

9-28-2015

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Erica W. Rutner

Lara B. Bach

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Recommended Citation

Rutner, Erica W. and Bach, Lara B. (2015) "Florida's "Brave New World": The Transition from Frye to Daubert Will Transform the Playing-Field for Litigants in Medical Causation Cases," *Barry Law Review*: Vol. 20: Iss. 2, Article 4.
Available at: <http://lawpublications.barry.edu/barryrev/vol20/iss2/4>

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FLORIDA'S "BRAVE NEW WORLD": THE TRANSITION FROM *Frye* TO *Daubert* WILL TRANSFORM THE PLAYING-FIELD FOR LITIGANTS IN MEDICAL CAUSATION CASES

*Erica W. Rutner and Lara Bueso Bach**

For nearly a century, Florida followed the *Frye*¹ standard for admissibility of expert testimony. However, on June 4, 2013, Florida Governor Rick Scott signed into law House Bill 7015, amending Florida Statute section 90.702, and transforming Florida into a *Daubert* jurisdiction. After a number of failed attempts, Florida lawmakers finally succeeded in aligning Florida's standards for expert admissibility with the standards that govern in federal court and many states around the country.²

While the transition from *Frye* to *Daubert* will undoubtedly impact all cases utilizing expert testimony, as this article discusses, litigants relying on medical causation testimony are likely to encounter some of the most significant changes. That is because under *Frye*, Florida applied one of the most liberal admissibility standards to medical causation testimony, essentially allowing for the admission of this type of testimony without *any* judicial oversight.³ In contrast, *Daubert* requires courts to act as "gatekeepers" in every case by independently assessing the scientific reliability of the methodology, reasoning, and extrapolations underlying an expert's opinion.⁴ This article focuses on how these new standards, as articulated by amended Florida Statute section 90.702 and applicable Supreme Court precedent, will require far more rigorous scrutiny of medical causation opinions than has traditionally been the case in Florida. Because Florida courts have looked to the Eleventh Circuit Court of Appeals for guidance in the past when state and federal law are identical, this article also discusses the stringent criteria the Eleventh Circuit has imposed under *Daubert* with respect to medical causation opinions, and in particular, the types of data and methodologies it has deemed to be

* Erica W. Rutner is a complex commercial litigation associate at Weil, Gotshal & Manges LLP. Erica received a B.A. *summa cum laude* from Barnard College in 2006, and a J.D. *summa cum laude* from the University of Miami in 2009. Lara Bueso Bach is a complex commercial litigation associate at Weil, Gotshal & Manges LLP. Lara received a B.A. *summa cum laude* from Rollins College in 2007, and a J.D. from the University of Michigan Law School in 2010.

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

2. At the beginning of 2013, Florida was one of only ten remaining states still applying the *Frye* standard. The other states that still apply *Frye* include: California, District of Columbia, Illinois, Kansas, Maryland, Minnesota, New York, Pennsylvania, and Washington.

3. See Stephen E. Mahle, *The "Pure Opinion" Exception to the Florida Frye Standard*, 86 FLA. B.J. 41, 41 (2012).

4. See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589–92 (1993).

reliable—and unreliable—as a basis for inferring general causation.⁵ As the article concludes, litigants across the state who rely on medical causation testimony should be prepared to face a “brave new world”⁶ in preparing their cases and defending their claims, especially because *Daubert* decisions in medical causation cases are often dispositive.

I. THE FLORIDA LEGISLATURE ADOPTS THE STANDARDS DELINEATED IN *DAUBERT* AND ITS PROGENY WITH RESPECT TO THE ADMISSIBILITY OF EXPERT TESTIMONY

Frye requires that the scientific principles and methodology underlying an expert’s testimony be generally accepted in the scientific community.⁷ House Bill 7015 explicitly rejects *Frye* and instead adopts the standards outlined in *Daubert* and Federal Rule of Evidence 702.⁸ Specifically, the revisions to Florida Statute section 90.702 effectuated by House Bill 7015 now require courts to ensure that:

- (1) expert testimony is based on sufficient facts or data;
- (2) expert testimony is the result of reliable principles and methods; and
- (3) the expert witness has applied the principles and methods reliably to the facts of the case.⁹

While revised Florida Statute section 90.702 does not itself mention *Daubert*, House Bill 7015 explicitly states that by amending the statute to pattern it after Rule 702 of the Federal Rules of Evidence as amended in 2000, “the Florida Legislature intends to adopt the standards for expert testimony in the courts of this state as provided in”¹⁰ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,¹¹ *General Electric Co. v. Joiner*,¹² and *Kumho Tire Co. v. Carmichael*.¹³ House Bill 7015 further provides that the Florida Legislature “no longer [intends to] apply the standard in *Frye v. United States*, in the courts of this state.”¹⁴ Thus, pursuant to the express mandates of House Bill 7015, the various principles outlined in *Daubert* and its progeny should now govern the admission of expert testimony under Florida law.

5. General causation refers to “the question of whether the drug or chemical can, in general, cause the harm plaintiff alleges,” whereas specific causation focuses on “whether the chemical caused the plaintiff’s *specific* injury.” *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1196 (11th Cir. 2010).

6. Following the United States Supreme Court’s decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Ninth Circuit Court of Appeals, on remand, described the new *Daubert* standard as a “Brave New World.” *Daubert v. Merrell Dow Pharm. Inc. (Daubert II)*, 43 F.3d 1311, 1315 (9th Cir. 1995).

7. See *Castillo v. E. I. Du Pont De Nemours & Co.*, 854 So. 2d 1264, 1268 (Fla. 2003).

8. See H.B. 7015, 2013 Leg., 115th Reg. Sess. (Fla. 2013).

9. FLA. STAT. § 90.702 (2013).

10. H.B. 7015, 2013 Leg., 115th Reg. Sess. (Fla. 2013).

11. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

12. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997).

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

14. H.B. 7015, 2013 Leg., 115th Reg. Sess. (Fla. 2013) (citation omitted).

II. THE APPLICATION OF REVISED FLORIDA STATUTE SECTION 90.702 IN FLORIDA COURTS

While the Florida Legislature may have amended Florida Statute section 90.702, it is the Florida Supreme Court that is vested with the authority to adopt rules of practice and procedure for the courts in Florida.¹⁵ The Florida Supreme Court has yet to explicitly adopt the amendments;¹⁶ however, it appears that it implicitly adopted the changes in *Davis v. State*¹⁷ and *Perez v. Bell South Telecommunications*.¹⁸ Despite this implicit adoption of the changed rule, the Florida Supreme Court has still not provided any guidance as to how *Daubert* should be interpreted or applied. Nevertheless, Florida appellate and trial courts have regularly begun to apply *Daubert*.¹⁹ Indeed, since the amended statute went into effect, no published lower court decision has applied the *Frye* standard. Instead, for example, in both *Conley v. State* and *Perez v. Bell South Telecommunications*, the Florida appellate courts held that *Daubert* should apply to expert testimony previously subject to a *Frye* analysis because the Florida Legislature had adopted the *Daubert* standard during the pending appeal.²⁰ The *Perez* court reasoned that it “take[s] comfort . . . in the fact that the Florida Supreme Court periodically adopts all legislative changes to the Florida Evidence Code to the extent they are procedural.”²¹

While *Conley* remanded the case and ordered the trial court to apply *Daubert*, the court in *Perez* took it upon itself to analyze and apply *Daubert* to the facts of the case.²² Specifically, the court addressed the admissibility of the plaintiff's expert who sought to testify, based on his personal opinion, that the stress the plaintiff experienced in the workplace caused her placental abruption and early delivery of her child.²³ The plaintiff argued that the testimony, which was excluded by the lower court under *Frye*, should have been admitted under the “pure opinion” exception espoused in *Marsh* (described in more detail in Section III, *infra*).²⁴ The court, however, rejected the plaintiff's pure opinion argument and found that this exception no longer applies in Florida,²⁵ emphasizing that the “legislative purpose

15. FLA. CONST. art. V, § 2(a).

16. Notably, the Florida Supreme Court has stricken the references to *Frye* in the Florida Rules of Juvenile Procedure. See *In re Amendments to Fla. Rules of Juvenile Procedure*, 123 So. 3d 1128, 1130 (Fla. 2013).

17. *Davis v. State*, 142 So. 3d 867, 871–72 (Fla. 2014) (discussing revised section 90.702).

18. *Perez v. Bell S. Telecomms. Inc.*, No. SC14–1029, 2014 WL 5314497, at *1 (Fla. Oct. 16, 2014) (declining jurisdiction over a case in which petitioner argued that the Third District Court of Appeal improperly applied the *Daubert* standard); see also *Zakrzewski v. State*, No. SC13–1825, 2014 WL 2810560, at *1 (Fla. June 20, 2014) (holding that the *Daubert* standard should not be *retroactively* applied to the admissibility of the expert testimony proffered during a proceeding that occurred nearly two decades ago).

19. See *Perez v. Bell S. Telecomms. Inc.*, 138 So. 3d 492, 497–99 (Fla. Dist. Ct. App. 2014); *Conley v. State*, 129 So. 3d 1120, 1121 (Fla. Dist. Ct. App. 2013); *Booker v. Sumter Cnty. Sheriff's Office*, 166 So. 3d 189, 194–95 (Fla. Dist. Ct. App. 2015); *Giarno v. Fla. Autosport, Inc.*, 154 So. 3d 385, 387–89 (Fla. Dist. Ct. App. 2014).

20. See *Conley*, 129 So. 3d at 1121; *Perez*, 138 So. 3d at 498.

21. *Perez*, 138 So. 3d at 498 n.12 (citation omitted).

22. See cases cited *supra* note 19.

23. *Perez*, 138 So. 3d at 494–95.

24. *Id.* at 496.

25. *Id.* at 497.

of the new law is clear: to tighten the rules for admissibility of expert testimony in the courts of this state.”²⁶ The court also explicitly relied on Eleventh Circuit case law in finding that the expert’s opinion was merely his own personal opinion and was not supported by any credible scientific research.²⁷ Specifically, he had “never before related a placental abruption to workplace stress and knew of no one who had. There is no scientific support for this opinion. The opinion he proffers is a classic example of the common fallacy of assuming causality from temporal sequence.”²⁸

Thus, it is clear that Florida appellate courts intend to apply *Daubert* pursuant to the mandates of Florida Statute section 90.702, and they are likely to seek guidance from Eleventh Circuit case law in doing so. Indeed, because the amendments to Florida Statute section 90.702 are explicitly patterned after *Daubert* and Federal Rule of Evidence 702, Florida courts are likely to rely on federal courts, and the Eleventh Circuit in particular for guidance.²⁹ As one Florida appellate court put it, Florida courts have found it beneficial “to accord unusual weight to a decision on [an] issue, if there is one, of the federal circuit in which the state is located”³⁰ because this “approach has the virtue of establishing that the issue will be uniformly decided by both federal and state courts in the geographic area in which the state is located; thus discouraging forum shopping.”³¹ Given this preference, the remainder of the article focuses on the contrast between the liberal admissibility standards that have traditionally applied in Florida with respect to medical causation experts and the more rigorous standards that are now likely to apply, as well as the Eleventh Circuit’s application of those principles in the context of medical causation testimony.

III. THE COURT’S ROLE IN ASSESSING MEDICAL CAUSATION TESTIMONY WILL BE TRANSFORMED UNDER *DAUBERT* AND SUBSEQUENT SUPREME COURT PRECEDENT

The transition to *Daubert* will undoubtedly change the landscape of medical causation testimony. As the Ninth Circuit explained in *Daubert II*, “judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before.”³² At its most basic level, *Daubert* no longer considers “general acceptance” the relevant inquiry in determining the admissibility of an expert’s opinion.³³ Rather, *Daubert* focuses on

26. *Id.*

27. *Id.* at 499.

28. *Id.* (citing *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005)).

29. *See Ward v. Atl. Sec. Bank*, 777 So. 2d 1144, 1147 (Fla. Dist. Ct. App. 2001) (where state law is “nearly identical” to federal law, “Florida courts will look to interpretations of the federal . . . law for guidance in interpreting Florida’s . . . laws”); *Phenion Dev. Grp., Inc. v. Love*, 940 So. 2d 1179, 1184 n.5 (Fla. Dist. Ct. App. 2006); *see also Perez v. Bell S. Telecomms., Inc.*, 138 So. 3d 492, 499 (Fla. Dist. Ct. App. 2014) (citing Eleventh Circuit precedent in excluding plaintiff’s expert under *Daubert*).

30. *Wylie v. Inv. Mgmt. & Research*, 629 So. 2d 898, 900 (Fla. Dist. Ct. App. 1993).

31. *Id.*

32. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995).

33. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993).

the reliability underlying an expert's methodology: "the trial judge must ensure that [expert testimony] is not only relevant, but reliable;" which entails "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."³⁴

Although the Florida Supreme Court has described *Daubert* as "a more lenient standard" than *Frye*,³⁵ the exact opposite is true when it comes to Florida's application of *Frye* in the context of medical causation testimony.³⁶ Indeed, over the last decade, the Florida Supreme Court has adopted an increasingly lenient application of *Frye* as it pertains to medical causation testimony, amounting to what some have described as a "let it all in standard."³⁷ However, as the Florida appellate court in *Perez* noted, the transition to *Daubert* will "tighten the rules for admissibility of expert testimony in the courts of this state."³⁸ As discussed below, there are several reasons *Daubert* requires far greater scrutiny from judges in assessing medical causation testimony, which is likely to result in greater exclusions of causation experts than has traditionally been the case.

A. Under *Daubert*, Courts Must Act as "Gatekeepers" with Respect to All Medical Causation Testimony

According to the Florida Supreme Court, judges were not required to conduct a *Frye* analysis "in the vast majority of cases" because *Frye* "only applies when an expert attempts to render an opinion based upon *new or novel* scientific techniques."³⁹ This principle ultimately became the basis for the effective abdication of judicial oversight with respect to medical causation testimony.⁴⁰ Specifically, in *Marsh v. Valyou*,⁴¹ the court held that "an ordinary opinion on medical causation [is not] a new or novel principle subject to *Frye*." Instead, such testimony is subject to the "pure opinion" exception to the *Frye* standard, which provides that *Frye* is inapplicable to testimony that relies only on the expert's

34. *Id.* at 590–93.

35. *Brim v. State*, 695 So. 2d 268, 271 (Fla. 1997).

36. *See id.* at 271–72.

37. *See Mahle, supra* note 3, at 43 ("A complete analysis of *Frye* and *Daubert* consumes volumes, but positioning the [pure opinion exception] in the legal landscape reveals the fact that the [exception] constitutes a large hole in the *Frye* standard, which further weakens the already lax *Frye* test."). As another commentator put it:

In cases where a plaintiff needs the help of "junk science," it is all too common for a Florida resident, be it an individual or company, to be sued in a matter that chiefly involves an out-of-state defendant primarily for the reason that the plaintiff's attorney wants to prevent the case from being removed to federal court because of a preference for *Frye*, which is equivalent to no standard at all over *Daubert*.

Kenneth W. Waterway, *A Plea for Legislative Reform: The Adoption of Daubert to Ensure the Reliability of Expert Evidence in Florida Courts*, 36 NOVA L. REV. 1 (2011).

38. *Perez v. Bell S. Telecomms., Inc.*, 138 So. 3d 492, 497 (Fla. Dist. Ct. App. 2014).

39. *U.S. Sugar Corp. v. Henson*, 823 So. 2d 104, 109 (Fla. 2002) (emphasis added).

40. *See Mahle, supra* note 3, at 44.

41. *Marsh v. Valyou*, 977 So. 2d 543, 548 (Fla. 2007).

personal experience and training.⁴² As the *Marsh* court reasoned, “experts routinely form medical causation opinions based on their experience and training.”⁴³ Notably, the *Marsh* court held that the testimony in that case, which causally linked trauma to fibromyalgia, was not subject to any *Frye* analysis despite the fact that “the precise etiology of fibromyalgia may not be fully understood,” and, as the dissent pointed out, “the underlying theory of general causation is not accepted.”⁴⁴ In fact, federal courts around the country have excluded similar expert testimony linking trauma to fibromyalgia.⁴⁵

In the wake of *Marsh*, Florida courts routinely applied the “pure opinion” exception to abdicate any *Frye* analysis of the underlying basis for an expert’s medical causation opinion, particularly in cases where the plaintiff’s causal theory was still under investigation.⁴⁶ For instance, in *Andries v. Royal Caribbean Cruises, Ltd.*, the Third District Court of Appeal of Florida admitted medical causation expert testimony, based solely on the expert’s clinical observations—despite the fact that the precise etiology of the disease at issue was unknown—on the basis that “*Marsh* does not require scientific literature or other proof regarding the precise etiology. . . . The fact that the precise causation is still under investigation does not make the expert’s opinions in this case ‘new or novel.’”⁴⁷ The court in *Hood v. Matrixx Initiatives, Inc.* did the same, holding that an expert’s opinion that Zicam caused the plaintiff to lose his sense of smell—which had been uniformly rejected by federal courts across the country—was “pure opinion” that was not subject to any *Frye* analysis.⁴⁸

In contrast with this particularly lenient approach, the *Daubert* standard requires courts to act as “gatekeepers” in all cases with respect to all expert

42. See *id.* The pure opinion exception was first described by the Florida Supreme Court in *Flanagan v. State*, which noted that “pure opinion testimony, such as an expert’s opinion that a defendant is incompetent, does not have to meet *Frye*, because this type of testimony is based on the expert’s personal experience and training.” *Flanagan v. State*, 625 So. 2d 827, 828 (Fla. 1993).

43. *Marsh*, 977 So. 2d at 548.

44. *Id.* at 550–62. The court also concluded that even if *Frye* were to apply, the testimony would still be admissible because “numerous published articles and studies recognize an association between trauma and fibromyalgia,” despite a “lack of studies conclusively demonstrating a causal link.” *Id.* at 550. See also *infra* Section IV(B)(1) (discussing the admissibility of opinions based on associations).

45. See, e.g., *Vargas v. Lee*, 317 F.3d 498 (5th Cir. 2003):

We conclude that the admission of [the expert’s] testimony was an abuse of discretion. We do not, however, purport to hold that trauma does not cause fibromyalgia syndrome or that the admission of expert testimony on that subject is permanently foreclosed. Medical science may someday determine with sufficient reliability that such a causal relationship exists. As the Supreme Court recognized in *Daubert*: “[I]n practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.”

Id. at 502 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)).

46. See *Andries v. Royal Caribbean Cruises, Ltd.*, 12 So. 3d 260, 263 (Fla. Dist. Ct. App. 2009); *Hood v. Matrixx, Initiatives, Inc.*, 50 So. 3d 1166, 1175–76 (Fla. Dist. Ct. App. 2010); *State Farm Mut. Auto. Ins. v. Thorne*, 110 So. 3d 66, 72 (Fla. Dist. Ct. App. 2013).

47. *Andries*, 12 So. 3d at 263–65.

48. *Hood*, 50 So. 3d at 1175–76; *Thorne*, 110 So. 3d at 72.

testimony.⁴⁹ As the United States Supreme Court held in *Kumho*, *Daubert* “imposes a special obligation upon a trial judge to ensure that *any and all* scientific testimony . . . is not only relevant, but reliable [T]his basic gatekeeping obligation applies . . . to *all* expert testimony.”⁵⁰ In fact, consistent with this principle, House Bill 7015 expressly abolishes the “pure opinion” exception to expert testimony delineated in *Marsh*.⁵¹ Thus, the transition to *Daubert* will now require Florida courts to assess the admissibility of all medical causation opinions more rigorously in all cases.

B. Under *Daubert*, an Expert’s Opinion Must Be Based on More Than Experience and Training

While Florida courts are expressly prohibited from applying the “pure opinion” exception, it is clear that they also may not rely on the underlying basis for that exception—i.e., an expert’s experience and training—as sufficient for admitting a medical causation opinion under *Daubert*.⁵² Pursuant to the mandates of *Daubert*, “[t]he subject of an expert’s testimony must be ‘scientific knowledge’ [which] implies a grounding in the methods and procedures of science [and which] connotes more than subjective belief or unsupported speculation.”⁵³ The Supreme Court went on to explain that “[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.”⁵⁴

To determine whether a specific methodology constitutes reliable “scientific knowledge,” and is therefore admissible, the United States Supreme Court suggested a non-exclusive list of relevant factors to consider, including: (1) whether the expert’s theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community.⁵⁵ As the Ninth Circuit Court of Appeals noted in *Daubert II*, “something *doesn’t* become ‘scientific knowledge’ just because it’s uttered by a scientist.”⁵⁶ Indeed, the United States Supreme Court in *Kumho* specifically reinforced the fact that, at all times, the district court must

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

50. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (emphasis added).

51. H.B. 7015 states that “by amending s. 90.702, Florida Statutes, the Florida Legislature intends to *prohibit* in the courts of this state pure opinion testimony as provided in *Marsh v. Valyou*, 977 So. 2d 543 (Fla. 2007).” H.B. 7015, 2013 Leg., 115th Reg. Sess. (Fla. 2013) (emphasis added).

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

53. *Id.*

54. *Id.*

55. *See id.* at 593–94. Note that this is not to be construed as “a definitive checklist or test” because the *Daubert* inquiry is a “flexible” one. *Id.*

56. *Daubert v. Merrell Dow Pharm., Inc. (Daubert II)*, 43 F.3d 1311, 1315 (9th Cir. 1995) (emphasis added); *see also Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316–13 (11th Cir. 1999) (“Under the regime of *Daubert*, a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist.”).

determine the reliability of an expert's opinion, not merely the qualifications of the expert who offers the opinion.⁵⁷ In doing so, the court must "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."⁵⁸

C. Under *Daubert*, Courts Must Assess an Expert's Application of a Particular Methodology and Any Deductions or Extrapolations Made by the Expert

Even as to those medical causation opinions to which *Frye* would apply, Florida's old regime left judges extremely limited in the type of assessment they could conduct. Specifically, the Florida Supreme Court explained in *U.S. Sugar Corp. v. Henson*, that *Frye*'s requirement of general acceptance only applied to the general methodologies on which an expert relied, and that an "expert's deductions based thereon and opinions [do not need to be] generally accepted as well."⁵⁹ In fact, the court "explicitly disapproved" any notion that the "opinion and deduction themselves, must be generally accepted as a predicate for admissibility."⁶⁰ Thus, the court held admissible medical causation testimony simply because the toxicity of the agent at issue was generally accepted, without any inquiry as to the validity of the deductions the expert made in opining that the agent was capable of causing the plaintiff's specific disease.⁶¹

In *Castillo v. E. I. Du Pont De Nemours & Co.*,⁶² the Florida Supreme Court further narrowed the permitted assessment of medical causation testimony, holding that the lower court "went beyond the requirements of *Frye*" by considering the experts' "extrapolation of the data from . . . admittedly acceptable experiments" and their "application of the data generated from that science in reaching [their] ultimate conclusion."⁶³ Instead, the Florida Supreme Court accepted the plaintiff's experts' reliance on and extrapolation from in-vitro and animal studies simply because those are "commonly accepted" scientific studies and methodologies—without any assessment of the experts' methods of applying and extrapolating the data to reach their final causation conclusion.⁶⁴

This approach stands in stark contrast to amended Florida Statute section 90.702 and United States Supreme Court precedent, which *mandates* that a court

57. See, e.g., *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999); see also *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1197 (11th Cir. 2002) (in *Kumho*, the United States Supreme Court made it clear that testimony based solely on the experience of an expert would not be admissible).

58. *Kumho*, 526 U.S. at 152. Notably, the 11th Circuit has expressly enforced this principle in the context of medical causation testimony, holding that "clinical experience, used alone . . . [is] insufficient to show general causation." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1201 (11th Cir. 2010); see also *Wilson v. Taser Int'l, Inc.*, 303 F. App'x 708, 714 (11th Cir. 2008) ("A medical degree does not authorize [an expert] to testify [on causation] when he does not base his methods on valid science.").

59. *U.S. Sugar Corp. v. Henson*, 823 So. 2d 104, 110 (Fla. 2002).

60. *Id.* at 110.

61. See *id.* at 109–10.

62. *Castillo v. E. I. Du Pont De Nemours & Co.*, 854 So. 2d 1264, 1276 (Fla. 2003).

63. *Id.*

64. *Id.*; see also *infra* Section IV(B)(6) (discussing the admissibility of an opinion based on animal studies).

assess an expert's application of a particular methodology.⁶⁵ Amended Florida Statute section 90.702 expressly requires courts to ensure that the expert "has applied the principles and methods reliably to the facts of the case." *Daubert* requires the same, noting that a court must do "a preliminary assessment of whether the [expert's] reasoning or methodology . . . properly can be *applied* to the facts in issue."⁶⁶ Indeed, this principle is so fundamental to the Court's assessment that it formed the basis for the holdings in both *Kumho* and *Joiner*.⁶⁷ Specifically, in *Kumho*, the United States Supreme Court held that the issue before the trial court was "not the reasonableness *in general*" of a particular methodology; "[r]ather, it was the reasonableness of using such an approach . . . to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant*."⁶⁸ Thus, the *Kumho* Court rejected the plaintiff's argument that the expert's opinions were sufficiently reliable simply because he had employed a visual inspection method that is used by other experts; emphasizing that "the question before the trial court was specific, not general . . . [t]he particular issue in this case concerned the use of [the inspection method] to draw" the particular conclusions reached by the expert.⁶⁹

The United States Supreme Court went even further in *Joiner*, holding that courts must assess the extrapolations an expert makes in reaching his or her conclusions:

[C]onclusions 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 that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.⁷⁰

Consistent with this principle, the *Joiner* Court conducted the precise type of analysis of medical causation testimony that the Florida Supreme Court had foreclosed under *Frye*. Specifically, in addressing expert testimony causally linking PCB exposure to cancer, the Court held that whether the types of studies relied on by the plaintiff's expert "can ever be a proper foundation for an expert's opinion was *not* the issue. The issue was whether these experts' opinions were sufficiently supported by the [specific] studies on which they purported to rely."⁷¹ Thus, in

65. See FLA. STAT. § 90.702 (repealed 2014).

66. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–93 (1993) (emphasis added); see also FLA. STAT. § 90.702 (an expert witness may testify if "[t]he witness has applied the principles and methods reliably to the facts of the case").

67. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145 (1997).

68. *Kumho*, 526 U.S. at 153.

69. *Id.* at 156–57.

70. *Joiner*, 522 U.S. at 145.

71. *Id.* at 144 (emphasis added).

contrast with the court in *Castillo*—which accepted the plaintiff’s experts’ reliance on and extrapolation from in-vitro and animal studies simply because those are “commonly accepted” scientific studies and methodologies—the Court in *Joiner* specifically assessed the experts’ extrapolations from the studies on which they relied (which included animal studies) and ultimately concluded that the district court did not abuse its discretion in finding that the experts’ extrapolations could not reliably support their causation conclusions.⁷²

IV. TO THE EXTENT ELEVENTH CIRCUIT PRECEDENT IS PERSUASIVE, THE RELIABILITY OF A MEDICAL CAUSATION OPINION DEPENDS ON THE TYPES OF EVIDENCE ON WHICH THE EXPERT RELIES

In addition to the Supreme Court precedent outlined above, Florida courts—like the Third District Court of Appeal in *Perez*—are likely to find persuasive the well-developed body of Eleventh Circuit case law that has applied *Daubert* to medical causation expert testimony. Specifically, because experts must employ the same intellectual rigor that scientists in the field employ when investigating a causal link between an agent and a disease, the Eleventh Circuit has found that certain types of evidence can form the basis for a reliable causation opinion while other types of evidence cannot.⁷³ Many of these types of evidence are well described in the *Reference Manual on Scientific Evidence*, which is the leading reference source for federal judges in issues involving scientific testimony.⁷⁴ To the extent Florida courts look to the Eleventh Circuit for guidance, it is critical that plaintiffs seeking to offer medical causation testimony heed these guidelines in order to withstand the heightened statutory standard.

A. Scientifically Reliable Methods for Establishing Causation

1. Epidemiological Studies

The Eleventh Circuit has held that epidemiological studies are “the best evidence of causation in toxic tort actions” and are, therefore, a scientifically reliable method for establishing general causation.⁷⁵ Epidemiological studies (such as case control studies, cohort studies, and cross-sectional studies) have designs

^{72.} *Id.*

^{73.} Note that the Eleventh Circuit recognizes that toxic tort cases fall into two categories: (1) cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue; and (2) cases in which the medical community does not. *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005). The first category—with respect to which a court need not undertake an exacting *Daubert* analysis—is very narrow, limited to situations “where the reliability of an expert’s methods is properly taken for granted,” and “medical doctors routinely and widely recognize [causation] as true, like cigarette smoking causes lung cancer and heart disease, too much alcohol causes cirrhosis of the liver, and that the ingestion of sufficient amounts of arsenic causes death.” *Id.* at 1239 n.5.

^{74.} Barbara J. Rothstein & Ralph J. Cicerone, *Forward* to REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at ix (3d ed. 2011).

^{75.} *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1198 (11th Cir. 2002); *see also Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1197–98 (11th Cir. 2010).

and controls that allow an expert to determine whether there is an increased association between an agent and a disease.⁷⁶ It must be emphasized, however, that when epidemiological studies do not yield "statistically significant results,"⁷⁷ they may not supply an adequate foundation for a causation opinion.⁷⁸ Moreover, in order to be admissible, an expert must explain "how the findings of those studies may be reliably connected to the facts of the particular case."⁷⁹

As an example, in *Rider v. Sandoz Pharmaceuticals Corp.*, none of the four epidemiological studies presented by plaintiffs contained statistically significant results linking Parlodel to stroke.⁸⁰ In the absence of statistically significant epidemiological studies, the court demanded alternative proof of medical causation.⁸¹ But as discussed *infra*, the remaining evidence the plaintiff presented—case reports, animal studies, FDA findings, and dechallenge/rechallenge—were all similarly unreliable.⁸²

2. The Dose-Response Relationship

Another reliable method for establishing causation is through evidence of the dose-response relationship, which is the "relationship in which a change in amount, intensity or duration of exposure to an agent is associated with a change—either an increase or decrease—in risk of disease."⁸³ In other words, an expert should be able to opine as to how much is too much. The Eleventh Circuit has held that the dose-response relationship is the "hallmark of basic toxicology" and "the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect. . . . [An] expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology."⁸⁴

This principle was discussed at length in *McClain v. Metabolife International, Inc.*, where the Eleventh Circuit found that an expert's testimony was suspect and ultimately unreliable because the expert could not determine the dose of Metabolife required to injure the plaintiff or anyone else.⁸⁵ The court observed that:

Often low dose exposures—even for many years—will have no consequence at all, since the body is often able to completely

76. See Green et al., *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 549, 556–57 (3d ed. 2011) [hereinafter *Reference Manual*].

77. *Rider*, 295 F.3d at 1198; see also *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 (11th Cir. 1999).

78. See *Rider*, 295 F.3d at 1198.

79. *Hendrix*, 609 F.3d at 1196–97.

80. See *Rider*, 295 F.3d at 1198.

81. See *id.* at 1202.

82. See generally *id.* at 1199–201 (excluding the evidence as speculative, and the theory to be unreliable, because it did not support the hypothesis it was offered to prove).

83. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241–42 (11th Cir. 2005) (quoting *Reference Manual*, *supra* note 76, at 622).

84. *Id.* at 1242; see also *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1339 (11th Cir. 2010).

85. See *McClain*, 401 F.3d at 1241–43.

detoxify low doses before they do any damage. Furthermore, for most types of dose-response relationships following chronic (repeated) exposure, thresholds exist, such that there is some dose below which even repeated, long-term exposure would not cause an effect in any individual.⁸⁶

In *McClain*, however, the expert continually testified that any amount of Metabolife was dangerous, contradicting basic toxicological principles and thus casting doubt on his testimony.⁸⁷

3. Background Risk

Yet another method for reliably establishing causation is through evidence of the background risk of the disease.⁸⁸ This is the risk that members of the general public have of suffering the disease without exposure to the challenged product and the additional risk that those exposed to the product have of suffering the disease.⁸⁹ Without this information, it is difficult to determine whether any incidence of the disease is anything more than coincidence.⁹⁰ Thus, the Eleventh Circuit has held that “a reliable methodology should take into account the background risk” and that in the absence of any evidence that exposure to the product causes additional risk of the disease, the court “must assume” that no such risk exists.⁹¹

The court in *McClain* explained the usefulness of this methodology:

[I]t would help to know how much additional risk for heart attack or ischemic stroke Metabolife consumers have over the risks the general population faces. If ephedrine or an ephedrine/caffeine combination do not increase the incidence of heart attack and ischemic stroke in persons who ingest it, as opposed to all those who do not and still have heart attacks and strokes, that fact would reduce the likelihood that Metabolife harmed Plaintiffs. Likewise, if Plaintiffs could show that taking Metabolife increases the risk of heart attack and ischemic stroke beyond the usual incidence of these common diseases, that would support their methodology in this case.⁹²

86. *Id.* at 1242 (internal citations and quotations omitted).

87. *See id.* at 1243.

88. *Id.*

89. *Id.*

90. *See id.* at 1244.

91. *McClain*, 401 F.3d at 1243–44; *see also* Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1342 (11th Cir. 2010) (concluding the expert’s failure to take into account background risk “place[s] the reliability of [his] conclusions in further doubt”).

92. *McClain*, 401 F.3d at 1244.

Plaintiffs' experts admittedly did not know the background risk of the disease and, as a result, the court assumed it did not exist.⁹³

4. Physiological Mechanism

Finally, "[a]n expert's opinion will likely also survive *Daubert* if the expert described the physiological process, derived by the scientific method, by which a particular cause leads to the development of a given disease or syndrome."⁹⁴ The physiological or biological mechanism depends upon the existing state of the science as it involves "knowledge about the cellular and subcellular mechanisms through which the disease process works."⁹⁵ As discussed *infra*, animal studies suffer from a number of limitations, but they can be useful in demonstrating the physiological mechanism.⁹⁶ The Eleventh Circuit has held that an expert who does not offer evidence of the physiological mechanism lacks one of "the underlying predicates of any cause-and-effect medical testimony."⁹⁷ Although the Eleventh Circuit has not addressed the notion of physiological mechanism at length, the *Reference Manual* suggests that in cases where the biology of a disease is not well understood, hypothesized physiological mechanisms may be accepted.⁹⁸

B. Scientifically Unreliable Methods for Establishing Causation

Although no specific type of evidence is required to reliably prove general causation, the Eleventh Circuit has found that experts who failed to rely on any of the aforementioned types of evidence did not employ a reliable methodology in reaching their causation opinions.⁹⁹ Indeed, the Eleventh Circuit recently stated that epidemiological studies, knowledge of the dose-response relationship, and background risk of the disease are methodologies that are "indispensable to proving the effect of an ingested substance."¹⁰⁰ In doing so, the Eleventh Circuit has explicitly foreclosed various types of evidence from reliably establishing

93. *See id.*

94. *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010).

95. *Reference Manual*, *supra* note 76, at 605.

96. *See id.* at 563.

97. *McClain*, 401 F.3d at 1253 (quoting *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999)).

98. *See Reference Manual*, *supra* note 76, at 605.

99. *See, e.g., Chapman v. Procter & Gamble Distrib.*, 766 F.3d 1296, 1308 (11th Cir. 2014) (affirming the exclusion of causation testimony based on case reports, animal studies, FDA recommendations, and a differential diagnosis as unreliable); *McClain*, 401 F.3d at 1251, 1255 (affirming the exclusion of causation testimony based on chemical analogies, case reports, adverse event reports, FDA recommendations, dechallenge/rechallenge data, and a differential diagnosis as unreliable); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201–03 (11th Cir. 2002) (affirming the exclusion of causation testimony based on case reports, dechallenge/rechallenge data, chemical analogies, animal studies, and FDA findings as unreliable); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1336–40 (11th Cir. 2010) (affirming the exclusion of causation testimony based on case reports and case studies, literature reporting an association between the agent and the disease, animal studies, in-vitro studies, and a differential diagnosis as unreliable).

100. *See, e.g., Chapman*, 766 F.3d at 1308.

general causation—in many cases, the very same types of evidence the Florida Supreme Court had held acceptable under *Frye*.¹⁰¹

1. Literature Reporting a Potential Association

The Eleventh Circuit has held that “[s]howing an *association* is far removed from proving *causation*.”¹⁰² As defined by the *Reference Manual*, “[a]n association between exposure to an agent and a disease exists when they occur together more frequently than one would expect by chance.”¹⁰³ Mere association, however, does not rise to the level of a causal relationship.¹⁰⁴ Issues such as sampling errors, confounding, or bias can make it appear that an association exists.¹⁰⁵ For these reasons, the court in *Kilpatrick v. Breg* noted, where “all of the articles [relied on by the plaintiff’s expert] merely stated potential associations . . . the literature [the plaintiff’s expert] based his conclusions upon was insufficient to create a reliable methodology which passes *Daubert* muster.”¹⁰⁶

This stands in stark contrast with *Marsh* and subsequent lower court decisions. *Marsh* held that even if subject to *Frye*, the expert testimony in that case was admissible simply because “numerous published articles and studies recognize an *association* between trauma and fibromyalgia.”¹⁰⁷ The Fourth District reiterated this principle in *Hood v. Matrixx*, noting that a medical causation opinion is admissible so long as “the scientific literature recognizes an association or possible etiology between a medical condition and a predicate event.”¹⁰⁸

2. Causation Conclusions That Go Beyond the Conclusions Reached by Authors in the Field

The Eleventh Circuit has held that an expert does not utilize a reliable methodology if he or she makes “unauthorized conclusions from limited data—conclusions the authors of the study d[id] not make,” because that shows a “lack of scientific rigor.”¹⁰⁹ As the *McClain* court explained, where the authors of published research “limit the conclusions authorized from their study by saying that it does not prove causation . . . [this] demonstrates the intellectual rigor in this field of science, an intellectual rigor that is conservative and does not leap to specific conclusions about causation or toxicity from incomplete evidence or broad

101. See *id.* at 1311.

102. *Kilpatrick*, 613 F.3d at 1338 (quoting *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 n.16 (11th Cir. 1999)).

103. *Reference Manual*, *supra* note 76, at 566.

104. See *id.*

105. See *id.* at 568.

106. *Kilpatrick*, 613 F.3d at 1341.

107. *Marsh v. Valyou*, 977 So. 2d 543, 550 (Fla. 2007) (emphasis added).

108. *Hood v. Matrixx Initiatives Inc.*, 50 So. 3d 1166, 1175 (Fla. 2010).

109. *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1248 (11th Cir. 2005); see also *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145 (1997) (“Given that [the authors] were unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the expert’s conclusion that Joiner’s exposure to PCB’s causes his cancer.”).

principles.”¹¹⁰ Again, this is a significant departure from Florida Supreme Court precedent. In *Marsh*, all three studies on which the plaintiff’s expert relied concluded that more research was needed to determine whether trauma causes fibromyalgia, and that the existing data was insufficient to establish a causal relationship.¹¹¹ Yet, the *Marsh* court held that this evidence was sufficient under *Frye* to the extent it applied, noting that “calls for further research do not preclude admission of the testimony.”¹¹²

3. Case Reports and Adverse Event Reports

The Eleventh Circuit has also made clear that general causation may not be inferred based solely on case reports or adverse event reports because “such studies lack control and thus do not provide as much information as controlled epidemiological studies do.”¹¹³ A case study is a medical account of a particular patient or group of patients, but it “reflect[s] only reported data, not scientific methodology. Some case reports are a very basic form report of symptoms with little or no patient history, description of course of treatment, or reasoning to exclude other possible causes.”¹¹⁴ As a result, “[c]ausal attribution based on case studies must be regarded with caution.”¹¹⁵ As the court in *McClain* held, “case reports raise questions, they do not answer them.”¹¹⁶ Similarly, adverse event reports are simply “uncontrolled anecdotal information that [offer] one of the least reliable sources to justify opinions about . . . causation.”¹¹⁷ This too appears to be inconsistent with the approach Florida courts have taken under *Frye*. As the dissent pointed out in *Marsh*, the majority of the articles suggesting an association in that case were “case reports and anecdotal accounts.”¹¹⁸ The same appears to be true of the published articles the expert relied on in *Andries v. Royal Caribbean Cruises, Ltd.*¹¹⁹

4. Differential Diagnosis

The Eleventh Circuit has explained that a differential diagnosis—i.e., a method whereby a physician identifies the cause of a plaintiff’s condition through the elimination of potential alternative causes—is used only after general causation is

110. *McClain*, 401 F.3d at 1248.

111. *See Marsh*, 977 So. 2d at 568.

112. *Id.* at 550.

113. *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1338 (11th Cir. 2010).

114. *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002).

115. *Kilpatrick*, 613 F.3d at 1338.

116. *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1254 (11th Cir. 2005); *see also Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010) (case reports by themselves are “insufficient to show general causation”).

117. *McClain*, 401 F.3d at 1250.

118. *Marsh v. Valyou*, 977 So. 2d 543, 567 (Fla. 2007).

119. *See Andries v. Royal Caribbean Cruises, Ltd.*, 12 So. 3d 260, 263 (Fla. 2009).

established; it is not a substitute for reliable proof of general causation.¹²⁰ In other words, a differential diagnosis cannot “overcome the [plaintiffs’ experts’] fundamental failure to lay the scientific groundwork” for their causal theory through the application of scientifically valid methodologies.¹²¹

Here too, Florida Supreme Court precedent has long held to the contrary, allowing for the admission of causation testimony simply if it is based on the generally accepted differential diagnosis technique. Specifically, in *U.S. Sugar Corp.*, the Florida Supreme Court held that “there is no question that the differential diagnosis technique . . . is generally accepted in the scientific community” and thus it is not necessary that “the expert’s deductions based thereon and opinion also be generally accepted.”¹²² The Florida Supreme Court again emphasized this principle in *Marsh*, holding that differential diagnosis is not a new or novel scientific test subject to *Frye*.¹²³

5. Temporal Relationship

In the same vein, courts in the Eleventh Circuit have held that a temporal relationship is not ordinarily sufficient to prove a causal relationship.¹²⁴ A temporal relationship exists when a person is exposed to a substance and thereafter experiences injury.¹²⁵ It is often the starting point for investigating the cause of an injury in clinical practice; but drawing a causation conclusion from this relationship “leads to the blunder of the *post hoc ergo propter hoc* fallacy.”¹²⁶ This fallacy—literally translated to “after this, because of this”—assumes causality from a mere temporal sequence, and standing alone, “is entitled to little weight in determining causation.”¹²⁷

6. Unreliable Extrapolations

As discussed in Section II(C) *supra*, *Daubert* requires that courts assess the basis for any extrapolations an expert makes in reaching his or her conclusions. In

120. See *Chapman v. Procter & Gamble Distrib.*, 766 F.3d 1296, 1308 (11th Cir. 2014); *Hendrix*, 609 F.3d at 1202 (holding that differential analysis could not prove that traumatic brain injury caused plaintiff’s autism because experts did not first prove that traumatic injury can, in general, cause autism); *Kilpatrick*, 613 F.3d at 1342 (differential diagnosis “assumes the existence of general causation”).

121. *Hendrix*, 609 F.3d at 1195. Indeed, an expert’s application of the differential diagnosis method does not, by itself, even render a specific causation opinion reliable. Rather, “the reliability of the method must be judged by considering the reasonableness of applying the differential etiology approach to the facts of this case and the validity of the experts’ particular method of analyzing the data and drawing conclusions therefrom.” *Id.*

122. *U.S. Sugar Corp. v. Henson*, 823 So. 2d 110, 110 (Fla. 2002); see also *Gelsthorpe v. Weinstein*, 897 So. 2d 504, 510–11 (Fla. Dist. Ct. App. 2005) (holding that “the use of the technique differential diagnosis by an expert medical witness in determining causation does not raise concerns under *Frye*. Differential diagnosis is an established scientific methodology . . . [that] is generally accepted in the scientific community.”).

123. See *Marsh*, 977 So. 2d at 549.

124. See *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005).

125. See Craig T. Smith, *Peering into the Microscope: The Rise of Judicial Gatekeeping After Daubert and its Effect on Federal Toxic Tort Litigation*, 13 B.U. J. SCI. & TECH. L. 218, 242 (2007).

126. *McClain*, 401 F.3d at 1243.

127. *Id.* at 1254.

light of that mandate, the Eleventh Circuit has routinely excluded medical causation opinions based on unsupported extrapolations.¹²⁸ For instance, the Eleventh Circuit has rejected extrapolations from: (a) studies regarding different substances,¹²⁹ (b) studies regarding different diseases,¹³⁰ (c) animal studies,¹³¹ and (d) in-vitro studies.¹³² While these types of data are not *per se* invalid, an expert cannot simply presume they are sufficient without providing a scientifically reliable basis for his or her extrapolations. In particular, relying on animal and in-vitro studies in a reliable manner under *Daubert* requires that the expert demonstrate how the test results would transfer to a human subject.¹³³ In contrast, unexplained extrapolations from these types of data were held to be sufficient under Florida's application of *Frye*, as extrapolation was considered a "commonly accepted methodology," the basis of which courts were prohibited from assessing.¹³⁴

7. Weight of the Evidence

Although the Eleventh Circuit has yet to address the reliability of the so-called "weight of the evidence" or "totality of the evidence" methodology, it bears mentioning in this article because plaintiffs in toxic tort cases have begun to routinely rely on this approach in the absence of any of the aforementioned reliable methodologies. Specifically, weight of the evidence is a methodology employed by regulatory and advisory agencies in conducting risk assessment analyses.¹³⁵ At its most basic, it is an analysis as to whether, in the "aggregate," the evidence cited by the expert "presents a stronger scientific basis" for finding causation than when the

128. See FEDERAL MOTIONS IN LIMINE § 5:7 (2014).

129. See *McClain*, 401 F.3d at 1246 (finding that the expert improperly relied on extrapolations from studies regarding different drugs in the same class because "even minor deviations in chemical structure can radically change a particular substance's properties and propensities" and the expert had "failed to show that the [drug] analogy is valid or that differences in chemical structure . . . make no difference").

130. See *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002) (noting that the plaintiff's experts' extrapolations from evidence regarding a different disease than the one at issue were an unsupported "leap of faith").

131. See *id.* (holding that the expert could not reliably extrapolate the results of animal studies to humans because "what happens in an animal would not necessarily happen in a human being" and the plaintiffs had not offered a rationale that, in the context of what was being studied, animals and humans were sufficiently similar to justify the extrapolation).

132. See *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1341 (11th Cir. 2010) (noting that experts cannot extrapolate from the results of in-vitro studies unless the expert can "state how their test results would transfer when conducted on live human subjects").

133. See *id.*; see also *Rider*, 295 F.3d at 1202.

134. *Castillo v. E.I. Du Pont De Nemours & Co.*, 854 So. 2d 1264, 1278 (Fla. 2003).

135. See, e.g., *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (noting that "weight of the evidence" is a method used by "[r]egulatory and advisory bodies such as IARC, OSHA and EPA . . . to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure"); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002) (noting that "weight of the evidence" is a methodology "recognized by the United States Environmental Protection Agency as well as the Internal Agency for Research of Cancer," in which "the quality and adequacy of the data and the kinds and consistency of responses induced by a suspected carcinogen" are considered).

evidence is considered individually.¹³⁶ The Middle District of Florida has described the method as “reviewing the totality of the literature . . . including studies in which the authors found no evidence of a causal connection,” then “appl[ying] a generally-accepted set of guidelines to the evidence,” and finally “arriving at [the] conclusion that the weight of the evidence support[s] a causal connection.”¹³⁷

Courts have grappled with the “weight of the evidence” methodology. It is an amorphous concept and, in employing this approach, “reasonable scientists may come to different judgments about whether such an inference [of causation] is appropriate.”¹³⁸ Despite this limitation, the First Circuit Court of Appeals, in *Milward v. Acuity Specialty Products Group, Inc.*, held that “weight of the evidence” can be “a scientifically sound and methodologically reliable foundation” for a causation opinion and that the admissibility of such an opinion “must turn on the particular facts of the case.”¹³⁹ In *Milward*, the plaintiff’s expert utilized “weight of the evidence” to establish that benzene caused a rare leukemia.¹⁴⁰ In doing so, the expert relied on a large body of reliable evidence to form his causation opinion, such as epidemiological studies, case-control studies, and near consensus among governmental agencies.¹⁴¹

On the other hand, the Fifth Circuit Court of Appeals has rejected this methodology as *per se* unreliable because it requires a threshold that is too low for judicial use.¹⁴² In *Allen v. Pennsylvania Engineering, Corp.*, the court rejected the use of the weight of the evidence methodology to demonstrate a link between a chemical, known as ethylene oxide, and brain cancer because, at bottom, the experts had relied on epidemiological evidence that was merely suggestive of causation but not statistically significant.¹⁴³ The experts thus could not circumvent the frailties of their scientific evidence by simply aggregating unreliable pieces of evidence.¹⁴⁴ Both the Eighth and Tenth Circuits have also rejected the use of this methodology for similar reasons.¹⁴⁵ Given the Eleventh Circuit’s particularly rigorous scrutiny of causation expert testimony, we suspect that if presented with the question, they will follow the approach adopted by the Fifth, Eighth, and Tenth Circuits.

136. *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 992 (8th Cir. 2001); *see also Caraker v. Sandoz Pharm. Corp.*, 188 F. Supp. 2d 1026, 1040 (S.D. Ill. 2001) (“Whether, in aggregate, the evidence cited supported an inference that would enable plaintiffs’ experts to offer an admissible causation opinion.”).

137. *In re Seroquel Prods. Liab. Litig.*, No. 6:06-MD-1769-ORL-22D, 2009 U.S. Dist. LEXIS 15653, at *159 (M.D. Fla. June 23, 2009).

138. *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 17 (1st Cir. 2011).

139. *Id.* at 17.

140. *Id.* at 17–20.

141. *See id.*

142. *See Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 196 (5th Cir. 1996).

143. *See id.* at 196–98.

144. *See id.* at 198.

145. *See Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1216 n.21 (10th Cir. 2002) (holding that the “weight of the evidence” methodology is “inconsistent with *Daubert*. To suggest that those individual categories of evidence deemed unreliable by the district court may be added to form a reliable theory would be to abandon the level of intellectual rigor of the expert in the field.”) (internal citation omitted); *see also Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 992 (8th Cir. 2001) (rejecting expert testimony that relied on case reports, medical treatises, a handful of human “rechallenge” and “dechallenge” events, dissimilar animal studies, internal company documents, and FDA recommendations).

V. CONCLUSION

Regardless of whether Florida state courts look to Eleventh Circuit case law for guidance in applying *Daubert*, it is clear that *Daubert* and its progeny will themselves usher in a "brave new world" for litigants who rely on medical causation testimony. The principles expressed by the Eleventh Circuit in the context of medical causation cases only further manifest the new landscape that Florida litigants are facing under *Daubert*. Indeed, while the regime of *Frye* has rendered Florida judges extremely limited in their ability to keep junk science and unreliable expert testimony out of the courtroom, the amendments to Florida Statute section 90.702 now compel far more scrutiny of medical causation testimony than has ever been the case. As the Eleventh Circuit explained in *Allison*, "[w]hile meticulous *Daubert* inquiries may bring judges under criticism for donning white coats and making determinations that are outside their field of expertise, the Supreme Court has obviously deemed this less objectionable than dumping a barrage of questionable scientific evidence on a jury."¹⁴⁶

Attorneys around the state should be prepared for these imminent changes. Expert testimony can make or break any type of case requiring proof of medical causation—such as a products liability or toxic tort litigation. Indeed, not only do juries place a great deal of reliance on expert witnesses in cases such as these, but plaintiffs are unlikely to even get to a jury in the first place without offering admissible expert witness testimony as to causation.¹⁴⁷ As a result, the transition to *Daubert* will likely bring a significant increase in the number of challenges made to medical causation experts, and that has the potential to impact the success that plaintiffs experience in litigating these types of cases.

146. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1310 (11th Cir. 1999).

147. *See, e.g., Marsh v. Valyou*, 977 So. 2d 543, 545 (Fla. 2007) (holding that the admissibility of expert testimony was the determining issue as to whether the defendant was entitled to the entry of summary judgment).