

**INCONSISTENT GATEKEEPING UNDERCUTS
THE CONTINUING PROMISE OF *DAUBERT***

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Mr. Miller's product liability experience includes successfully defending a Fortune 500 automobile parts manufacturer in a federal consumer class action alleging defective product design, false advertising, and consumer fraud by defeating class certification through a preemptive motion to strike the class allegations and obtaining summary judgment on all counts. In addition, he has defended large corporations in the context of serial and multidistrict litigation against personal injury allegations stemming from the use of prescription pharmaceuticals.

INCONSISTENT GATEKEEPING UNDERCUTS THE CONTINUING PROMISE OF *DAUBERT*

More than 25 years have now elapsed since the Supreme Court decided *Daubert v. Merrell-Dow Pharmaceuticals*, 509 U.S. 579 (1993), its seminal decision interpreting Federal Rule of Evidence 702 as a mandate instructing courts to act as gatekeepers to prevent junk science from reaching juries. At the time, *Daubert* was a “revolution in the criteria for the admissibility of scientific testimony” and “evolutionary in scope.”¹ Some predicted *Daubert* would “substantially reduce[] the likelihood that the sellers of expert opinion will be able to take control of the process by which their own testimony is admitted.”²

Daubert remains the law in federal (and in the majority of state) courts. But in the time since *Daubert* was first issued, courts have taken different approaches to how it is applied. Some courts have embraced the *Daubert* view of Rule 702, rejecting junk science and forestalling the burden on the judicial system caused by protracted litigation of claims with little if any scientific merit. Other courts interpret *Daubert* in a way that has regressed from the Supreme Court’s mandates on gatekeeping. A recent decision from the *In re Roundup Products Liability Litigation* multidistrict litigation (“MDL”) highlights an example of the implications when a court, more

¹ William J. Blanton, *Reducing the Value of Plaintiff’s Litigation Option in Federal Court: Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 2 GEO. MASON U. L. REV. 159, 159 (1995).

² *Id.* at 190.

specifically the U.S. Court of Appeals for the Ninth Circuit, lowers the Supreme Court's bar for what is considered admissible scientific evidence.

In *In re Roundup*, the defendant challenged the plaintiffs' experts' specific causation evidence for a variety of reasons, including that the experts failed to rule out idiopathic causes in a differential diagnosis that concluded the defendant's glyphosate product allegedly caused non-Hodgkins lymphoma ("NHL").³ The experts even admitted there is no scientific way to prove that "NHL presents differently when caused by exposure to glyphosate."⁴ The trial court recognized that, "[u]nder a strict interpretation of *Daubert*, perhaps that would be the end of the line for the plaintiffs and their experts (at least without much stronger epidemiological evidence). But in the Ninth Circuit, that is clearly not the case."⁵ The court continued that "the Ninth Circuit's recent decisions reflect a view that district courts should typically admit specific causation opinions that lean strongly toward the 'art' side of the spectrum" and the Ninth Circuit's "opinions are impossible to read without concluding that district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits."⁶ Thus, the trial court was compelled to admit expert evidence

³ *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2019 WL 917058, at *2 (N.D. Cal. Feb. 24, 2019).

⁴ *Id.*

⁵ *Id.* (citing *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1233–37 (9th Cir. 2017); *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1198–99 (9th Cir. 2014)).

⁶ *Id.*

that, in its view, “barely inched over the line” of the lower admissibility bar for expert testimony in the Ninth Circuit.⁷

I. **DAUBERT BACKGROUND**

Daubert has been the subject of much scholarly writing since it was first announced.⁸ To summarize, *Daubert* rejected the “general acceptance” test, established in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). Under *Daubert*, courts now evaluate the scientific reliability of an expert’s theory or technique, including whether it (1) can be and has been tested; (2) has been subjected to peer-review and publication; (3) has a known or potential error rate; and (4) has general acceptance within a relevant scientific community. The Supreme Court gave ample further guidance on the application of its evidentiary test in two other cases,⁹ and in

⁷ *Id.* at *1; see also *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2018 WL 3368534, at *2 (N.D. Cal. July 10, 2018) (declining to exclude questionable general causation evidence from plaintiffs’ experts, because “the case law—particularly Ninth Circuit case law—emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it’s shaky, or because he thinks the jury will have cause to question the expert’s credibility.”).

⁸ See, e.g., Joe Hollingsworth & Eric Lasker, *Daubert in Toxic Tort Litigation*, <https://www.hollingsworthllp.com/uploads/23/doc/media.379.pdf> (part 1), <https://www.hollingsworthllp.com/uploads/23/doc/media.376.pdf> (part 2), and <https://www.hollingsworthllp.com/uploads/23/doc/media.777.pdf> (part 3); Eric G. Lasker, *It is Time to Amend Federal Rule of Evidence 702*, IADC Civil Justice Response & Toxic & Hazardous Substances Litig. Joint Newsletter (Apr. 2016), https://www.hollingsworthllp.com/uploads/1353/doc/EGL&Bernstein_Time_to_Amend_Fed_Rule_Evidence_702_IADC_Newsletter_April2016.pdf.

⁹ *General Electric Co. v. Joiner*, 522 U.S. 136 (1997) (courts may exclude expert testimony when the evidence relied on by the evidence does not support the expert’s conclusion); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999) (the gatekeeping obligation applies to “non-scientific” and “scientific” experts alike).

December 2000, the Federal Judicial Conference amended Rule 702 to incorporate *Daubert's* standards, mandating “a rigorous exercise requiring the trial court to scrutinize, in detail, the expert’s basis, methods, and application.”¹⁰

Following *Daubert* and Rule 702’s amendment, courts began to exclude “junk science.” In a string of cases known as the “Parlodel® Trilogy,”¹¹ *Daubert* was used to end what would have been massive serial litigation. Parlodel® is an FDA-approved drug that doctors still prescribe today for a variety of uses. But in 1995 the FDA withdrew its approval for the prevention of postpartum lactation based on the conclusion that the possible risks outweighed the drug’s utility. Numerous lawsuits followed in which the plaintiffs’ experts claimed that Parlodel® caused a narrowing of blood vessels, which can result in stroke, seizures, myocardial infarction, and death. District judges nationwide excluded this expert testimony and instead required affirmative and reliable scientific support for the hypotheses expressed. These decisions closely examined the testimony of the proffered experts, holding, among other things, that reliance on regulatory standards as proof of causation was not sound science and hence inadmissible, and focusing on the importance of

¹⁰ Mem. from Dan Capra, Reporter to Advisory Comm. on Evidence Rules at 47 (Mar. 1, 1999), www.uscourts.gov/sites/default/files/fr_import/EV1999-04.pdf.

¹¹ The Parlodel® Trilogy, cited more than 2,500 times in cases, articles and other court documents, consists of *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986 (8th Cir. 2001), *Hollander v. Sandoz Pharmaceutical Corp.*, 289 F.3d 1193 (10th Cir. 2002), and *Rider v. Sandoz Pharmaceutical Corp.*, 295 F.3d 1194 (11th Cir. 2002).

epidemiology.¹²

Daubert continues to be an important tool in challenging questionable expert evidence, at least in some courts, and the decision in *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016), is such an outcome. *In re Mirena* was a products liability MDL litigation filed against the manufacturers of intrauterine devices (“IUDs”) alleging that, after implantation, the IUDs caused patients to develop uterine perforation. The defendants moved to exclude the plaintiffs’ general causation experts under *Daubert*, and the court granted the motion. The court held that the plaintiffs’ experts, among other things, (1) were first given the preferred conclusion by the plaintiffs’ lawyers, and worked backwards to find support for that conclusion, a process lacking any scientific methodology; (2) reached speculative conclusions from studies exceeding the limitations the study authors placed on the studies; and (3) relied upon admittedly flawed studies without explaining how those studies could be used to support the experts’ opinions.¹³ The plaintiffs’ lack of reliable general causation evidence, “doom[ed] hundreds of cases,” and the court then granted the

¹² *Glastetter* held that regulatory decisions are based on lesser, prophylactic causation standards than required in courts, 252 F.3d at 991, and differential diagnoses are flawed if they fail to rule out other known potential causes, *id.* at 989–91. *Rider* held that epidemiological evidence is highly persuasive to causation questions, 295 F.3d at 1198, and causation evidence for one drug in a class is not evidence of causation for another drug, *id.* at 1201–02. *Hollander* opined that merely criticizing another expert’s scientific evidence does not meet the burden to show reliability. 289 F.3d at 1213.

¹³ 169 F.3d at 429–34.

defendants summary judgment, ending the MDL.¹⁴

There are more examples of courts exercising proper gatekeeping duties as well. In 2018, the Eleventh Circuit affirmed the exclusion of the plaintiff's general causation expert in the bisphosphonate litigation, finding that he had no epidemiological evidence regarding the drug at issue but instead improperly relied on evidence pertaining to the drug class to extrapolate causation.¹⁵ The Fourth Circuit also has continued to apply *Daubert* strictly to causation evidence. In affirming an MDL-ending summary judgment motion, the court held in 2018 that “[t]o hand to the jury the [expert] evidence here and ask it to reach a conclusion as to causation with any amount of certainty would be farcical and would likely result in a verdict steeped in speculation.”¹⁶ Other recent decisions have also excluded unreliable science and noted the continued importance of a court's gatekeeper role.¹⁷

II. THE REGRESSION OF *DAUBERT*'S PRINCIPLES

Ninth Circuit courts are unfortunately not the only federal courts that do not meet the standard the Supreme Court set for admission of expert evidence in

¹⁴ *In re Mirena IUD Prod. Liab. Litig.*, 202 F. Supp. 3d 304, 328 (S.D.N.Y. 2016), *aff'd*, 713 F. App'x 11 (2d Cir. 2017).

¹⁵ *Jones v. Novartis Pharms. Corp.*, 720 F. App'x 1006, 1008 (11th Cir. 2018).

¹⁶ *In re Lipitor Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 647 (4th Cir. 2018).

¹⁷ *See, e.g., Glenn v. B & R Plastics, Inc.*, No. 1:16-CV-00508-MWB, 2018 WL 3448212, at *9 (D. Idaho July 16, 2018) (courts have an “active role as a gatekeeper to prevent[] shoddy expert testimony and junk science from reaching the jury” (quotations omitted; alteration in original)).

Daubert. In *Canary v. Medtronic, Inc.*, No. 16-11742, 2018 WL 5921327 (E.D. Mich. Nov. 13, 2018), the plaintiff alleged that she suffered severe allergic reactions after being implanted with the defendant’s spinal cord stimulator. The plaintiff did not retain any general or specific causation experts, and instead chose to rely on the causation opinion of her treating physician.¹⁸ The physician testified that it was possible and plausible that the implant could have caused the allergic reaction, but did not otherwise conduct a differential diagnosis or testify to a reasonable degree of medical certainty.¹⁹ The court allowed the physician’s testimony, and did not consider the defendant’s *Daubert* challenge because, in the Sixth Circuit, the “general rule . . . is that ‘a treating physician may provide expert testimony regarding a patient’s illness, the appropriate diagnosis for that illness, and the cause of that illness.’”²⁰ While true that a treating physician is permitted to opine on causation, “a treating physician’s testimony remains subject to the requirement set forth in *Daubert* that an expert’s opinion testimony must have a reliable basis in the knowledge and experience of his discipline.”²¹ Had the *Canary* court conducted a proper *Daubert* analysis, it should

¹⁸ 2018 WL 5921327, at *2.

¹⁹ *Id.* at *2–3.

²⁰ *Id.* at *5 (quoting *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009)).

²¹ *In re Aredia & Zometa Prod. Liab. Litig.*, No. 3:06-MD-1760, 2009 WL 2496921, at *1 (M.D. Tenn. Aug. 13, 2009) (citing *Gass*, 558 F.3d at 426).

have excluded the treating physician’s expert testimony, because, at the very least, it was not stated to a reasonable degree of medical certainty.²²

The decision in *In re Abilify (Aripiprazole) Products Liability Litigation*, 299 F. Supp. 3d 1291 (N.D. Fla. 2018), is another instance of a court ignoring the Supreme Court’s *Daubert* gatekeeping mandate. In this MDL litigation, the plaintiffs allege that the defendant’s atypical antipsychotic drug caused them to develop “impulsive and irrepressible urges to engage in certain harmful behaviors, including impulsive gambling, eating, shopping, and sex.”²³ The defendants challenged the opinions of the plaintiffs’ general causation experts because, among other things, the experts “failed to provide *reliable* scientific evidence demonstrating a statistically significant association between Abilify and impulsive behaviors,” but the court nonetheless admitted the evidence.²⁴

The court’s analysis began by identifying the types of general causation evidence typically deemed valid under Eleventh Circuit precedent: “epidemiological studies, dose-response relationship, and background risk of disease.”²⁵ The plaintiffs

²² See *id.* at *3–4 (“Plaintiff has not carried her burden of showing that [the treating physician] is qualified to offer expert causation testimony,” because he could not testify to a reasonable degree of medical certainty that the defendant’s medications caused the alleged injury).

²³ *In re Abilify (Aripiprazole) Products Liability Litigation*, 299 F. Supp. 3d 1291, 1300 (N.D. Fla. 2018).

²⁴ *Id.* at 1304 (emphasis in original).

²⁵ *Id.* at 1306 (citing *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014)).

did not have—as the court should have determined—valid epidemiological evidence, because the “epidemiological” study the experts relied upon was prepared by an ophthalmologist who had contacted plaintiffs’ counsel for their input *before* he developed the research protocol for his study and considered as “adverse events” conditions the drug was designed to treat. The ophthalmologist further failed to obtain the study patients’ medical records to determine how much of the defendant’s drug they ingested, if any.²⁶

The court allowed the plaintiffs to rely on such questionable evidence under a “weight of the evidence” approach.²⁷ While the court cited the Supreme Court’s *Joiner* opinion,²⁸ had the court faithfully applied *Joiner* and *Daubert*, it would have come to a different conclusion. In *Joiner*, the Supreme Court affirmed a trial court opinion rejecting a “weight of the evidence” analysis as scientifically unacceptable. Like the experts in *In re Abilify*, the plaintiffs’ expert in *Joiner* could not show “that any one study provided adequate support for their conclusions.”²⁹ Instead, the plaintiffs’ “weight of the evidence” was based upon the “substantial judgment on the part of the expert.”³⁰ While exercising “substantial judgment” may be appropriate for a scientist

²⁶ *Id.* at 1317–25.

²⁷ *Id.* at 1311–12.

²⁸ *See, e.g., id.* at 1310.

²⁹ 522 U.S. at 152–53.

³⁰ *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d at 1311.

postulating new theories or a regulatory agency setting exposure limits, establishing legal causation requires more.³¹

Certain courts have also taken a more relaxed view on the importance of statistical significance. Statistical significance eliminates chance results by measuring how likely it is that repeated data sets of similar size would yield similar outcomes. Statistical significance is inherent in the “known or potential rate of error” *Daubert* factor, and *Joiner* held that, without it, a “court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”³² In 2017, however, the Third Circuit refused to establish a bright-line rule requiring statistical significance to prove causation in an MDL alleging that a prescription antidepressant caused birth defects.³³ The plaintiffs’ experts did not rely upon statistically significant studies showing a causal association. Despite *Joiner*, the Third Circuit viewed statistical significance as not required in the *Daubert* reliability analysis and indicated that causation can be proven through a variety of means, including “weight of the evidence” (rejected in *Joiner*), the “Bradford Hill criteria,” or a “differential diagnosis.”³⁴ The court’s *Daubert* inquiry thus focused not on the reliability of the

³¹ See, e.g., *Glastetter*, 252 F.3d at 991 (regulatory decisions are based on lesser, prophylactic causation standards than required in courts).

³² 522 U.S. at 145–46.

³³ *In re Zolof Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017).

³⁴ *Id.* at 795.

expert's opinion, but rather on whether the expert consistently applied the methodology he chose. Ultimately the court excluded the expert's methods as inconsistently applied under any of these approaches, but the opinion provides ways in which otherwise questionable expert evidence could be admitted despite the mandates in *Daubert* and its progeny.

Courts even have split on whether it is permissible under *Daubert* for an expert to rely on favorable data while ignoring contrary data, a process called "cherry-picking," even though the need for exclusion of such testimony should be obvious.³⁵ There are numerous other recent opinions highlighting how some courts and appellate circuits have not strictly applied *Daubert*, in favor of letting a jury decide whether an expert's testimony is credible.³⁶

The Ninth Circuit provides the best illustration of the departure from *Daubert's* gatekeeping requirements, constraining the courts within the Circuit on what evidence can be excluded. In *In re Roundup*, Ninth Circuit precedent compelled the trial court was required to admit a differential diagnosis that failed to rule out

³⁵ Compare, e.g., *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018) ("Result-driven analysis, or *cherry-picking*, undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion." (emphasis added)), with, e.g., *Kim v. Crocs, Inc.*, No. CV 16-00460 JAO-KJM, 2019 WL 923879, at *8 (D. Haw. Feb. 25, 2019) ("any questions about the weight of this [expert] opinion [based on cherry-picked data] should be resolved by a jury").

³⁶ E.g., *Adams v. Toyota Motor Corp.*, 867 F.3d 903, 916 (8th Cir. 2017) (affirming admission of expert testimony, reiterating the flexibility of the *Daubert* inquiry and emphasizing that defendant's concerns could all be addressed with "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof").

idiopathic causes of the alleged NHL.³⁷ In other words, the expert was permitted to say the defendant’s product caused the injury, even though the expert could not exclude the fact that some people get cancer and there is no known cause of their cancer. The *In re Roundup* court had to admit this evidence because of Ninth Circuit precedent allowing “shaky” expert testimony that falls on the “‘art’ side of the spectrum.”³⁸ In other circuits more closely following *Daubert*, an expert’s failure to rule-out idiopathic causes in rendering a specific causation opinion would require the exclusion of that opinion.³⁹

III. POTENTIAL SOLUTIONS TO BRING BACK STRICTER *DAUBERT* ANALYSES

Several reasons may explain the growing split within the federal judiciary’s approach to *Daubert* and Rule 702. Less rigorous *Daubert* opinions could be the result of an improper understanding of the gatekeeping function. To that extent, the issue can be rectified through better advocacy. Defendants favoring sound science in the courtroom should encourage counsel to take the time to learn the science, to develop

³⁷ *In re Roundup Prod. Liab. Litig.*, 2019 WL 917058, at *2.

³⁸ *Id.*; *In re Roundup Prod. Liab. Litig.*, 2018 WL 3368534, at *2 (“the case law—particularly Ninth Circuit case law—emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it’s shaky . . .”).

³⁹ *Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1190–91 (W.D. Okla. 2017) (Excluding specific causation opinion, because the expert “did not consider ‘idiopathic causes [for plaintiff’s AML], additionally rendering his differential diagnosis unreliable. Although idiopathic or de novo is not a cause, per se, courts have repeatedly faulted experts for their failure to consider idiopathic or unknown causes for diseases when rendering their differential diagnoses.” (citing *Milward v. Rust–Oleum Corp.*, 820 F.3d 469, 475–76 (1st Cir. 2016); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1311 (11th Cir. 2014))), *aff’d sub nom. Hall v. Conoco Inc.*, 886 F.3d 1308 (10th Cir. 2018).

a detailed record exposing an expert's methodological flaws, and then to educate the judge about what a proper *Daubert* analysis entails.

Less strict views on *Daubert* may also reflect philosophical leanings against gatekeeping. If so, advocating not just in courts, but in a jurisdiction's legislative arena may be required. There are current discussions on amending Rule 702 to clarify the courts' obligations when conducting *Daubert* inquiries.⁴⁰ The Advisory Committee on the Federal Rules of Evidence can consider amendments to make clear how courts should conduct the required assessment of reliability, instead of courts viewing disputes over expert testimony as a question of weight rather than admissibility.⁴¹

Altering *Daubert* views at the state level may be more complicated. Progress has occurred, with a number of state legislatures adopting *Daubert's* standards. *Daubert* has been adopted to varying degrees by 43 of the states, most recently by the District of Columbia in October 2016, Missouri in March 2017, New Jersey (to a degree) in August 2018, and Florida on May 23, 2019 following several battles between the state's legislature and supreme court.⁴² Some of the remaining *Frye*

⁴⁰ See Lasker, *supra* n.3, *It is Time to Amend Federal Rule of Evidence 702*. Perhaps the more difficult question is why, at the federal level, amending Rule 702 is necessary. The existing Rule incorporates *Daubert's* standards, as it has for almost 20 years. Pursuant to Federal Rule of Evidence 101, federal courts are supposed to follow that rule as well as the decisions of the Supreme Court interpreting the Rules of Evidence. As discussed above, however, that is not always the case.

⁴¹ See, e.g., *Liquid Dynamics Corp. v. Vaughan Corp.*, 449 F.3d 1209, 1221 (Fed. Cir. 2006) ("The identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination." (quotations omitted)).

⁴² See *In re Amendments to Fla. Evidence Code*, No. SC19-107, 2019 WL 2219714, at *3 (Fla.

states, which have a historically “liberal” bent like California, may not be receptive to *Daubert*, which critics may view as part of the “conservative” agenda.

Sound science is neither conservative nor liberal. Advocates of *Daubert* and the admissibility of appropriate scientific evidence should thus continue to pursue requirements for such evidence in the appropriate legislative or judicial arenas.

May 23, 2019) (“in accordance with this Court’s exclusive rule-making authority and longstanding practice of adopting provisions of the Florida Evidence Code as they are enacted or amended by the Legislature, we adopt the [*Daubert*] amendments”); *In re Accutane Litig.*, 234 N.J. 340, 399 (2018) (“In adopting use of the *Daubert* factors, we stop short of declaring ourselves a ‘*Daubert* jurisdiction.’ Like several other states, we find the factors useful, but hesitate to embrace the full body of *Daubert* case law as applied by state and federal courts.”); Michael Morgenstern, *Daubert v. Frye – A State-by-State Comparison*, The Expert Inst. (Apr. 3, 2017), <https://www.theexpertinstitute.com/daubert-v-frye-a-state-by-state-comparison/>.