “[D]epending on the circumstances, a temporal

relationship between exposure to a substance and the onset of a disease or a worsening of symptoms can provide compelling evidence of causation.” Westberry v. Gislaved Gummi AB, 178 F.3d 257, 265 (4th Cir. 1999) (okay for expert to rely on temporal relationship when plaintiff’s symptoms worsened while working and improved when not working).

10. **Lack of Published Studies Okay.** “[R]eference to a published study . . . is not necessary to demonstrate minimum scientific reliability” where scientific literature “may not be extensive.” United Fire & Cas. Co. v. Whirlpool Corp., 704 F.3d 1338, 1342 (11th Cir. 2013) (citing Daubert, 509 U.S. at 593). “We first note, as has the Third Circuit, that ‘we do not believe that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness.’” Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1208 (8th Cir. 2000) (quoting Heller v. Shaw Indus., Inc., 167 F.3d 146, 155 (3rd Cir.1999)); see also Hollander v. Sandoz Pharma. Corp., 289 F.3d 1193, 1212 (10th Cir. 2002).

11. **Lacking Daubert Factors.** “The question, then, is whether expert opinion evidence that does not meet three of the four Daubert factors nevertheless can be admitted. In the right circumstances, the answer to that question is ‘yes.’” U.S. v. Brown, 415 F.3d 1257, 1267 (11th Cir. 2005).

12. **Daubert Factors May Be Unhelpful.** “[T]he four specific factors utilized in Daubert may be of limited utility in the context of non-scientific expert testimony. We noted that ‘[i]f [the Daubert] framework were to be extended to outside the scientific realm, many types of relevant and reliable expert testimony—that derived substantially from practical experience—would be excluded. Such a result truly would turn Daubert, a case intended to relax the admissibility requirements for expert scientific evidence, on its head.’” First Tennessee Bank Nat. Ass’n v. Barreto, 268 F.3d 319, 334 (6th Cir. 2001) (finding “the Daubert reliability factors unhelpful” in a case involving expert testimony based upon 40 years in the banking industry).

13. **Mere General Acceptance Can Be Sufficient.** “We cannot say that the court abused its discretion in also concluding that the specific Daubert factors (such as testability and peer review) were not required in this particular situation. Nor can we say that its key credibility determination was clearly erroneous.” U.S. v. Brown, 415 F.3d 1257, 1267-68 (11th Cir. 2005) (trial court accepted as true the expert’s testimony that the methods used were generally accepted).

14. **Use in Industry Alone is Insufficient.** “[T]hat a laboratory has used a procedure for a number of years, without more, is not evidence of reliability. An unreliable test does not become reliable just because the test is used for a lengthy period of time. The confidence of the Commonwealth of Kentucky in its laboratory does not prove that the methods used by the lab are scientifically sound.” Nelson v. Freightliner, LLC, 154 Fed. Appx. 98, 110 (11th Cir. 2005).

15. **Agency Acceptance is Not the Same as Peer Review.** “[A]pproval and use by the agencies of the Commonwealth of Kentucky [is not] a form of peer review as suggested at the Daubert hearing. Peer review involves submission to the scrutiny of the scientific community. Peer review is not acceptance by a collection of agencies that are not qualified to comment on the reliability of a methodology.” Id.

16. **Flaws in Facts Underlying Analysis.** “[T]he court’s gatekeeping function focuses on an examination of the expert’s methodology. The 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, or, where appropriate, on summary judgment.” Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000).

C. General Causation: Epidemiology, Bradford Hill Criteria, Animal Studies, Case Studies

1. **Bradford Hill Criteria.** “Even when an appropriately designed study yields evidence of a statistical association between a given substance and a given health outcome, epidemiologists generally do

not accept such an association by itself as proof of a causal relationship between the exposure and the outcome. Epidemiologists generally look to several additional criteria to determine whether a statistical association is indeed causal. These criteria are sometimes referred to as the Bradford Hill criteria, after the author of a leading statement of the principles. They are: (1) Strength: How strong is the association between the suspected risk factor and the observed outcome?; (2) Consistency: Does the association hold in different settings and among different groups?; (3) Specificity: How closely are the specific exposure factor and the specific health outcome associated? I.e., how unique is the quality or quantity of the response? (4) Temporality: Does the hypothesized cause precede the effect?; (5) Biological plausibility: Does the apparent association make sense biologically?; (6) Coherence: Is the association consistent with what is known of the natural history and biology of the disease?; (7) Experimental verification: Does any experimental evidence support the hypothesis of an association?; (8) Biological analogy: Are there examples of similar risk factors and similar outcomes?; and (9) Dose-response relationship: Has a dose-response relationship been established, i.e., does the magnitude of the response increase as the magnitude of the dose increases? The last criterion, establishment of a dose-response relationship, is considered critical in toxicology.” Amorgianos v. Nat’l R.R. Passenger Corp., 137 F.Supp.2d 147, 168 (E.D.N.Y. 2001); see also Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc’y Med. 295 (1965).

2. Weighing Epidemiological Evidence. “Bradford Hill factors are essential to evaluating the weight of epidemiological evidence” In re Actos (Pioglitazone) Products Liability Litigation, 2014 WL 108923*5, n.31 (W.D.LA. 2014).

3. Epidemiology Trumps Conflicting Case Studies. “We find that the district court did not abuse its discretion by considering that the proffered conclusions in studies with questionable methodologies were out of sync with the conclusions

in the overwhelming majority of the epidemiological studies presented to the court.” Allison v. McGhan Med. Corp., 184 F.3d 1300, 1316 (11th Cir. 1999).

4. Epidemiology is Best Evidence in Toxic Tort Case. “Epidemiology, a field that concerns itself with finding the causal nexus between external factors and disease, is generally considered to be the best evidence of causation in toxic tort actions.” Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1198 (11th Cir. 2002).

5. Epidemiology Not Required In Toxic Tort Case. “This Court has long held that epidemiology is not required to prove causation in a toxic tort case.” Id. at 1199 (11th Cir. 2002) (citing Wells v. Ortho Pharm. Corp., 788 F.2d 741, 745 (11th Cir. 1986)).

6. Material Data Safety Sheet Can Support Opinion. “[The Defendant’s] strongest argument is that no published material confirms that inhalation of the chemical in Aqua EZ can cause anosmia. But ‘there is no requirement that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness.’” Best v. Lowe’s Home Centers, Inc., 563 F.3d 171, 180-81 (6th Cir. 2009) (quoting Kudabeck v. Kroger Co., 338 F.3d 856, 862 (8th Cir.2003) (holding that information contained on the product’s MSDS and the doctor’s own knowledge provided a sufficient basis for the doctor to “rule in” inhalation of a chlorine derivative as a cause of anosmia)); see also McCulloch v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995)).

7. Case Reports Are Insufficient. “[C]ase reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls;’ hence, they do not supply scientific knowledge upon which an opinion can be based under Daubert.” Allison, 184 F.3d at 1316 (quoting Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387, 1411 (D.Or. 1996)).

8. Case Studies Regarded With Caution. “Because they are anecdotal, case studies lack controls and thus do not provide as much information as controlled epidemiological studies do.... Causal

attribution based on case studies must be regarded with caution.” *McClain v. Metabolife Intern, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) (citing Mary Sue Henifin et al., *Reference Guide on Medical Testimony*, *Reference Manual on Scientific Evidence* 439-75 (Federal Judicial Center, 2d ed. 2000)).

9. Weight of the Evidence Approach. “No serious argument can be made that the weight of the evidence approach is inherently unreliable. Rather, admissibility must turn on the particular facts of the case. Here, the question is whether Dr. Smith, in reaching his opinion, applied the methodology with ‘the same level of intellectual rigor’ that he uses in his scientific practice.” *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 18-19 (1st Cir. 2011) (quoting *Kumho*, 526 U.S. at 152). See also *Joiner*, 522 U.S. at 153-55 (Stevens, dissenting) (“[T]he Court of Appeals expressly decided that a ‘weight of the evidence’ methodology was scientifically acceptable. To this extent, the Court of Appeals’ opinion is persuasive. It is not intrinsically ‘unscientific’ for experienced professionals to arrive at a conclusion by weighing all available scientific evidence – this is not the sort of ‘junk science’ with which *Daubert* was concerned. . . . In any event, it bears emphasis that the Court has not held that it would have been an abuse of discretion to admit the expert testimony.”).

D. Specific Causation

1. Differential Diagnosis Widely Accepted. “This court recognizes differential diagnosis as an appropriate method for making a determination of causation for an individual instance of disease. An overwhelming majority of the courts of appeals agree, and have held that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong [reliability] of the Rule 702 inquiry. *Best v. Lowe’s Home Centers, Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) (internal quotations and citations omitted).

2. Differential Diagnosis Contains Elements of Judgment, But Is Still Reliable. A “differential diagnosis can be considered to involve the testing of a falsifiable hypothesis (e.g. that PCBs caused a plaintiff’s cancer) through an attempt to rule out

alternative causes, that methodology involves far more elements of judgment than does a scientific study attempting to test a more general scientific proposition. But unlike a methodology used in conducting a scientific study, lack of general acceptance is not a sign of unreliability, it is merely a result of the fact that the medical community will rarely have considered the reliability of a particular process of differential diagnosis used in an individual case.” *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717, 758 (3d Cir. 1994).

3. Differential Diagnosis With Less Than Full Information. “[S]ometimes differential diagnosis can be reliable with less than full information, and, to the extent that the district court concluded otherwise, we hold that it abused its discretion. To provide a simplistic example, imagine a patient who comes in with medical records that include x-rays showing a fractured arm and who tells the doctor that he hurt the arm in a biking accident; the doctor could reliably conclude that the patient had a fractured arm caused by a biking accident even without physically examining the patient or taking a medical history.” *Paoli*, 35 F.3d at 759-60.

4. Sixth Circuit follows Third Circuit’s Three Part Test. “We hereby adopt the following differential-diagnosis test, adapted from the Third Circuit’s well-reasoned opinion: A medical-causation opinion in the form of a doctor’s differential diagnosis is reliable and admissible where the doctor (1) objectively ascertains, to the extent possible, the nature of the patient’s injury, see [*Paoli*] at 762 (‘A physician who evaluates a patient in preparation for litigation should seek more than a patient’s self-report of symptoms or illness and ... should ... determine that a patient is ill and what illness the patient has contracted.’), (2) ‘rules in’ one or more causes of the injury using a valid methodology, and (3) engages in ‘standard diagnostic techniques by which doctors normally rule out alternative causes’ to reach a conclusion as to which cause is most likely.” *Best v. Lowe’s Home Centers, Inc.*, 563 F.3d 171, 179 (6th Cir. 2009) (quoting *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994)).

5. Eleventh Circuit Requires Differential Diagnosis + General Causation. “A valid differential diagnosis, however, only satisfies a Daubert analysis if the expert can show the general toxicity of the drug by reliable methods.” McClain v. Metabolife Intern, Inc., 401 F.3d 1233, 1241 (11th Cir. 2005).

6. “Relative Risk” Greater Than 2.0. “The threshold for concluding that an agent more likely than not caused a disease is 2.0. A relative risk of 1.0 means that the agent has no causative effect on incidence. A relative risk of 2.0 thus implies a 50% likelihood that the agent caused the disease. Risks greater than 2.0 permit an inference that the plaintiff's disease was more likely than not caused by the agent.” Allison v. McGhan Med. Corp., 184 F.3d 1300, 1315 (11th Cir. 1999) (citing Federal Judicial Center, *Reference Manual on Scientific Evidence* 168–69 (1994)).

7. Physical Exam Not Necessary. “[A] physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available. In fact, it is perfectly acceptable, in arriving at a diagnosis, for a physician to rely on examinations and tests performed by other medical practitioners.” Kannankeril v. Terminix Int’l, Inc., 128 F.3d 802, 807 (3d Cir. 1997).

8. Differential Diagnosis Defined. “Differential diagnosis is defined as: ‘[t]he method by which a physician determines what disease process caused a patient's symptoms. The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history.’” Hardyman v. Norfolk & W. Ry. Co., 243 F.3d 255, 260 (6th Cir. 2001) (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* 214 (1994)).

9. Differential Diagnosis Described. “A reliable differential diagnosis typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for

the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.” Westberry v. Gislated Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (quoting Kannankeril v. Terminix Int’l, Inc., 128 F.3d 802, 807 (3d Cir. 1997)).

E. Standard of Care Opinions

1. “Dr. Rosenthal's application of her extensive, relevant experience contributed to the reliability of her methodology. See, e.g., Dickenson v. Cardiac & Thoracic Surgery of E. Tenn., 388 F.3d 976, 982 (6th Cir.2004) (holding that the district court abused its discretion in excluding a doctor's standard-of-care testimony that was ‘supported by extensive relevant experience’).” Adams v. Lab. Corp. of America, 760 F.3d 1322, 1331 (11th Cir., July 29, 2014).

2. An expert’s competence under state substantive law renders the expert qualified to testify as to the standard of care. See McDowell v. Brown, 392 F.3d 1283 (11th Cir.2004) (“In accordance with Georgia law, we find the experts competent to render opinions as to the applicable standard of care for Wexford's nurses.”); see also Adams v. Lab. Corp. of America, 760 F.3d 1322, 1338 (11th Cir. July 29, 2014) (J. Garza, concurring) (“Because the admissibility of Dr. Rosenthal's testimony hinges on the reliability of her knowledge of a cytotechnologist's standard of care rather than the reliability of any ‘methodology,’ her competence renders her testimony admissible under McDowell v. Brown, 392 F.3d 1283 (11th Cir.2004)”).

3. “Thus, testimony on the standard of care usually concerns what other physicians do in similar situations, rather than whether the defendant–physician’s diagnosis and treatment are based on good medical science (although customary physician practice and good medical science will generally coincide). As a result, the admissibility of expert opinion on the standard of care is decided according to whether the witness is qualified to opine on the same field as the malpractice defendant.” Mary Sue Henifin et al., *Reference Guide on Medical Testimony*, in *Reference Manual of Scientific Evidence*, 446 (Federal Judicial Center, 2d ed. 2000). NOTE: The third edition

of the Reference Manual on Scientific Evidence was published in 2011, but is completely silent on standard of care.

F. Economists

1. Magelky v. BNSF Ry. Co., 579 F.Supp.2d 1299, 1308 (D.N.D. 2008) (Economist's calculations based upon "peer group" analysis were reliable and sufficient to support testimony as to future wage loss.).

2. Poosh v. Phillip Morris USA, Inc., 287 F.R.D. 543, 549 (N.D.CA. 2012) (Weaknesses in economist's testimony – such as only having an undergraduate degree in economics, spending most of his career as a litigation-based damages expert, and basing opinions on unreliable assumptions – could be brought out on cross examination and did not provide a basis for exclusion.).

G. Accident Reconstruction

1. North v. Ford Motor, Co., 505 F.Supp.2d 1113, 1118 (D. Utah 2007) (allowing accident reconstruction expert to testify and use a PC Crash simulation when opinions were based on accident scene photos and measurements taken by Highway Patrol, even though expert never inspected the accident vehicle).

H. Forensic Expert

1. U.S. v. Gist-Holden, 629 F. Supp. 3d 841 (N.D. Ind. 2022) ("Forensic examiner's expert testimony on toolmark identification, used to determine whether casings recovered from bank and casings found in defendant's home were cycled through same firearm, was based on methodology that was sufficiently reliable under *Daubert*, as required for testimony to be admissible in prosecution for armed bank robbery; examiner followed methodology used by Association of Firearms and Toolmark Examiners (AFTE), which was generally accepted by federal courts, error rate using AFTE method was low, AFTE method had been studied and subjected to peer review, and examiner's work in case, which was documented in detail in accordance with industry standards, was reviewed and verified by another examiner who agreed with conclusion. Fed. R. Evid. 702.")

I. Areas of Questioning to Test Reliability

1. What materials were you provided in this case? Who provided you with those materials? Did you ask counsel for any additional materials?

2. Please list each and every source of information you relied on in forming your opinions? Depositions read? Did you peruse or read the whole thing? Each and every medical record you reviewed? Going through each medical record/deposition/document from case:

- i. Find anything significant in that document?
- ii. Please describe the information in that document that supports your opinion.

3. Have you conducted any tests as part of your work in this case? If yes, when? Where? How? Why did you choose those parameters? What was your goal in performing the test? Did you form a hypothesis before the test? Differences between your test and the facts and circumstances in this case? Would they make a difference? Why not?

4. Has your opinion been tested by others? Previous to this litigation? Any conflicting results?

5. What information did you use to conduct the test? What factual assumptions did you make? How many times did you repeat the test? Are the results verifiable? Did you document the results? Did you document all stages of testing? Did you make any notes? Photos? Videos?

6. What were the ancillary hypotheses of the test? – that is, every test/experiment includes underlying assumptions such as the reliability of the measuring equipment, other scientific principles, etc. Make sure to explore these assumptions with the expert.

7. Have you ever conducted a test like this before? Where did you learn how to conduct the test? Any standard for conducting testing? ASTM? Governmental? Industry Organizations? Do you perform similar tests in your professional life? Is this test or a similar test performed by professionals in your field? Is it known to be reliable?

8. Is there a better way to conduct the test, but you did not do it that way due to time/money/other reasons?

9. Your job is to consider all the evidence, right, not just the evidence that supports your opinions? What evidence in this case does not support your opinions? Please explain why and how that evidence does not support your opinions.

10. Assume your opinion is wrong and invalid. What steps would you go through to analyze and assess the opinion to find your error? Do the results of the test support the opinions? Did your opinions change in any way after conducting the test?

11. Did you test for other causes? Why/why not? Did you consider possible alternative explanations? How did you go about trying to identify possible alternative causes? Please take us through the steps you took to rule them out? Any confounding variables in your work?

12. What do you perceive as your purpose and function in this case? What further work do you intend to do and what further work have you been asked to do for this case?

13. Have your opinions been peer-reviewed? Have you published anything related to your opinions in this case? Have you relied on any publications in forming your opinions? Please list each and every publication that supports your opinion? Are your opinions/methods generally accepted? How do you know?

14. Did you conduct any research related to the issues in this case independent of litigation? Who funded the research? What was purpose of research?

15. Does opinion suffer from *post hoc ergo propter hoc* fallacy? Does expert speculate or make assumptions without proper basis?

VII. RELEVANCY - FIT

1. “The party offering the expert testimony has the burden of demonstrating that the testimony is ‘relevant to the task at hand’ and ‘logically advances a material aspect’ of its case. The ‘basic standard of relevance ... is a liberal one,’ but if an expert opinion

does not have a ‘valid scientific connection to the pertinent inquiry’ it should be excluded because there is no ‘fit.’ Boca Raton Community Hosp., Inc. v. Tenet Health Care Corp., 582 F.3d 1227, 1232 (11th Cir. 2009) (citations omitted).

2. “The fit requirement directs the Court to look beyond the qualifications of a witness in the abstract, and focus on whether those qualifications provide a foundation for a witness to answer a specific question.” Johnson v. Manitowoc Boom Trucks, Inc., 406 F. Supp.2d 852, 859 (M.D. Tenn. 2005), *aff’d* by 484 F.3d 426 (6th Cir. 2007).

3. “Because scientific testimony does not assist the trier of fact unless it has a justified scientific relation to the facts, the Eleventh Circuit has opined that ‘there is no fit where a large analytical leap must be made between the facts and the opinion.’ An expert must know ‘facts which enable him to express a reasonably accurate conclusion instead of mere conjecture or speculation,’ and an expert’s assurances that he has used generally accepted scientific methodology are insufficient. Further, to assist the trier of fact, expert testimony must concern ‘matters that are beyond the understanding of the average lay person ... expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments.’” Block 60 Holdings, LLC v. Sothern-Owners, Ins. Co., 2015 WL 226008*3 (M.D.Fla., January 16, 2015) (finding civil engineers qualified and their opinions on sink holes reliable) (citations omitted).

4. Animal studies don’t fit. “Plaintiffs’ experts admitted that with respect to animal studies generally, what happens in an animal would not necessarily happen in a human being. Accordingly, it is necessary for plaintiffs to offer some rationale for the suggestion that the vascular structures of humans and animals are sufficiently similar in this context to conclude that bromocriptine’s effects on animals may be extrapolated to humans. Plaintiffs have not done so. . . . As the Supreme Court held in Joiner, scientific evidence must ‘fit’ the plaintiff’s theory of causation. In this case, neither the chemical compound evidence

nor the animal study evidence ‘fits’ as evidence relevant to the cause of plaintiffs’ injuries.” Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1202 (11th Cir. 2002).

VIII. DEFEATING DAUBERT CHALLENGES

A. Practice Tips

1. Reference Manual on Scientific Evidence.

The Third Edition of the Reference Manual on Scientific Evidence is an invaluable resource and is relied on by the judiciary. Plus it’s free. Just Google it, download it, and use it.

2. **Utilize Expert Reports.** Even if there is no requirement under state law for your expert to create an expert report, you may want to have your expert do so anyway. It will help the judge understand the expert’s opinions much better than a deposition transcript.

3. Stipulate to Confidentiality of Draft Reports.

While drafts of expert reports are not discoverable in federal court, they are completely discoverable in many state courts. You may be able to stipulate with defense counsel at the beginning of a case that all draft reports and communications regarding expert reports will not be discoverable. Many if not most attorneys will agree. Confidentiality of draft reports is important because most experts do not know how to write a report that will meet all the Daubert requirements. They will need your guidance.

4. **Supplementing the Deposition.** You can supplement your expert’s opinion with an affidavit from the expert. But, make sure that the affidavit only clarifies and does not contradict the deposition testimony. Also, you can request a Daubert hearing for your own expert, offering the judge the opportunity to speak directly to your expert.

5. **Motion to Admit Expert Testimony.** You can file what in essence is a preemptive Daubert motion – a motion to admit the testimony of your expert. You have the burden of proof so you can make an affirmative showing to the court whenever you feel

you ready to do so—and then you get to file a reply brief as well.

B. Outline For Expert Reports

1. **Summary.** Provide summary of case and roadmap of opinions.

2. **Qualifications.** Elaborate on the expert’s qualifications and work/experience/research independent of litigation.

3. **Materials.** List case specific materials provided to and reviewed by the expert so the judge knows the opinions are based upon “sufficient facts and data.” Be specific and thorough. Also list any other materials/sources/publications relied on or referenced by the expert.

4. **Background.** Provide background information on the science involved in the case. Educate the judge.

5. **Intellectual Rigor.** Explanation of how the method used to reach the opinions in the case would have been acceptable in the relevant professional field and how professionals in the field would have relied upon the opinions reached in this manner.

6. **Narrative.** Step by step narrative of the work and analyses the expert performed in the case (and how it was just like work done in professional life). The judge should be able to follow the expert’s thought process – from first being contacted through forming a final opinion. In other words, an expert must “show her work.” Include pictures, illustrations, graphs, charts, etc., wherever possible.

7. **Alternative causes.** Discuss how potential alternative causes were identified. Discuss the consideration and rejection of alternative causes.

8. **Authority.** Citations to (and discussion of) publications and authority that support the opinions.

9. **Opinions.** Concise statement of each and every opinion – and sub-opinions, if any – using appropriate language as necessary (e.g., “more likely than not,” “reasonable certainty,” etc.).

10. **CV/Billing.** Attach the expert’s CV, bills for the case, and history of testimony as exhibits to the report.