Copyright 2024 Bloomberg Industry Group, Inc. (800-372-1033) Reproduced with permission. Early Returns: 60 Days Of New Fed. R. Evid. 702 In Product Liability Litigation.

Early Returns: 60 Days Of New Fed. R. Evid. 702 In Product Liability Litigation

*By: **Jessica Davidson**, **Jordan Schwartz** and **Luis Chu***

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On December 1, 2023, a long-anticipated amendment to **Federal Rule of Evidence 702** took effect, marking the first substantive change to the rules governing the admissibility of expert evidence in 23 years. Courts have already begun to weigh in on this development, and the early returns suggest that the recent amendment presents litigants with significant opportunities for challenging expert evidence. While such opportunities apply across practice areas, cases involving allegedly defective products may be particularly ripe for **FRE 702** challenges given their complexity and presentation of technical, scientific questions.

Caselaw research identified 41 opinions in December 2023 and 33 in January 2024 that reference the amended **FRE 702** or the amendments. These decisions have generally focused on the two most important clarifications of the new rule: (1) that the burden is on the proponents of the testimony to prove the admissibility of their experts' opinions by a preponderance of the evidence; and (2) that challenges to the reliability of those opinions are matters for courts as gatekeepers of expert evidence, not questions of weight that should be decided by jurors.

Judge Thomas D. Schroeder, the Chair of the Subcommittee of the federal Advisory Committee on Evidence Rules that developed the Rule 702 changes, highlighted some of the concerning decisions that led to the changes in a law review article at the start of the amendment process. *See* Thomas D. Schroeder, *Toward a More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039 (2020). According to Judge Schroeder, one of those cases was Milward v. Acuity Specialty Prod. Grp., Inc., **639 F.3d 11** (1st Cir. 2011), in which the First Circuit reversed the district court's exclusion of the plaintiff's toxicology expert, who had opined that exposure to benzene causes Acute Promyelocytic Leukemia.

In *Milward*, after conducting a four-day hearing featuring live testimony from both sides' experts, the district court ruled that the plaintiff's primary expert on causation "lack[ed] sufficient demonstrated scientific reliability to warrant admission under Rule 702." *Id.* at 13. Although the expert purported to have applied a Bradford Hill analysis—a generally accepted approach to assessing potential causal relationships in the field of epidemiology—the district court reasoned that the witness's primary reliance

on data that lacked statistical significance was "a deviation from sound practice of the scientific method." Milward v. Acuity Specialty Prods. Grp., Inc., **664 F. Supp. 2d 137**, 149 (D. Mass. 2009).

Reversing the district court's ruling, the First Circuit held that the "district court read too much into the paucity of statistically significant epidemiological studies" and inappropriately "evaluat[ed] . . . the weight of the evidence, which is an issue that is the province of the jury[.]" **639 F.3d at 21**-24. Essentially, according to the Court of Appeals, because the expert claimed to have performed a weight-of-the-evidence Bradford Hill methodology, the district court was not permitted to carefully scrutinize whether the expert's application of that methodology was itself reliable. Judge Schroeder's article pointed to *Milward*'s reasoning as an example of the type of hands-off approach to scientific evidence that necessitated **FRE 702**'s amendment. 95 Notre Dame L. Rev. at 2044-45.

Although it is impossible to predict precisely how decisions like *Milward* would have fared under the new amendment to **FRE 702**, a recent decision in a multidistrict litigation proceeding suggests that the approach to gatekeeping rejected by the First Circuit is contrary to law. See In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22MD3043 (DLC), **2023 BL 457952**,

--- F. Supp. 3d --- (S.D.N.Y. Dec. 18, 2023). (note: Jessica Davidson is Attorney of Record for In re Acetaminophen). That ruling addressed allegations that use of acetaminophen during pregnancy causes autism spectrum disorder and attention-deficit/hyperactivity disorder.

As the *In reAcetaminophen* court noted, a principal "purpose" of the recent amendment to **FRE 702** was to "emphasize that '[j]udicial gatekeeping is essential,'" requiring courts to scrutinize whether experts who purport to have performed generally accepted weight-of-the-evidence and Bradford Hill methodologies actually applied those methodologies reliably. *Id.* at *19 n.27, *21-22 (citations omitted). In a nearly 150-page opinion excluding the plaintiffs' causation experts, the court explained how their opinions unreliably conflated two distinct neurological disorders, could not be reconciled with the U.S. Food & Drug Administration's conclusions that the epidemiological literature was inconsistent, and rested largely on statistically insignificant data. *Id.* at *42-43, *40, *46-47.

Although In re Acetaminophen appears to be the only post-amendment decision to address the admissibility of general causation evidence in product liability litigation, it may finally signal the post-amendment retirement of the jurors-know-best approach reflected by the First Circuit in *Milward*, as well as other decisions that were the impetus for the recent rule change. The amendment's clarification of the applicable law may have the greatest impact in cases where plaintiffs try to insulate their experts from **FRE 702** challenges by asserting that the witnesses applied methodologies that are generally accepted as reliable approaches to scientific evidence (even if they applied them unreliably).

For example, epidemiologists routinely employ the Bradford Hill approach to assessing whether a product is capable of causing the complained-of injury. Similarly, differential diagnosis—a process by which a

medical doctor rules in and rules out potential causes of a plaintiff's specific injury—is a recognized method of evaluating specific causation. And damages experts in all sorts of cases increasingly use conjoint analyses to isolate a purportedly misrepresented attribute of a product and ascribe specific value to that quality.

While each of these methodologies can be a generally accepted approach to scientific evidence, a plaintiff should not be able to survive an **FRE 702** challenge by simply *claiming* that his or her expert applied them. Rather, the onus is on the proponent to prove—by a preponderance of the evidence—that the expert faithfully *applied* those methodologies in a reliable manner.

Evidentiary hearings may take on heightened importance, given the fundamental gatekeeping function that the recent amendment sought to clarify for district court judges. In addition, the recent amendment may provide defendants with an avenue for seeking reconsideration of prior rulings in which courts suggested that methodological challenges implicated the weight of the testimony rather than its admissibility. While those earlier decisions technically constitute law of the case, that doctrine is not inexorable and must yield to legal developments, particularly where (as here) the changes essentially sought to clarify existing law. However, parties seeking to revisit prior decisions should act in a prompt manner and, at a minimum, lodge proper objections at trial and prior to the entry of final judgment.

Finally, although **FRE 702** motions are more frequently brought by defendants than plaintiffs in product liability litigation, defendants should be prepared to minimize the risk of their experts being challenged under **FRE 702**. They can do so by clearly delineating their methodologies up front in their reports and then explaining how they followed them.

Although it is still too early to appreciate the full impact of the recent amendment to Rule 702 on product liability litigation, the early tea leaves suggest that some courts are beginning to take Rule 702 and their gatekeeping responsibilities more seriously. The practice points highlighted in this article can help defendants facilitate that important objective more broadly.

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