



# WHAT'S BEHIND THE CURTAIN?

## JUDICIAL SCRUTINY OF “DIFFERENTIAL DIAGNOSIS” UNDER *FRYE* AND *DAUBERT*

by Sean P. Costello and Brooke Werner McEckron

The past several years have witnessed significant legal reforms at both the state and federal levels, many aimed at curbing the excesses of mass tort and class action litigation. The Class Action Fairness Act, or “CAFA,” is easily the most famous among the latest legal reforms. Enacted in 2005, it promised to open the federal courthouse doors to more mass torts and class actions, and by all reliable measures, it has delivered.<sup>1</sup>

This has been good news for corporate defendants. Given a choice, most would prefer federal court, particularly in mass tort and class action litigation. The usual litany of reasons for this is familiar to most—federal judges are not dependent upon plaintiff-lawyer contributions to win elections, Federal Rule of Civil Procedure 23 is more demanding than many state analogues and allows the chance to appeal a class-certification decision, and so on. But one reason that often escapes mention is that along with federal court come *Daubert* and the Federal Rules of Evidence. Mass tort and exposure-based class actions that survive to the merits stage often turn on expert testimony about the plaintiffs’ alleged injuries (or diseases) and their causes. Surveys show that expert testimony to establish injury and causation is the most frequent type of expert testimony among *all* cases.<sup>2</sup>

Through an analysis of recent decisions, this article seeks to explain why the distinction between *Daubert* and *Frye*—and thus between federal and some state courts—can make a difference. We focus on expert testimony based on “differential diagnosis” to establish cause and effect. In one *Frye* jurisdiction, the state’s *highest court* recently was hypnotized by an expert’s incantation of the phrase “differential diagnosis” to the point that it deemed expert testimony claiming a cause-and-effect relationship admissible despite the fact that dozens of courts in jurisdictions around the country had

rejected virtually identical testimony. Courts that countenance this form of sophistry transform a clinical diagnostic tool designed to identify one disease among several into a dangerous litigation weapon that serves no higher good than supporting a lawyer's pet theory of causation.

### **FRYE AND DAUBERT: A REVIEW**

*Frye* became the prevailing test in federal and state courts for many decades by virtue of a federal appellate court's decision in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). In *Frye*, the defendant in a murder trial passed a polygraph test—back when this was a relatively new technology—and sought to have the results admitted. The court of appeals held that the test results and expert testimony about them were not admissible because polygraphs were too experimental. In so doing, the court set forth what has come to be called the “*Frye* test” in this famous passage (*id.* at 1014): “[T]he thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.” Most states subsequently adopted *Frye*'s “general acceptance” test.

Seventy years later, interpreting then Rule 702 of the Federal Rules of Evidence, the United States Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In *Daubert*, a woman sued Merrell Dow Pharmaceuticals, alleging that the drug she took during pregnancy (Bendectin) was responsible for her child's birth defects. Experts for the plaintiff testified at trial that animal studies had shown that Bendectin had negative effects on early development, and they also recalculated data from previous epidemiological studies showing that Bendectin was a human teratogen (a substance that causes development problems in infants).

The Supreme Court held that the testimony of the plaintiff's expert should not have been allowed. In so doing, the Court established the following four-part test of nonexclusive and nondispositive factors that courts are to consider when deciding whether expert testimony should be admitted: (1) whether the testimony was based on generally acceptable means of predicting effects on humans (incorporating this aspect of *Frye*); (2) whether the methodology used was published; (3) whether the methodology had been subjected to peer review; and (4) whether the results are testable. *Id.* at 594.

According to *Daubert*'s four-part test, refined in subsequent decisions like *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), and *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997), the expert's chosen tool must be demonstrably the right tool for the job *and* the expert must use it properly. The fundamental difference between *Frye* and *Daubert* is thus reduced to this: *Frye* tests “the thing from which the deduction is made”; *Daubert* tests both the deduction and its premise.<sup>3</sup> As Professor Julia Luyster explains, “[W]hen a party proffers expert testimony on causation, *Frye* requires the trial judge to examine whether the scientific community recognizes the underlying principle, while *Daubert* requires the judge to examine the merit of the underlying scientific research.”<sup>4</sup>

Based as it was on Federal Rule of Evidence 702,<sup>5</sup> *Daubert* became the governing standard for expert testimony in federal court. Several states soon jumped on the *Daubert* bandwagon.<sup>6</sup> But not all. Sixteen years after *Daubert*, 12 jurisdictions continue to follow *Frye* or a variation thereof.<sup>7</sup> And in a few of these jurisdictions, mischief is being made that would not be possible under *Daubert*.

### **ETIOLOGY VERSUS “DIFFERENTIAL DIAGNOSIS”: DIFFERENT TOOLS FOR DISTINCT JOBS**

Empirical evidence confirms what common wisdom assumes: the test that is applied to scrutinize expert testimony strongly affects whether that testimony is allowed. A Federal Judicial Center survey showed that federal judges excluded some or all of a proposed expert's testimony in 25 percent of the cases in 1991; in 1998, five years after *Daubert*, judges reported that they excluded some or all of a proposed expert's testimony in 41 percent of the cases.<sup>8</sup>

Reliable subsequent data is not available, but Judge Janis Jack's headline-grabbing decision in the silica MDL litigation is strong anecdotal evidence that federal court and *Daubert* have a potentially case-killing impact on gargantuan mass tort litigation. Indeed, Judge Jack's decision excluding expert testimony has been identified as one of the causes of the mass tort's reported death.<sup>9</sup> Excluding the plaintiffs' proposed expert testimony and sanctioning the plaintiffs' lawyers in the process, Judge Jack wrote that “[i]n a majority of cases, [the plaintiffs' experts'] diagnoses were more the creation of lawyers than of doctors.” *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563, 635 (S.D. Tex. 2005). In a scathing indictment of the practice among mass tort lawyers, she rejected outright

the attempted use of mass diagnoses: “[I]t is apparent that truth and justice had very little to do with these diagnoses—otherwise more effort would have been devoted to ensuring they were accurate. Instead, these diagnoses were driven neither by health nor justice; they were manufactured for money.” *Id.* So much for assembly-line litigation.

The differences between *Daubert* and *Frye* are starkest when it comes to causation evidence in the tort context. This is no small matter, since causation is a central issue—perhaps the central issue—in nearly all tort or product liability litigation. And if the tort or product liability case is a mass tort or class action, the significance is exponentially larger.

Experts often claim to base their causation opinions on a so-called “differential diagnosis,” but courts often confuse “differential diagnosis” with “differential etiology.” The distinction can make a difference. “Differential diagnosis” is a “term used by physicians to refer to the process of determining which of two or more diseases with similar symptoms and signs the patient is suffering from, by means of comparing the various competing diagnostic hypotheses with the clinical findings.”<sup>10</sup> A “differential diagnosis” is *not* a tool for determining the *external* cause of a disease or illness. Therefore, it cannot *establish* external cause.

“Differential etiology” is the proper tool for identifying external cause. Put differently, etiology is the tool an expert should be using when he or she is attempting to show general causation (*i.e.*, “rule in” potential causes) and specific causation (“rule out” candidate causes in order to arrive at a single cause). Differential diagnosis and differential etiology thus address “fundamentally different questions: the nature of the illness as opposed to the cause of the illness.”<sup>11</sup>

While a differential diagnosis may counsel a specific treatment, it does not dictate a disease’s specific cause, with some exceptions where the disease and the cause are clearly and inextricably linked. But exceptions prove the rule; they do not make it. As a general matter, physicians are “inexperienced and uncomfortable” when it comes to performing a differential etiology because, while the process of elimination is common to both procedures, the skills, knowledge, and relevant literature differ for each.<sup>12</sup> Indeed, a court put it even more bluntly: “The ability to diagnose medical conditions is not remotely the same... as the ability to deduce,

delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions.” *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205, 1209 (E.D. Tenn. 2000). Because diagnosis and etiology are different tools with distinct purposes, the Federal Judicial Center’s *Reference Manual on Scientific Evidence* advises that “an expert’s opinion on diagnosis and his or her opinion on external causation should generally be assessed separately, since the bases for such opinions are often quite different.”<sup>13</sup>

Nonetheless, courts routinely say “differential diagnosis” when they mean to say “etiology,” and *Daubert* courts are as guilty of this as *Frye* courts. In *Daubert* jurisdictions, the gaffe amounts to semantics. But in *Frye* jurisdictions, the error is more serious. Under *Frye*, at least as applied in some jurisdictions, an expert’s claimed use of “differential diagnosis” may preclude the court from even treating the analysis as expert analysis at all, thereby avoiding judicial scrutiny altogether. We will start with the good news.

## LOOKING BEHIND THE CURTAIN: DIFFERENTIAL DIAGNOSIS UNDER DAUBERT

In *Daubert* jurisdictions, it does not matter what the court calls the analysis used to determine a cause-and-effect relationship, because the court is duty-bound to scrutinize whether the methodology used was (a) suited for the job, and (b) properly employed to reach the claimed conclusion. Some examples make the point.

The Fifth Circuit’s analysis in *Black v. Food Lion, Inc.*, 171 F.3d 308 (5th Cir. 1999), is a good starting point. In *Black*, the Fifth Circuit held that expert testimony purporting to link fibromyalgia to a plaintiff’s car accident was inadmissible under *Daubert*. The court explained that neither the plaintiff’s doctor nor medical science generally “knows the exact process that results in fibromyalgia or the factors that trigger the process.” *Id.* at 314. Thus, the physician’s “use of a general methodology [like differential diagnosis] cannot vindicate a conclusion for which there is no underlying medical support.” *Id.* The court acknowledged that “[n]o one doubts... the process by which doctors rule out some known causes of disease in order to finalize a diagnosis. But such general rules must, under *Daubert* [and] *Kumho Tire*... be applied fact-specifically in each case.” *Id.* Only with that fact-specific application of a generally accepted methodology is it “possible to fasten legal liability for a person’s disease or injury.” *Id.*

The Third Circuit's 2008 decision in *Feit v. Great-West Life and Annuity Ins. Co.*, No. 07-1481, 2008 WL 847930 (3rd Cir. Mar. 31, 2008), provides a more recent example. There, the plaintiff's expert purported to rely on a "differential diagnosis" in concluding that the plaintiff's husband died from head and neck injuries; the expert also rejected myocardial infarction as a cause of death. The Third Circuit got the name of the analysis wrong but reached the right result. After acknowledging that "differential diagnosis" is a "generally recognize[d]" methodology, the court went on to caution that it nonetheless must be properly performed. *Id.* The physician's claimed differential diagnosis failed that test, because it neglected to "rule in" all potential causes (to establish general causation), as well as "rule out" causes in order to arrive at the most likely candidate (to establish specific causation). *Id.* As the court explained, the conclusion should "reliably flow from the data and methodology." *Id.* at \*8. In *Feit*, that was not the case.

Most recently, the Eighth Circuit confronted the attempted use of differential diagnosis to arrive at a causation opinion in *Bland v. Verizon Wireless, L.L.C.*, \_\_\_ F.3d \_\_\_, No. 07-3010, 2008 WL 3474178 (8th Cir. Aug. 14, 2008). The Eighth Circuit began, like the Third Circuit in *Feit*, with the proposition that "a medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*." *Id.* at \*4 (citation omitted). The court, predictably, confused "diagnosis" and "etiology," describing the former as "a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated." *Id.* (citation omitted). But that was of no consequence, because the court applied *Daubert* to determine whether the methodology had been properly employed.

The issue in *Bland* concerned the plaintiff's claim that his ingesting of Freon in a water bottle (a practical joke that went wrong and hit the wrong target) caused his asthma. The Eighth Circuit concluded that the plaintiff's expert could not make such a claim to the jury. It held that the attempted use of differential diagnosis to establish the cause and effect failed *Daubert*, because the scientific literature shows that the cause of asthma in most cases is unknown. Where the cause is unknown, a physician cannot claim to have employed a *proper* differential diagnosis to identify a single cause as the "most probable" cause of the illness. *Id.* at \*4. In other words, the expert could not "rule in" all other causes of the asthma to establish general causation. *Id.* The court also concluded

that the expert "failed to eliminate scientifically other possible causes as part of her differential diagnosis," thus neglecting to "rule out" other causes sufficient to establish specific causation. *Id.* Instead, what the expert did was to conclude that there was a cause-and-effect relationship between ingestion and asthma based on the "temporal link" alone. *Id.* That was speculation, not science. *Id.*

## PERPETUATING THE MYTH OF THE WIZARD: DIFFERENTIAL DIAGNOSIS UNDER *FRYE*

The above decisions—and many others like them—stand in sharp contrast to the way *Frye* jurisdictions approach similar claims. In some *Frye* jurisdictions, the courts are unwilling to pull aside the curtain and expose an expert's "differential diagnosis" as speculation.

Our first example is from New York. In *Friedman v. Madison 40 Assoc. LP*, No. 29065-01, 2008 N.Y. Misc. LEXIS 3532, at \*15, 239 N.Y.L.J. 111 (N.Y. Sup. Ct. June 10, 2008), the court denied the defendants' motion to preclude the causation testimony of plaintiffs' experts in a toxic-mold case. The plaintiffs' treating physician intended to testify that, based on a "differential diagnosis," he had concluded that exposure to mold in the defendants' premises caused one plaintiff to suffer from hypersensitivity pneumonitis and the other plaintiff to suffer mucous membrane irritation, skin irritation, and chronic rhinitis/sinusitis. *Id.* at \*6–8. Deeming the testimony admissible, the court explained that "[t]he issues related to specific causation" were issues that a jury could resolve at trial. *Id.* at \*15.

Florida has taken *Frye* to the extreme. Though Florida's evidentiary rule on expert testimony is virtually indistinguishable from Federal Rule 702 at the time *Daubert* was decided,<sup>14</sup> Florida applies *Frye*, sort of. The "sort of" is that Florida courts apply *Frye only* to "new or novel scientific techniques." *United States Sugar Corp. v. Henson*, 823 So.2d 104, 109 (Fla. 2002). This means that the *Frye* test is not applied to what Florida courts call "pure opinion testimony." *Flanagan v. State*, 625 So.2d 827, 828 (Fla. 1993). "Pure opinion testimony" is testimony that is based on an "expert's personal experience and training." *Id.* In Florida, differential diagnosis is generally regarded as "pure opinion." That is troubling.

The troubling consequences of Florida's uncritical *Frye* analysis are on full display in the Florida Supreme Court's recent decision in *Marsh v. Valyou*, 977 So.2d 543 (Fla. 2007), *reh'g denied*.

In *Marsh*, a woman claimed that the trauma of a car accident caused her to suffer from fibromyalgia, a soft-tissue disorder causing chronic pain. Her treating physician intended to so testify, even though there was no general consensus that trauma causes fibromyalgia and virtually every court in the country that had considered the issue—under *either Frye or Daubert*—had rejected such a theory of causation.

In the trial court, the defendants succeeded in getting the expert testimony excluded on the ground that the opinion that trauma can cause fibromyalgia had not been “generally accepted” in the scientific community. Because the plaintiff was unable to establish causation without expert testimony, the court then granted the defendants’ motion for summary judgment. The plaintiff appealed; the court of appeals affirmed. So far, so good. Even under *Frye*, the court had reached the right result. But then the issue wound its way up to the Florida Supreme Court. In a splintered 4–3 decision, the Florida Supreme Court in *Marsh* reversed.

The court held that the testimony should have been admitted for two principal reasons. First, because the treating physician’s testimony that a plaintiff’s fibromyalgia was caused by trauma (a car accident) was premised on a differential diagnosis, it was based on “personal experience and training,” not a “new or novel scientific test[] or procedure[.]” *Id.* at 549. Therefore, it was “pure opinion testimony” and as such was not even subject to *Frye*. *Id.* In the court’s view, “Experts routinely form medical causation opinions based on their experience and training.” *Id.* at 548. Second, the court held that, even assuming that “differential diagnosis” is subject to *Frye*, it was a “generally accepted method for determining specific causation.” *Id.* at 549 (citations omitted). Moreover, said the court, “[n]umerous published articles and studies recognize an association between trauma and fibromyalgia.” *Id.* at 550. The court acknowledged a “lack of studies conclusively demonstrating a causal link between trauma and fibromyalgia” and that other studies had “call[ed] for further research,” but it concluded that this did not preclude the testimony. *Id.* The Florida Supreme Court harrumphed that “*Frye* does not require unanimity.” *Id.* It was thus up to the jury to decide whether to accept the testimony.

For people accustomed to thinking in *Daubert* terms, the result is hard to swallow. The dissenting justices could barely believe it themselves. Justice Cantero authored the dissent,

in which Justices Bell and Wells joined. (Justices Cantero and Bell resigned from the Florida Supreme Court last fall.) The dissent demonstrated the fundamental flaws with the majority’s analysis and conclusion.

The dissent properly took issue with the majority’s conclusion that the testimony was “pure opinion.” Testimony is “pure opinion” “only when it is based *solely* on experience and training, and does not rely [in any manner] on a novel scientific principle, test, or methodology.” *Id.* at 560 (Cantero, J., dissenting). Consequently, if an expert purports to base an opinion on his own personal experience and training (while examining a patient) *and* his examination of external studies, outside analyses, or other matters, his opinion is not “pure opinion” at all. *Id.* If an expert (in the form of a treating physician) is correctly performing a differential etiology—though calling it a “diagnosis”—then he or she *must* refer to outside materials to identify potential causes; such information simply cannot be found merely by examining the patient. Thus, a proper differential *etiology* can never be “pure opinion.” As the dissent explained, by “holding that an opinion about specific causation need not pass the *Frye* test, even where the underlying theory of general causation is not accepted,” the majority had effectively rendered “specific causation testimony always admissible as the ‘pure opinion’ of the expert.” *Id.* at 562. And the dissent cited to numerous cases in which expert-opinion testimony claiming that a car accident or other trauma caused fibromyalgia had been excluded. *Id.* The dissent made its point with strong words: “Differential diagnosis is not a wild card that can be used to introduce novel scientific theories into the courtroom. Any other logic would revert us to the science of the Salem Witch Trials.” *Id.* at 565.

The dissent’s fundamental point was that there is no reason simply to take an expert’s word that he or she performed a proper “differential diagnosis” and then based his or her conclusion on it. The court should look to see what is behind the curtain, for that is the only way to expose the expert as a sophist or his wizardry as a sham. The majority’s approach in *Marsh* invites fraud. Its legacy will be forcing corporations to spend enormous sums to defend against scientifically baseless claims.

The dissent had the better of the argument, but that is cold comfort. With two of the dissenters leaving the court and rehearing having been denied, *Marsh* is and will remain the

law in Florida, unless the legislature sees fit to change things. Thus, we can only hope that Florida's hands-off approach to differential diagnosis in the context of causation determinations does not spread to other *Frye* jurisdictions.

## MORE REFORM IS NEEDED, AND EXISTING REFORMS SHOULD BE PROTECTED

A lazy application of *Frye* may deserve more of the blame for results like *Marsh* than the *Frye* test itself. Arguably, a more vigorous application might have led to a proper result; in fact, other courts applying *Frye* had excluded testimony purporting to link trauma and fibromyalgia based on "differential diagnoses." But not even the most otiose application of *Daubert* would result in a decision like *Marsh*, because *Daubert* forces courts to look behind the curtain. More troubling still is the fact that *Marsh* was not the decision of a trial court or even an intermediate appellate court. The decision belonged to the state's highest court.

What is science in one state is what Professor David Bernstein would call "quackspertise" in another.<sup>15</sup> That imbalance should be fixed. Until then, however, corporate defendants at risk for mass tort and class action claims should be thankful for CAFA, and they should make sure that its reforms are not washed away with changing political tides. ■

### SEAN P. COSTELLO

1.404.581.8327

scostello@jonesday.com

### BROOKE WERNER McECKRON

1.404.581.8339

bwmceckron@jonesday.com

<sup>1</sup> See Emery G. Lee III and Thomas E. Willging, Federal Judicial Center, *The Impact of the Class Action Fairness Act of 2005 on the Federal Courts: Fourth Interim Report to the Judicial Conference Advisory Committee on Civil Rules* 12 (April 2008).

<sup>2</sup> Carol Krafka et al., Federal Judicial Center, *Judge and Attorney Experiences, Practices, and Concerns Regarding Expert Testimony in Federal Civil Trials* at 10–11, 13 (2002).

<sup>3</sup> See, e.g., Julia Luyster, "Frye and Daubert Challenges: Unreliable Options vs. Unreliable Science," 26 *Trial Advocacy Q.* 29, 30, 31 (Spring 2007).

<sup>4</sup> *Id.* at 30.

<sup>5</sup> Rule 702 of the Federal Rules of Evidence was subsequently amended and now incorporates *Daubert's* principles: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the

evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

<sup>6</sup> Alaska, Arkansas, Colorado, Connecticut, Delaware, Idaho, Indiana, Iowa, Kentucky, Louisiana, Maine, Michigan, Mississippi, Montana, Nebraska, New Hampshire, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, West Virginia, and Wyoming. See 90 A.L.R. 5th 453, §§ 3–27.

<sup>7</sup> Arizona, California, the District of Columbia, Florida, Illinois, Kansas, Maryland, Minnesota, New York, North Dakota, Pennsylvania, and Washington. See *id.* at §§ 28–43. Although Alabama, Hawaii, Massachusetts, Missouri, Nevada, and New Jersey have not rejected *Frye*, they have evaluated the reliability of expert testimony using *Daubert* factors. See *id.* at §§ 44–49. Georgia, Utah, Virginia, and Wisconsin have developed their own peculiar tests for the admissibility of scientific and expert testimony, which may include some elements of *Daubert* and some of *Frye*. *Id.* at §§ 50–53.

<sup>8</sup> See Krafka et al., *supra*, at 15.

<sup>9</sup> See Allison Frankel, "Who Killed the Mass Torts Bonanza?" (Dec. 12, 2006) (available at <http://www.law.com>; last visited Feb. 6, 2009).

<sup>10</sup> Federal Judicial Center, *Reference Manual on Scientific Evidence* 481 (2d ed. 2000).

<sup>11</sup> Edward J. Imwinkelried, "The Admissibility and Legal Sufficiency of Testimony about Differential Diagnosis (Etiology): Of Under- and Over-Estimations," 26 *Baylor L. Rev.* 391, 405 (2004); see also *McClain v. Metabolife International, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005) (noting that differential diagnosis "leads to the diagnosis of the patient's condition, not necessarily the cause of that condition").

<sup>12</sup> Imwinkelried, *supra*, at 405.

<sup>13</sup> Federal Judicial Center, *Reference Manual on Scientific Evidence* 472 (2d ed. 2000).

<sup>14</sup> Fla. Stat. Ann. 90.702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact in understanding the evidence or in determining a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify about it in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial."

<sup>15</sup> David Bernstein, "Quackspertise," *AEI-Brookings Joint Center Policy Matters* 06-23 (Oct. 2006).