Daubert, Then and Now

By Pamela J. Yates and Brendan M. Gibbons

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A Look Back over Thirty Years

Daubert's Beginning

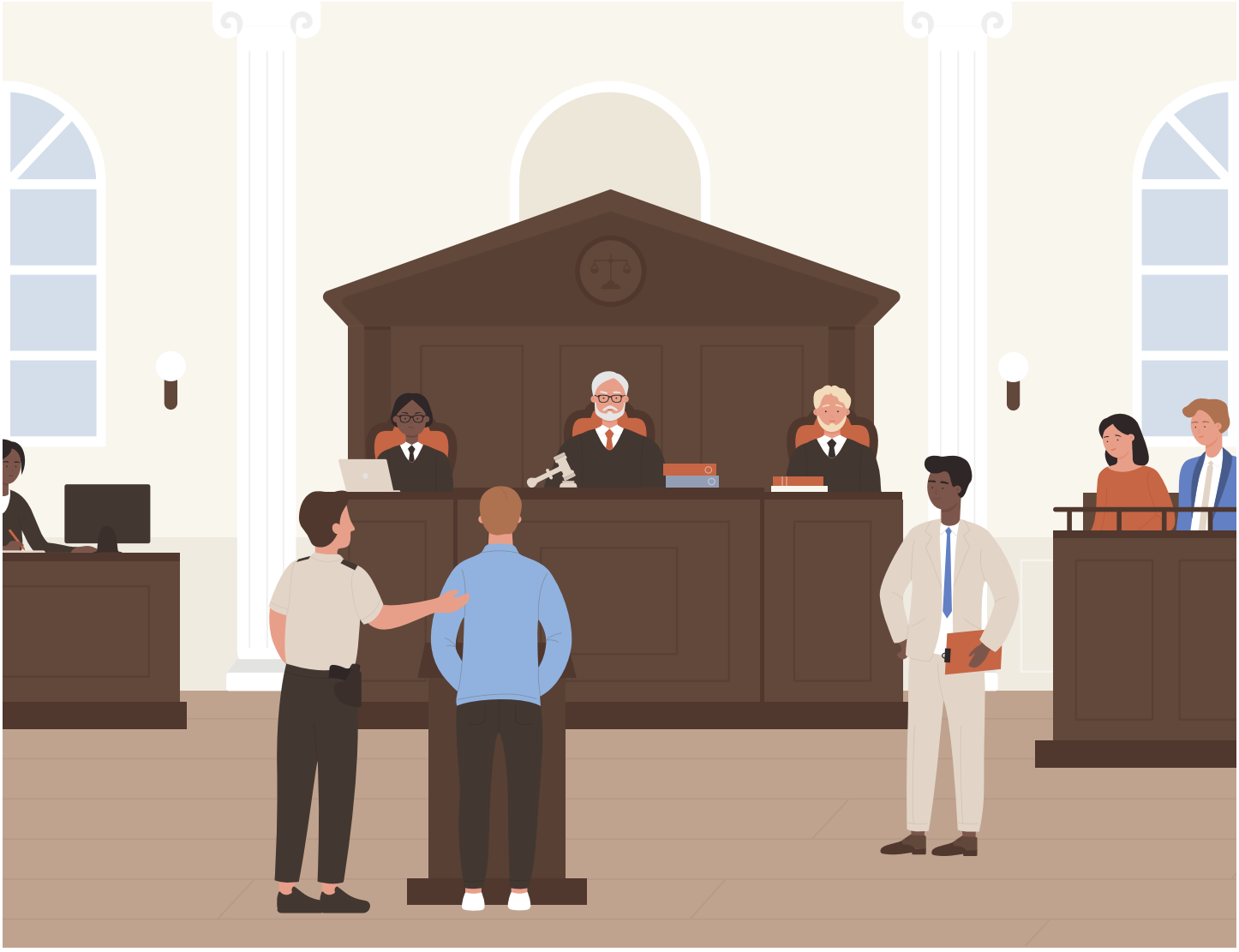
Thirty years ago, in the landmark decision *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), the Supreme Court overruled the 70-year-old "general acceptance test" from *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and identified additional criteria required to analyze and admit expert opinion testimony. The New York Times wrote shortly after the decision that legal scholars "see repercussions for nearly every case," and that complying with Daubert would be "more work for judges." Natalie Angier, *Ruling on Scientific Evidence: A Just Burden*, N. Y. TIMES, June 30, 1993, ***https://www.nytimes.com/1993/06/30/us/ruling-on-scientific-evidence-a-just-burden.html***. The Times was correct on both points, but *Daubert* arguably did not result in the seismic shift that was anticipated. Indeed, even though *Daubert* motions are brought in almost every case involving experts, Courts usually admit expert testimony and are wary of disposing of complex cases before trial. Over the past thirty years, Circuit Courts have added their own factors, states have adopted *Daubert* (or rejected it), and Rule 702 has been amended and will be significantly amended again at the end of this year. Still, Daubert remains the most significant decision regarding expert testimony and will remain so for the foreseeable future.

In *Daubert*, to prove a morning sickness drug caused birth defects, plaintiffs' expert testified based on animal and cell studies, but did not rely on actual human data. In an effort to inform the judge on the scientific case on the eve of trial, the Defendant filed a summary judgment motion on the grounds that plaintiffs failed to sustain their causation burden. The Defendant's motion, in part, argued that plaintiffs' expert's testimony did not meet the Frye standard because the scientific community generally agreed that human studies were necessary to identify a cause of birth defects and plaintiffs' experts did not evaluate human studies.

As the young lawyer who wrote the summary judgment motion, I had the privilege of attending the oral argument, where early on it became clear that District Judge Earl B. Gilliam fully understood the importance of the issue and quickly noted that Defendant carried its burden based on the moving papers. Judge Gilliam then asked to hear from plaintiffs' counsel and asked, "if you had an expert come in here and testify that the earth is flat, should that case get to the jury?" Instead of pivoting or distinguishing, plaintiffs' counsel said, "yes." This statement showed Judge Gilliam that plaintiffs' counsel would (and did) try to admit junk science in support of their causation case.

The plaintiffs argued that their expert actually performed a human study, but this was only a recalculation of previous studies and was never peer-reviewed, nor did it show any statistical significance. With no human studies showing a statistical significance, the trial court held that there were no genuine issues of material fact with respect to causation because the plaintiffs

Pamela J. Yates is a partner Arnold & Porter's Product Liability practice and is located in Los Angeles, CA. She is a Chambers ranked, highly successful life sciences and product liability trial lawyer internationally recognized as a "Life Science Star." She tries cases in multiple state and federal court venues, and has extensive experience in MDL and class action work. Pamela has successfully acted as national coordinating counsel in various mass tort cases, responsible for all aspects of litigation, including trial, trial preparation and strategy, science, and overall Daubert strategy. Pamela is a longstanding member of DRI and has spoken at the Drug & Medical Device Seminar on several occasions including at the most recent, May 2023 seminar, where she presented on Thirty Years of Daubert. **Brendan M. Gibbons** is a senior associate in Arnold & Porter's Product Liability practice group and is located in New York, NY. He focuses on product liability, mass tort defense, and complex commercial litigation matters. He represents pharmaceutical, biotechnology, and other consumer product manufacturers and retailers in product liability actions and other commercial disputes. He was recently included on Best Lawyers' "Ones to Watch" list for 2024.



could only prove the drug *possibly* may have caused birth defects. *Daubert*, 727 F. Supp. 570 (S.D. Cal. 1989). The Ninth Circuit affirmed the decision and held that epidemiological studies should be published, peer-reviewed, and should not only be created for purposes of the litigation. 951 F. 2d 1128 (9th Cir. 1991).

At the United States Supreme Court, plaintiffs argued that Federal Rule of Evidence 702 governs the admissibility of scientific evidence – which at the time simply provided that a witness qualified as an expert may provide an opinion – and not *Frye*. On June 28, 1993, the Supreme Court agreed and found that Rule 702 did not require general acceptance as a precondition of admissibility, technically overruling *Frye*, but maintained the general acceptance test while adding four additional questions:

- Whether the theory has been subjected to peer-review and publication;
- Whether the theory can be and has been tested;
- Whether the theory has a known error rate; and
- Whether the research was conducted independent of the particular litigation or dependent on an intention to provide the proposed testimony.

Establishing the Court's gatekeeper role, the Court also held that the burden is on the proponent of the expert testimony to establish its admissibility by a preponderance of proof and that the trial court judge bears responsibility to ensure that scientific testimony or evidence is reliable and relevant – in other words, not junk science. The Supreme Court remanded the decision to the Ninth Circuit, which upheld the summary judgment decision and added additional factors discussed below.

The morning sickness pill at issue in *Daubert* was already voluntarily pulled from the market in 1983 due to the pending litigation. But scientific studies on the drug and its ingredients continued throughout the 1990s, and in 1999, the FDA stated that there were no safety concerns. In 2013, twenty years after *Daubert*, the drug was rebranded and returned to the market for pregnant women. The New England Journal of Medicine noted in 2014 that "the decades-long history of doxylamine-pyridoxine emphasizes the importance of making clinical decisions on the basis of *scientific evidence* . . . and [the story]

reminds us that reliance on evidence-based practices, with the use of multiple streams of data, is the most appropriate way to evaluate drug safety." Slaughter, *FDA Approval of Doxylamine-Pyridoxine Therapy for Use in Pregnancy*, N. ENGL. J. MED 2014; 370:1081-1083, Mar. 20, 2014 (emphasis added). In hindsight, it seems clear that scientific evidence did not support removing the drug from the market, nor was there any reliable scientific support for the initial lawsuit.

Daubert's Progenies: The Four Factors Grow

The *Daubert* standard continued to be defined not only by the decision itself, but by several subsequent decisions that expanded it. In 1997, the Supreme Court in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), focusing on methodology, added a factor and held that an expert's conclusion must correlate with supportive data. There, the studies were too "dissimilar to the facts presented." *Id*. It also noted that abuse of discretion is the proper standard of review for expert testimony evidentiary rulings. *Id*. In 1999, the Supreme Court in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), extended the *Daubert* factors to cover all expert testimony including non-scientific experts (in that case, a tire analyst). *Kumho* also added two more factors: (1) that the expert must employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field, and (2) whether the field of expertise claimed by the expert is known to reach reliable results. *Id*. In *Kumho*, the testimony "fell outside the range where experts might reasonably differ . . . ." *Id*.

Although many Courts lean against excluding expert testimony at the Daubert motion stage, there still have been several important cases where Courts have excluded general causation experts, and some have been especially impactful.

The Ninth Circuit has likewise announced additional factors, including whether the expert has adequately accounted for obvious alternative explanations. *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499 (9th Cir. 1994). There, the experts failed to explain a basis for their conclusions and made no effort to rule out other chemicals or explain which chemicals caused injuries. *Id*. And on remand, the Ninth Circuit in *Daubert* added the factors of (1) whether experts are testifying about matters independent of the litigation and (2) whether the proposed testimony is relevant to the task at hand. 43 F.3d 1311 (9th Cir. 1995). The analysis used by the Ninth Circuit is commonly called the relevance test or the "fit" requirement. The Ninth Circuit, in upholding the *Daubert* summary judgment ruling, also found that the expert's testimony was not relevant because it did not attempt to show causation directly, but only presented "circumstantial proof of causation." *Id*.

In 2000, Rule 702 was amended to conform to the *Daubert* decision, its *Kumho* progeny, and other cases. Subject only to a stylistic change in 2011, that amendment remains the rule today. While the current rule has elements of the *Daubert* standard, it does not codify *Daubert* or any other case. It states:

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

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

Courts, including the *Daubert* court, note that the *Daubert* factors were neither exclusive nor dispositive. Therefore, the 2000 amendment was written broadly to require any or all of the *Daubert* factors, where applicable.

Daubert Adopted in State Courts

Forty-two states either follow or have nearly adopted *Daubert*, which – for some states – was not an easy task. In Florida, for example, the Florida Supreme Court initially rejected *Daubert* after the Florida Legislature codified it in 2017, *see DeLisle v. Crane Co.*, 258 So. 3d 1219 (Fla. 2018), but reversed its decision in 2019 and adopted *Daubert*. *See In Re: Amendments to the Florida Evidence Code,* No. SC19-107 (Fla. May 23, 2019). Florida had been using the *Daubert* standard since 2013; therefore, there was established case law in the state. Maryland also recently adopted *Daubert* in 2020 after chipping away at *Frye* and state court decisions case-by-case. See *Rochkind v. Stevenson*, 471 Md. 1 (2020).

Several states have come close to adopting *Daubert*, but not fully. California recognizes judges as gatekeepers and acknowledges that they have the ability to go beyond the *Frye* standard, but has not yet adopted *Daubert*. *See Sargon Enters., Inc. v. Univ. of S. Cal., 55 Cal.* 4th 747 (Cal. 2012). Indeed, *Sargon* adopted *Daubert* in California for opinion testimony but omits testimony on new scientific techniques. *Id*. Other states have adopted some of the *Daubert* factors or language similar to Rule 702 (such as Maine, Nevada, North Dakota, New Jersey [in civil cases], and Virginia). In Texas, the Texas Supreme Court identified six non-exhaustive factors, which resemble, but are not identical to, the *Daubert* standard. *See E.I. du Pont de Nemours & Co., Inc. v. Robinson*, 923 S.W.2d 549 (Tex. 1995). And five states, including New York, still either follow or nearly adopt the historical *Frye* standard. Defense litigants obviously prefer to be in a state that recognizes the *Daubert* standard rather than *Frye*.

Daubert: Defense Rulings Over the Years

Although many Courts lean against excluding expert testimony at the *Daubert* motion stage, there still have been several important cases where Courts have excluded general causation experts, and some have been especially impactful. In 2007, Pfizer successfully excluded the

testimony of several plaintiffs' experts in *In re Celebrex*, 524 F. Supp. 2d 1166 (N.D. Cal. 2007). Judge Charles Breyer found that the experts had not presented scientifically reliable evidence because, among other reasons, there were "no randomized controlled trials or meta-analyses of such trials" indicating a link between Celebrex and heart attacks or stroke. *Id*. at 1175-78. The Judge also ruled that one expert ignored contradictory evidence and based her opinion on cherry-picked studies, in addition to relying on unpublished studies. *Id*. at 1176.

In 2015, in *In re Zoloft Prods. Liab. Litig.,* Pfizer successfully excluded plaintiffs' general causation expert. MDL No. 2342, 2015 WL 7776911 (E.D. Pa. Dec. 2, 2015). There, Judge Rufe found the expert had failed to base her opinions on scientifically "valid methodology and reasoning," in part, because the expert applied her analysis in a way that was likely to prove her own hypothesis. *Id*. at *7-10. Judge Rufe also excluded plaintiffs' other general causation experts, but allowed plaintiffs to offer a new causation expert in one area of claimed injury. *See id*. Upon completing a second *Daubert* hearing, Judge Rufe also excluded this expert because he similarly failed to consider epidemiological studies that did not support his opinions. *In re Zoloft Prods. Liab. Litig.,* 176 F. Supp. 3d 483 (E.D. Pa. 2016).

In 2015, Pfizer again moved to exclude an expert's opinion, in part, because he had also engaged in a results-driven methodology. *In re Lipitor*, 227 F. Supp. 3d 452, 462-65 (D.S.C. 2017). Judge Gergel found that the expert statistician's selection of evidence changed based on the results he produced and that he chose to ignore and exclude his own analyses that did not support his ultimate opinions. *Id*. at 465. Judge Gergel therefore granted Pfizer's summary judgment motion and the decision was upheld by the Fourth Circuit in 2018. 892 F.3d 624 (4th Cir. 2018).

In July 2022, AstraZeneca moved to exclude plaintiffs' expert who opined that a proton-pump inhibitor drug "may have contributed" to her kidney disease because the opinion was obviously speculative, and the court agreed. *Chapman v. AstraZeneca Pharms. LP,* No. N17C-04-320 PPI, 2022 WL 4740721 (Del. Super. Ct. Oct. 3, 2022). Under Delaware's interpretation of *Daubert*, a medical opinion must be stated in terms of "reasonable medical probability" or certainty, although experts do not need to use those words. *Id*. at *1. Judge Cecchi properly excluded the testimony because it was stated in terms of possibility and granted summary judgment as plaintiff had no admissible specific causation opinion. *Id*. at *2.

Recently, in December 2022, Judge Rosenberg in *In re Zantac*, excluded MDL plaintiffs' general causation experts and granted defendants' motions for summary judgment. ___ F. 3d. ___, 2022 WL 17480906 (S.D. Fla. Dec. 6, 2022). The Judge there found that the plaintiffs' experts failed to offer credible scientific evidence that Zantac causes cancer, in part because the experts did not rely on any form of reliable primary evidence in support of their general causation opinions. *Id*. at *159. Nor did the experts provide a threshold dose at which Zantac becomes toxic to humans. *Id*. at *158. Judge Rosenberg held the no-threshold opinions inadmissible under the Daubert factors. *Id*.

And more recently, on June 12, 2023, Judge Barber in *Thelen v. Somatics,* excluded plaintiffs' general causation expert after concluding that the expert cited to no epidemiological studies supporting the theory that electroconvulsive therapy caused neurologic damage. *Thelen v. Somatics*, 8:20-cv-1724-TPB-JSS, 2023 WL 3947945 (M.D. Fla. June 12, 2023). Falling into dangerous *Daubert* territory, the expert only read the abstracts of certain articles, and chose only one side of existing medical and scientific literature (that benefited his opinion), among other failures. *Id*. at *4. Embracing his gatekeeping role, the Judge reviewed the materials submitted by the expert to support his opinion and found that there was no scientific consensus that ECT caused neurologic damage. *Id*. Although the Judge allowed a second general causation expert to testify in the case, the jury found for the defense.

On June 23, 2023, Judge Christine Reiss in *MacSwan v. Merck*, excluded plaintiff's general and specific causation expert and granted defendant's motion for summary judgment in a case involving the osteoporosis medication Fosamax. 20-CV-1661, 2023 WL 3990673 (W.D.N.Y. June 14, 2023). The Court found that because plaintiff's expert could not cite to any scientific literature or clinical data that the drug caused harm, the analysis was insufficient to prove causation. *Id*. at *4-5. The expert also argued that his experience, rather than his review of the studies (or lack thereof), would support his opinions. *Id*. Citing other decisions, the Court noted that the expert "constructs no bridge from his experience to his conclusions." *Id*.

Daubert: Plaintiff Rulings

There have also been some impactful rulings for plaintiffs in recent years. In 2019, the Eleventh Circuit reversed the district court in *Taylor v. Mentor Worldwide LLC*, 940 F.3d 582 (11th Cir. 2019), a pelvic mesh case. In *Taylor*, the Eleventh Circuit allowed a general causation theory lacking a threshold dose because it was a medical device rather than a toxic substance. *Id*. at 595. Such a theory, often termed a single molecule theory, was unique to the Eleventh Circuit at the time. Notably, at trial the expert also materially changed his dose opinions. But in March 2023, the Eleventh Circuit excluded plaintiffs' experts in *Pinares v. Raytheon*, No. 19-14831, 2023 WL 2661521 (11th Cir. 2023), and found that plaintiffs' expert failed to conduct a dose-response assessment to show the amount of chemicals needed to cause cancer and never explained how much exposure was too much. Without a reliable dose-response assessment to establish general causation, the specific causation experts had "no reliable groundwork" to support their opinions. *Id*. at *5.

In 2021, the Eighth Circuit reversed the trial court and allowed a general causation expert's opinion to proceed where the trial court found the opinion had no scientific support. *In re Bair Hugger Prod. Liab. Litig.*, 9 F.4th 768 (8th Cir. 2021). Bair Hugger is a forced-air patient warming device used during medical procedures and in hospitals that plaintiffs alleged caused infections. The Eighth Circuit acknowledged weaknesses in the expert's opinions, but nonetheless found that the opinions had a reasonable factual basis. In so finding, the Eighth Circuit essentially ruled that any expert testimony should be allowed unless it is so fundamentally unsupported that "it can offer no assistance to the jury." *Id*.

at 778. Questioning whether this analysis met the Daubert standard, 3M argued in its Writ of Certiorari that the trial court had abdicated its responsibility of acting as a gatekeeper. 2022 WL 414082 (Feb. 7, 2022). The Supreme Court denied the writ in May 2022, 142 S.Ct. 2731 (2022), but the Eighth Circuit's opinion might soon be superseded by the amendments to Rule 702.

Daubert Thirty Years Later: Gone in Name, but not Forgotten

In several cases, such as the one described above, courts have found expert testimony admissible even though the proponent has plainly not satisfied the *Daubert* standard or Rule 702. And courts frequently continue to apply outdated standards from caselaw, some pre-dating even the 2000 amendment to Rule 702. To remedy this, the Judicial Standing Committee has drafted a proposed amendment clarifying two points: (1) admissibility requirements are to be determined by a court under the preponderance standard, and (2) that an expert's opinion must reflect a reliable application of the principles and methods to the facts of the case. The Supreme Court approved the amendment and now the only action that could stop the amendment is a congressional veto. Unless there is a veto, which would be highly unlikely, then the amendment to Rule 702 will become law in December of 2023.

The change – from "expert has reliably applied" to "expert's opinion reflects a reliable application" – requires trial courts to look at the expert's methodology and determine that the opinion is a reliable application to the facts. Therefore, the amendments should make crystal clear that the trial court judge – not the jury – is the gatekeeper of all expert testimony, as well as putting the expert's methodology in direct focus.

Some commentators have even said that the term "*Daubert*" motion should then be called a "Rule 702" motion, thus confirming that the Rule is the guiding law, rather than the myriad of inconsistent case law. But although Daubert may soon be gone in name from Federal courtrooms and briefings, it will not be forgotten. In Federal Court, it has played a role in the admissibility of expert opinion testimony for thirty years and prevented, at least in some cases, opinions based on junk science from being presented to juries. It remains to be seen whether states following *Frye* or other standards will amend their evidence rules to incorporate the gatekeeping function in the new Rule 702. But in the many dozens of states that still use the Daubert precedent, it will remain the law, unless or until they adopt the new Rule 702.