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Expert Analysis

Expert Evidence In The Federal Courts: A Historical Perspective

By Arvin Maskin, Esq., and Isabella C. Lacayo, Esq.
Weil, Gotshal & Manges

Mass-tort and product liability cases can involve a broad range of sometimes novel liability and damage theories, including increased risk of disease, fear of disease, immunotoxicity, and medical monitoring. For this reason, experts with a wide range of specialties are called upon in mass-tort cases, including in the fields of dispersion modeling, epidemiology, immunology, analytical chemistry, statistics, toxicology and oncology.

These experts are used by both plaintiffs and defendants to prove and disprove various parts of the cases, including causation, which is the key element of most mass-tort cases. It is therefore no surprise that the admission of expert evidence has become critical to prosecuting and defending mass-tort cases.

It is helpful to have an understanding of the historical development of the guiding principles for the admissibility of expert evidence, especially since the modern admissibility rules were largely shaped in the context of mass-tort cases. Any discussion on the history of the admissibility of expert evidence must begin with *Frye v. United States*.[1]

1923: *FRYE* ESTABLISHES THE 'GENERAL ACCEPTANCE' TEST

In 1923 the District of Columbia U.S. Circuit Court of Appeals issued its decision in *Frye* and established the "general acceptance" standard for the admissibility of novel scientific evidence. Its legacy is remarkable as 90 years later and despite significant changes in federal jurisprudence, a handful of states, including New York, New Jersey and Pennsylvania, still follow *Frye*.

James Frye was a convicted second-degree murderer who appealed his conviction, arguing that the trial court improperly disallowed testimonial expert evidence relating to the results of a systolic blood pressure deception test (a precursor to the polygraph test). The trial court had found that the test results were inadmissible because the deception test had not gained recognition from psychological and physiological authorities.

The D.C. Circuit affirmed the trial court's ruling, finding that deception tests were not sufficiently established and had not gained general acceptance in the relevant fields.

The *Frye* standard permitted trial courts to exclude any science deemed to be insufficiently established within the pertinent fields. As a result, the standard required deference to the opinions of scientists, so long as the opinions were consistent with conventional scientific wisdom. While the *Frye* general acceptance test was the law in the federal courts until the U.S. Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals*[2] in 1993, there were several events that paved the way for *Daubert*.

1975: ADOPTION OF THE FEDERAL RULES OF EVIDENCE IMPACTS *FRYE*

In 1965 Supreme Court Chief Justice Earl Warren appointed an advisory committee to draft a codification of common-law rules of evidence. After several drafts and lengthy delays, the Federal Rules of Evidence were enacted in 1975.

Of particular importance to the admissibility of expert evidence is Federal Rule of Evidence 702, which, at the time of adoption, was titled "testimony by experts" and read, "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."[3]

In the time after the Federal Rules of Evidence were enacted, the use of scientific-expert evidence increased, and some courts interpreted Rule 702 as encouraging the admission of any evidence that may help the jury.[4] This weakened the *Frye* general acceptance test.[5] It thus became increasingly common for judges to accept a broad range of expert scientific testimony without much regard to the inherent validity of the testimony.[6]

Some judges, though, refused to allow questionable science into their courtrooms. These judges (like U.S. District Judge Jack B. Weinstein of the Eastern District of New York) were the pioneers of expert-evidence gatekeeping before *Daubert* made judicial gatekeeping an accepted practice.

1985: JUDGE WEINSTEIN'S GATEKEEPING IN THE 'AGENT ORANGE' LITIGATION

Nearly a decade before *Daubert* was decided by the Supreme Court, Judge Weinstein crafted and applied a rigorous test to determine the admissibility of causation evidence in the "Agent Orange" litigation. In that litigation, certain Vietnam veterans opted out of the settlement class that had been created by the defendant chemical companies. With respect to those plaintiffs, the defendants moved for summary judgment.

During a time when concerns were being voiced about the dilution of the *Frye* general acceptance test, Judge Weinstein found that the plaintiffs' experts' causation opinions were not admissible under *Frye* and Rule 702. Without causation evidence, the plaintiffs could not meet their burden of proof, and Judge Weinstein granted summary judgment in favor of the defendants.

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In granting the defendants' motion, Judge Weinstein referenced the "false aura of scientific infallibility" that experts can bring to court and the corresponding risk of jury confusion.[7]

He recognized early on that, if left unbridled, expert testimony can actually undermine the integrity of the fact-finding process. Judge Weinstein was also one of the first judges to make practical use of Federal Rules of Evidence 104, 702, 703 and 403 and Federal Rule of Civil Procedure 56 to resolve difficult scientific admissibility issues relating to causation, relevance and burden of proof. Ultimately, though, the role of the judge as the gatekeeper in the federal court system was not made clear until the Supreme Court issued its *Daubert* opinion.

1993: THE SUPREME COURT'S *DAUBERT* DECISION AND THE BENDECTIN LITIGATION

The landmark *Daubert* decision arose from yet another mass-tort case. Thousands of plaintiffs claimed that Bendectin, an anti-nausea drug intended to treat morning sickness during pregnancy, was responsible for their or their babies' birth defects. Among these lawsuits was one filed in California state court by Jason Daubert and Eric Schuller (and their parents), who both were born with serious birth defects.

Merrell Dow Pharmaceuticals removed the case to federal court and moved for summary judgment with an expert affidavit showing that no published scientific study had demonstrated a link between Bendectin and birth defects. In their opposition, the plaintiffs submitted an expert affidavit that claimed that, based on animal studies, pharmacological studies and reanalysis of other published studies, Bendectin *could* cause birth defects.

Since* Frye*, the law has developed to both strengthen the role of the judge as gatekeeper and provide judges with the tools for tackling challenging issues of scientific evidence.

The District Court excluded the plaintiffs' expert's testimony regarding Bendectin's ability to cause birth defects in humans, finding that the expert's methodologies were not generally accepted within the general scientific community, and granted Merrell Dow's motion for summary judgment. The 9th Circuit affirmed the District Court's decision, and the plaintiffs then appealed to the U.S. Supreme Court.

The Supreme Court in *Daubert* held that the *Frye* "general acceptance" test was superseded by the enactment of the Federal Rules of Evidence and that the rules do not require a "general acceptance" standard for the admission of scientific evidence in federal courts. The court described the general process by which a district judge determines whether scientific evidence should be admitted pursuant to Rule 702.

Although noting that "general acceptance" can still be a factor in determining admissibility, the court emphasized that Rule 702 establishes the role of the district judge as a "gatekeeper" to ensure that proposed expert scientific testimony is both relevant and reliable. A primary concern of Rule 702 is to help the fact finder.

Expert testimony that is unrelated to the particular issue for which it is offered is not relevant and therefore not helpful. The relationship between expert testimony and the facts of the case has been described as one of "fit." A valid scientific connection to the case must be made under Rule 702 to admit expert testimony.

Emphasizing that the inquiry under Rule 702 is a flexible one, the Supreme Court did not set out a definitive checklist or specific test for determining admissibility of expert testimony, and instead recited four factors worthy of consideration:

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- Whether the theory or technique can be or has been tested.
- Whether the theory or technique has been subjected to peer review and publication.
- The known or potential rate or error and the existence and maintenance of standards controlling the technique's operation.
- The "general acceptance" of the theory or technique (*i.e.*, the *Frye* standard).

The court went on to affirm the grant of summary judgment in favor of Merrell Dow based on its expert's affidavit concluding that maternal use of Bendectin had not been shown to be a risk factor for human birth defects. Although the plaintiffs' experts had presented testimony concluding that Bendectin could, in fact, cause birth defects, these conclusions were based on animal studies, pharmacological studies and a reanalysis of previously published studies — none of which were admissible under Rule 702.

As the Supreme Court observed, "'Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses.'"[8] After *Daubert*, it became clear that federal judges must act as the gatekeepers of expert evidence.

The post-Frye legal landscape has seen expert evidence become more sophisticated and more critical to winning mass-tort cases.

But by the time the *Daubert* case was decided by the Supreme Court, Bendectin had been off the market for 10 years. Merrell Dow voluntarily removed Bendectin from the market in 1983, citing the related litigation and exorbitant insurance premiums — not safety — as the reason. Even though the drug was discontinued, litigation persisted, with thousands of plaintiffs claiming Bendectin was to blame for birth defects.

Despite inflamed public fears as to Bendectin's safety (plaintiffs' experts did, after all, compare Bendectin to Thalidomide[9]) plaintiffs never had credible evidence that Bendectin caused birth defects. After years of litigation and millions of dollars spent on litigation, Merrell Dow (and Bendectin, even though no longer available) were vindicated. The litigation, in large part due to the Supreme Court's 1993 *Daubert* decision, ended favorably for Merrell Dow.

The Food and Drug Administration published a statement in 1999 in the Federal Register that it "ha[d] determined that the drug product Bendectin ... was not withdrawn from sale for reasons of safety or effectiveness."[10] The great delay, though, not only cost Merrell Dow millions but also cost doctors and patients an effective treatment. Dr. Michael Greene, director of maternal-fetal medicine at Massachusetts General Hospital in Boston, commented that "Bendectin was the archetypical case of junk science scuttling a perfectly safe product[;] [i]t was a sad episode in American jurisprudence."[11]

The case had a chilling effect on the development and manufacture of drugs to be used during pregnancy, and only two medications were FDA-approved for such use between 1962 and 2010.[12] Despite the unfortunate circumstances of the Bendectin litigation, it gave rise to one of the most important evidence decisions in Supreme Court history.

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THE SUPREME COURT'S POST-*DAUBERT* EXPERT EVIDENCE DECISIONS

Four years after *Daubert*, in 1997, the Supreme Court further strengthened the role of district court judges in expert evidence matters. In *General Electric v. Joiner*,[13] the Supreme Court held that *Daubert* decisions should be reviewed under the same abuse-of-discretion standard applied to all other evidentiary decisions.

The case enhanced the federal judiciary's gatekeeping authority by holding that it is not an abuse of discretion for a trial court to consider whether the conclusions drawn by experts, even if proper scientific methodologies are employed, make too great a leap from the data presented.

This presented district courts with an invaluable tool in the fight against "junk" scientific testimony. Before *Joiner*, plaintiffs were able to use *Daubert*'s instruction to district courts to focus on proper methodology as a shield to protect some of their experts' more dubious opinions. Now, a court could conclude there is simply too great an analytical gap between the data and the opinion offered.

In 1999 the Supreme Court issued its decision in *Kumho Tire v. Carmichael*,[14] which famously held that *Daubert* applies to all expert evidence, not just novel or scientific evidence. The case arose when the right rear tire of a Ford minivan blew out, and seven passengers were injured and one was killed. Survivors of the accident sued the tire manufacturer, claiming the tire was defective.

The plaintiffs based their case in significant part on the testimony of an expert in "tire failure analysis" who concluded the accident was due to a manufacturing defect rather than wear or poor performance of the tire — which was old, bald in spots and had imperfect repairs of two punctures. The defendants moved to exclude the proposed testimony of plaintiffs' expert and for summary judgment, arguing that the methodology of plaintiffs' expert failed the Rue 702 reliability requirement.

The District Court excluded the expert testimony and granted summary judgment because, although the proposed testimony was more technical than scientific in nature, the reliability-related factors set forth in *Daubert* (testability, whether a theory has been peer-reviewed or published, potential rate of error, and degree of acceptance in the relevant scientific community) nonetheless applied to the reliability of plaintiffs' expert's methods.

The 11th Circuit reversed, reasoning that because the expert's conclusions were based on personal experience and skill — not scientific principles — the District Court had erred in applying the *Daubert* factors.

The Supreme Court reversed the 11th Circuit's decision and held that:

- The *Daubert* "gatekeeping" obligation applies to all expert testimony, not just scientific expert testimony.
- A trial judge may consider one or more of the *Daubert* factors in determining the admissibility of expert evidence in any case.
- A trial court must have the same kind of latitude in determining how to test an expert's reliability as it enjoys when deciding whether the expert's testimony is reliable.

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- The District Court did not err in excluding plaintiffs' proposed expert testimony because it could not be considered reliable.

POST-*DAUBERT* GATEKEEPING IN BREAST IMPLANT LITIGATION

Along with the Supreme Court's clarification of the role of the trial court judge post-*Daubert* came the practical strengthening of a judge's position as gatekeeper. Specifically, judges have often used Rule 706 to appoint their own experts to assist in complex litigation by educating the court.

A paradigmatic example is the vast litigation involving injury claims arising from silicone gel breast implants, which included more than 400,000 cases filed in federal and state courts. A key issue in each case was the extent to which the implant leakage or rupture could have caused the resulting connective-tissue diseases or immune system dysfunction.[15]

The complicated scientific issues underlying the causation question led multiple judges involved in the litigation (including Chief U.S. District Judge Sam C. Pointer Jr. of the Northern District of Alabama, U.S. District Judge Robert E. Jones of the District of Oregon and Judge Weinstein) to appoint panels of experts to address the link between the breast implants and the diseases.

Chief Judge Pointer, who oversaw the consolidated *In re Silicone Gel Breast Implants Products Liability Litigation*,[16] essentially adopted Judge Weinstein's approach to the selection of a scientific panel, and asked the experts to submit reports and give videotaped testimony with the intention of having that testimony become part of the record for the cases. Judge Pointer thus used his position as gatekeeper to task experts with the responsibility of assessing, within the confines of the litigation, the conflicting scientific research regarding causation.

2000: RULE 702 AMENDED TO REFLECT *DAUBERT* AND *KUMHO TIRE*

In 2000 Rule 702 was amended in response to *Daubert* and *Kumho Tire*. The amendment explicitly "affirms the trial court's role as gatekeeper and provides some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony." The notes of the advisory committee to Rule 702 also enumerated a non-exhaustive list of factors that may be relevant in determining whether expert evidence is sufficiently reliable to be heard by the jury:

- Whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.
- Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion.
- Whether the expert has adequately accounted for obvious alternative explanations.
- Whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting.
- Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.

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Significantly, the Rule 702 advisory committee notes also make clear that "[i]f the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion and how that experience is reliably applied to the facts."

EXPERT EVIDENCE AND CLASS CERTIFICATION

Although certain facets of expert evidence are now well-settled, other issues remain unsettled. One important issue that remains open is the extent to which *Daubert* and Rule 702 apply to expert evidence presented at the class-certification stage. The Supreme Court recently considered the issue in an antitrust case, *Comcast Corp. v. Behrend*, 133 S. Ct. 1426 (Mar. 27, 2013).

In Comcast's appeal to the 3rd Circuit, it argued that the Supreme Court's ruling in *Wal-Mart Stores v. Dukes,* 131 S. Ct. 2541 (2011), required district courts to resolve any questions bearing on class certification prior to certification, including the admissibility of expert evidence.

While the *Dukes* decision did not decide specifically whether a full *Daubert* analysis of a challenged expert is required prior to certifying a class, the Supreme Court did hold in *Dukes* that courts must apply a rigorous analysis of all the prerequisites for class certification, even if the rigorous analysis entails some overlap with the merits of the underlying claims.In addition, the court noted, albeit in *dicta*, that it "doubted" that *Daubert* would not apply to expert evidence at the class-certification stage.

The 3rd Circuit, however, affirmed the District Court and thus created a conflict among the circuits on the issue of whether *Daubert* applies with respect to class certification. The 7th Circuit had taken the approach espoused by Comcast when it held that when an expert's report or testimony is "critical to class certification," a district court "must perform a full *Daubert* analysis before certifying the class." *Am. Honda Motor Co. v. Allen*, 600 F.3d 813, 815-16 (7th Cir. 2010).

And the 5th Circuit has recognized that, "[i]n many cases, it makes sense to consider the admissibility" of expert testimony at the Rule 23 certification stage, because "[i]n order to consider plaintiffs' motion for class certification with the appropriate amount of scrutiny, the court must first determine whether plaintiffs' expert testimony supporting class certification is reliable." *Unger v. Amedisys Inc.*, 401 F.3d 316, 323 n.6 (5th Cir. 2005).

The 8th Circuit, though, appears to have chosen a middle ground when it affirmed a district court's "tailored" *Daubert* analysis — an examination of the expert testimony with the requirements of Rule 23 in mind. *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 612 (8th Cir. 2011).

The 8th Circuit concluded that a full *Daubert* analysis would have been "impractical" because the parties had engaged in bifurcated discovery, resulting in a limited evidentiary record at the class certification stage that would have "prevented ... [a] full and conclusive *Daubert* inquiry." *Id.* at 612-13. The 8th Circuit noted that it was "not convinced that the [7th Circuit's] approach [in] *American Honda* would be the most workable in complex litigation or that it would serve case management better" than a more limited analysis. *Id.* at 612.

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In *Comcast*, the Supreme Court reversed the 3rd Circuit's decision, holding that class certification had been improper. But the opinion did not decide the specific question of whether *Daubert* applies at the class-certification stage.

Although the Supreme Court had announced that it would review "whether a district court may certify a class action without resolving whether the plaintiff class has introduced admissible evidence, including expert testimony, to show that the case is susceptible to awarding damages on a class-wide basis," the court's opinion did not focus on admissibility.

Rather, the court reinforced its *Dukes* decision, holding that class certification is improper absent a determination that all of Rule 23's requirements have been met. And the court clarified that such a determination must be made by "rigorous analysis" at the class-certification stage even if it requires a court to consider the merits of the underlying claim.

While the applicability of Rule 702 and *Daubert* at the class-certification stage continues to depend on the case law of the relevant circuit, it is only a matter of time until the Supreme Court determines the issue, especially given the court's recent interest in class-certification issues.

NOTES

1 293 F. 1013 (D.C. Cir. 1923).

2 509 U.S. 579 (1993).

3 Rule 702 has been amended a few times — most significantly after *Daubert* and *Kumho Tire v. Carmichael,* 526 U.S. 137 (1999), were decided — and, under the title "Testimony by Expert Witnesses," now reads: "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."

4 Anne M. Gaeta & Elizabeth A. Sitnick, Reliability and Admissibility Under Daubert, in Harvard Law School, The Judge's Role As Gatekeeper: Responsibilities & Powers (1999), *available at* http://cyber.law.harvard.edu/daubert/ch3.htm.

5 *Id.*

6 *Id.*

7 *In re "Agent Orange" Prod. Liab. Litig.,* 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom.; see also Lombardi v. Dow Chem. Co.,* 487 U.S. 1234 (1988).

8 *Daubert*, 509 U.S. at 595-97 (quoting Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended,* 138 F.R.D. 631, 632 (1991)).

9 One of those experts, Dr. William McBride, an Australian physician, was famous for alerting the world to the dangers of thalidomide, a sedative that when taken by pregnant women caused horrific deformities. After working on the thalidomide cases, he set out to prove that Bendectin (marketed as Debendox in Australia and the U.K.) also caused birth deformities, but an Australian medical tribunal found him guilty of medical fraud for falsifying data relating to his Bendectin experiments. *See* http://www.independent.co.uk/news/world/thalidomide-doctor-guilty-of-medical-fraud-william-mcbride-who-exposed-the-danger-of-one-antinausea-drug-has-been-disgraced-by-experiments-with-another-writes-robert-milliken-in-sydney-1474190.html.

10 64 Fed. Reg. 152 (Aug. 9, 1999).

11 Gina Kolata, *Controversial Drug Makes a Comeback,* N.Y. Times, Sept. 26, 2000.

12 D.A. Wing, B. Powers & D. Hickok, *U.S. Food and Drug Administration Drug Approval: Slow Advances in Obstetric Care in the United States*, Obstetrics & Gynecology (April 2010), at 825-33.

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[13] 522 U.S. 136 (1997).

[14] 526 U.S. 137 (1999).

[15] *See* Laural L. Hooper, Joe S. Cecil & Thomas E. Willging, *Assessing Causation in Breast Implant Litigation: The Role of Science Panels,* 64 L. Contemp. Probs. 139 (2001).

[16] 793 F. Supp. 1098 (J.P.M.L. 1992).

Arvin Maskin (L) is a litigation partner in the New York office of **Weil, Gotshal & Manges** and co-chair of the firm's product liability and mass-torts practice group. **Isabella C. Lacayo** (R) is an associate in the New York office's litigation department. She works primarily on product liability and mass-tort matters, as well as other complex litigation. The authors wish to thank associate Lisa Sokolowski for her invaluable assistance in preparing this article.

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