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INSIGHT

Delaware Supreme Court Shuts Down Flawed Expert Testimony

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The Delaware Supreme Court's [consequential ruling](#) for mass tort litigation and expert admissibility standards in *In re Zantac (Ranitidine) Litigation* reversed a decision to admit plaintiffs' expert testimony in a sprawling personal injury case that ranitidine, sold under the brand name Zantac, caused cancer.

Central to the decision is the court's interpretation of Delaware Rule of Evidence 702, its alignment with Federal Rule of Evidence 702, and the trial judge's gatekeeping obligations. This state court decision adds to the body of legal authority correcting prior errors and holding proponents of expert testimony to their proper admissibility burden.

Practitioners in state and federal courts can use the opinion as a guide for expert admissibility. For lawyers litigating mass torts, the message is clear: Scientific rigor, methodological transparency, and strict adherence to Rule 702 are non-negotiable prerequisites for expert testimony to reach the jury.

Litigation Background

Plaintiffs alleged ingesting ranitidine caused various cancers due to its potential to form N-Nitrosodimethylamine, which has been classified by some agencies as a probable human carcinogen.

Although some manufacturers of ranitidine products voluntarily recalled products in 2019, the Food and Drug Administration issued a recall in 2020. Litigation followed. In multidistrict litigation in the US District Court for the Southern District of Florida, the court excluded general causation expert testimony for failing to meet FRE 702's requirements.

Because the MDL created a tolled census registry for claimants who had not yet filed in the MDL, many registry claimants exited and refiled in Delaware.

In the Delaware filings, claimants expanded their allegations to include additional types of cancer. The trial court denied the defendant's motions to exclude the opinions of plaintiffs' general causation experts.

The Supreme Court of Delaware accepted an interlocutory appeal of the trial court's evidentiary rulings, finding that, "a ruling on the issues regarding the Plaintiffs' general causation experts could be dispositive for some or all of the almost 75,000 claims filed in Delaware" and that "the Superior Court's decision raises substantial issues regarding the *Daubert* standard generally and mass tort litigation specifically."

'Wayward' Ruling

The trial court's ruling reflects the improperly lax review of expert testimony that led to public calls for the amendment to FRE 702. Prior to the amendment, a pervasive problem of "["wayward case law"](#)" existed in which federal courts were "far more lenient about admitting expert testimony than any reasonable reading of the Rule would allow."

The Federal Rules of Evidence Advisory Committee [concluded](#) that several federal "judges did not apply the preponderance standard of admissibility to [Rule 702's] requirements of sufficiency of basis and reliable application of principles and methods, instead holding that such issues were ones of weight for the jury." The December 2023 amendment to FRE 702 clarified the standards of admissibility to correct this flawed jurisprudence.

Nevertheless, the Delaware trial court followed the footsteps of other "wayward" courts and made mistakes the amendment sought to correct. The trial court claimed Delaware's rule embodies a "liberal thrust favoring admission," differentiating it from the federal rule, and that methodological criticisms raised by defendants went to the "weight," not the admissibility, of the experts' testimony.

Course Correction

The Delaware Supreme Court reversed, holding that the trial court misapplied DRE 702 in four ways.

First, the court made clear that "Delaware follows the federal standard." Delaware's rule is intended to mirror the federal rule. The court reiterated its prior holdings that require trial courts to examine whether expert methods are reliably applied to the facts of the case. It disapproved of the trial court's reliance on trial court opinions that reached faulty conclusions in an effort to justify methodological leniency.

Second, the trial court’s “liberal thrust” interpretation was rejected. The Supreme Court held there’s no presumption of admissibility of expert testimony. The court noted Delaware’s rule aligns with FRE 702 and pointed to the 2023 amendment and guidance from the Advisory Committee on Rules’ Report, which rejected this “liberal thrust” approach.

The court emphasized expert testimony must meet each requirement of DRE 702 by a preponderance of the evidence and that the gatekeeping standard is rigorous and not deferential.

Third, the court found the trial court abdicated its gatekeeping role by treating major methodological flaws—including cherry-picking data, reliance on animal and occupational NDMA studies unrelated to ranitidine, and lack of a dose-response analysis—as jury issues. The trial court’s repeated dismissal of these critiques as questions of “weight” rather than “admissibility” was found to be legal error.

The court explained that a trial court must ensure experts reliably apply scientific principles to the facts, especially in complex toxic tort cases. That reasoning directly aligns with the FRE 702 amendment, which requires the expert’s opinion reflect a reliable application of the principles and methods employed to the facts of the case.

Last, the court took umbrage with the trial court’s framing of the general causation inquiry. The lower court allowed experts to rely broadly on NDMA data—even from food and occupational exposure studies—without connecting NDMA exposure from ranitidine to the claimed cancers.

The court held that this failed to provide a “reliable bridge” between the product and the scientific evidence. General causation requires evidence that ranitidine, as used, can cause the alleged harms—not just that NDMA can.

Practitioner Takeaways

To date, [six states](#) have adopted rule reforms aligning with the FRE 702 amendment and at least a dozen more have initiated efforts to amend their rules. Practitioners in state and federal courts that follow FRE 702 should use the amendment and drafting history as tools for structuring arguments for the exclusion or inclusion of expert testimony and for educating judges on gatekeeping responsibilities.

The burden of proof lies with the party offering expert testimony, which must establish sufficiency and reliability by a preponderance of the evidence. When seeking to exclude expert testimony, the court can’t defer these determinations to the jury.

Expert opinions must link the alleged harm to the specific product, not merely to a component or theoretical contaminant.

The expert must explain how their opinion reflects a reliable application of the methodology to the facts of the case. Courts can’t simply “take the expert’s word for it.”

The Delaware Supreme Court's opinion in *In re Zantac* serves as another step on the road toward proper enforcement of the rigorous standard for expert admissibility in complex litigation.

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