

## Delaware Supreme Court Reverses Trial Court Decision on Zantac Expert Testimony

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Winston has previously analyzed several key aspects of Judge Rosenberg’s decision in the Zantac (ranitidine) MDL that excluded the plaintiffs’ experts and granted summary judgment for the defendants (available [here](#), [here](#), and [here](#)). Recently, the Delaware Supreme Court (the Court) addressed, and ultimately overruled, a different result reached at the Delaware trial-court level.<sup>[1]</sup> In a sweeping opinion, the Court reversed the trial court’s ruling, which had admitted the same categories of expert opinions that had been excluded by the MDL court.<sup>[2]</sup> The Court’s analysis focused on two primary errors by the trial court: (1) misapplication of Delaware Rule of Evidence 702 (DRE 702) and (2) incorrect framing of the general causation question at issue.

### FACTUAL BACKGROUND

The Delaware state court litigation involves nearly 75,000 plaintiffs who allege that their ingestion of ranitidine (Zantac) caused them to develop cancer. Notably, almost 80% of the Delaware plaintiffs originally registered their claims in the federal MDL, and almost 90% alleged one of the five types of cancer for which the MDL plaintiffs had acknowledged there was insufficient evidence of causation.<sup>[3]</sup>

The Delaware plaintiffs presented an entirely new slate of general causation experts who had not appeared in the federal MDL.<sup>[4]</sup> In November 2023, the defendants moved to exclude these general causation experts under DRE 702, arguing that “all Plaintiffs’ experts’ reports and conclusions suffered from the same methodological flaws identified by the MDL court in its decision to exclude the expert reports in that litigation.”<sup>[5]</sup>

On May 31, 2024, the Delaware trial court denied the defendants’ motion to exclude, holding that the general causation question could focus on NDMA—an alleged impurity in formulated Zantac—rather than ranitidine itself, that Delaware law did not require a threshold dose for general causation,<sup>[6]</sup> and that Delaware law requires a trial court to apply a “liberal thrust” favoring admissibility of expert testimony.<sup>[7]</sup> The trial court denied certification for interlocutory appeal, but the Delaware Supreme Court nevertheless granted review, recognizing that the issues presented could be dispositive for the tens of thousands of claims and “raise[] substantial issues regarding the *Daubert* standard generally and mass tort litigation specifically.”<sup>[8]</sup> The Court ultimately reversed the trial court on two grounds.

### 1. THE TRIAL COURT’S MISAPPLICATION OF DRE 702 AND THE GATEKEEPING FUNCTION

The Court first emphasized that it has “interpreted DRE 702 to be consistent with its analogue, Federal Rule of Evidence (FRE) 702, and we look to the federal rule and judicial application of it as persuasive authority.”<sup>[9]</sup> While the Court observed that DRE 702 has not been amended to mirror the 2023 amendments to FRE 702, it recognized that those amendments “are not substantive and instead only clarified the existing federal standard,” which the Court therefore viewed “as important material to consider in reviewing our trial courts’ decisions and providing guidance to litigants.”<sup>[10]</sup> Operating under this framework, the Court held that the trial court had “misinterpreted DRE 702 and the Plaintiffs’ burden in three ways.”<sup>[11]</sup>

**First**, the trial court erred by holding that DRE 702 should be applied with a “liberal thrust favoring admission.”<sup>[12]</sup> The Court stressed that *Daubert* never created a presumption of admissibility. To the contrary, “the proponent of an expert opinion must prove its admissibility by a preponderance of the evidence,” and “[u]nless that threshold is met, expert testimony is not admissible, and trial courts should not approach a challenge to expert testimony with any presumption toward admissibility.”<sup>[13]</sup> Describing the lower court’s approach as one that “failed to hold Plaintiffs to their burden of proof,” the Court reiterated that “a trial judge must act as a gatekeeper and determine that the evidence is both (1) reliable and (2) relevant.”<sup>[14]</sup>

**Second**, the Court disagreed with the trial court’s determination that Delaware law differed from federal law and “required the court to apply standards distinct from those used by the MDL court,” finding that the trial court’s “dismissal of the significant methodological flaws identified by the MDL court—flaws that also appeared in the expert reports in Delaware—on the basis that Delaware has a different standard, was in error.”<sup>[15]</sup> While the Court noted that “[t]he Superior Court was free to reach a different conclusion from the MDL court,” it was “required to faithfully apply the sufficiency and reliability standards set forth in Delaware and pertinent federal law.”<sup>[16]</sup>

**Third**, the Court disagreed with the trial court’s repeated determination that methodological critiques went to “weight, not admissibility.”<sup>[17]</sup> The Court called that approach “inconsistent with a trial court’s gatekeeping function, DRE 702 and its federal analogue, and Delaware caselaw.”<sup>[18]</sup> In support of its decision, the Court documented numerous instances of the trial court failing to “determin[e] whether the challenged experts reliably applied appropriate methodologies” and instead “dismiss[ing] these objections and label[ing] them as questions for the jury.”<sup>[19]</sup> For example, the Court noted that the trial court “did not require the challenged experts to explain their rejection of epidemiological, peer-reviewed studies.”<sup>[20]</sup> Similarly, the trial court failed to require the plaintiffs’ experts to justify their reliance on lower-quality, non-statistically significant, and far less relevant publications.<sup>[21]</sup> The Court held that “[t]his is not the correct standard under Delaware law,” and that “[t]hese collective errors resulted in the court finding that Plaintiffs’ experts’ opinions were admissible even though their sufficiency and reliability was not established by a preponderance of the evidence.”<sup>[22]</sup>

## 2. THE TRIAL COURT’S IMPROPER FRAMING OF GENERAL CAUSATION

The Delaware Supreme Court also found that the trial court erred by framing the general causation question to focus on the alleged carcinogenic agent—NDMA—rather than the actual product at issue—ranitidine. It emphasized that the proper focus of general causation is “whether the substance at issue is capable of causing the harm alleged” and clarified that “an expert offering an opinion regarding general causation for a product must opine as to the product itself.”<sup>[23]</sup> The Court rejected the trial court’s approach, which permitted the plaintiffs’ experts to rely on studies regarding NDMA “without connecting the NDMA exposure in those studies to the exposure caused by ranitidine—the product at issue.”<sup>[24]</sup> This approach, the Court held, was “inconsistent with DRE 702 and Delaware law.”<sup>[25]</sup>

Echoing concerns raised in the federal MDL, the Court observed that the plaintiffs’ experts relied on studies involving NDMA exposure from processed meats and occupational settings such as rubber manufacturing.<sup>[26]</sup> The Court found this methodology insufficient, stating that it is not enough for the plaintiffs’ experts to show “that NDMA—a pervasive substance found in air and water—causes cancer, ranitidine contains or degrades into NDMA, and therefore ranitidine causes cancer.”<sup>[27]</sup> The Court made clear that while experts may rely on studies concerning a toxic agent within a product, they must also “reliably link the toxic agent (here, NDMA) and the product at issue in order to opine that the product is capable of causing the harm alleged.”<sup>[28]</sup>

The Court also found that the plaintiffs’ experts failed to establish this necessary link between NDMA exposure from ranitidine and the exposures studied in the cited literature. Specifically, the Court observed that the plaintiffs’

experts failed to “examine NDMA exposure from ranitidine or establish that the exposure to NDMA in the occupational and dietary studies could be scientifically linked to the exposure to NDMA caused by ingesting ranitidine.”<sup>[29]</sup> Although one of the plaintiffs’ experts attempted to convert inhaled NDMA doses to oral doses, the Court found this opinion flawed as it relied on a single occupational study and faced significant methodological challenges that the trial court did not resolve.<sup>[30]</sup>

Ultimately, the Court concluded that the trial court “failed to require the experts to apply a reliable scientific methodology to reach their conclusion that the exposure to the toxic agent in the studies on which the experts relied was comparable to the exposure to the toxic agent caused by the product.”<sup>[31]</sup>

## CONCLUSION

In reversing and remanding the trial court’s decision, the Delaware Supreme Court reaffirmed that DRE 702 must be applied in line with its federal counterpart, including the clarifying 2023 amendments to FRE 702. The ruling underscores the trial court’s gatekeeping obligation to ensure that expert opinions are both methodologically sound and meaningfully tied to the product at issue. It also sends a clear message that as in federal court proceedings, speculative science and disconnected causation theories will not withstand scrutiny under Delaware law.

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[1] *In re Zantac (Ranitidine) Litig.*, No. 255, 2024, 2025 WL 1903760, at \*1 (Del. July 10, 2025).

[2] *Id.*

[3] *Id.* at \*4.

[4] *Id.* at \*5-6.

[5] *Id.* at \*5.

[6] The Delaware Supreme Court determined that it did not need to reach the “threshold dose” question appellants raised but observed that “there is no consensus in Delaware law as to ‘threshold dose’” in product liability and mass tort proceedings. *Id.* at \*12.

[7] *Id.* at \*6.

[8] *Id.* at \*7.

[9] *Id.* at \*8.

[10] *Id.* at \*10.

[11] *Id.* at \*14.

[12] *Id.* at \*10-11.

[13] *Id.* at \*11.

[14] *Id.* at \*8, \*11.

[15] *Id.* at \*11.

[16] *Id.* at \*12.

[17] *Id.*

[18] *Id.*

[19] *Id.* at \*13.

[20] *Id.*

[21] *Id.* at \*13-14.

[22] *Id.* at \*14.

[23] *Id.* at \*1, \*16.

[24] *Id.* at \*15.

[25] *Id.*

[26] *Id.* at \*16.

[27] *Id.*

[28] *Id.* at \*16.

[29] *Id.* at \*18.

[30] *Id.* at \*17.

[31] *Id.* at \*1.

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