



## Delaware Supreme Court Embraces Federal Rule 702 Amendments, Emphasizes Trial Courts' Evidence-Gatekeeping Role

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The Delaware Supreme Court recently confirmed that “Delaware’s evidentiary rules governing expert testimony are consistent with federal law,” fully embracing the 2023 amendments to Federal Rule of Evidence (FRE) 702.<sup>1</sup> In so doing, the court unanimously rejected an attempt by plaintiffs’ lawyers to pursue tens of thousands of mass tort claims in the Delaware Superior Court that did not withstand scrutiny in federal multidistrict litigation. The ruling is a victory for application of sound expert testimony standards in Delaware courts and an example of rigorous gatekeeping for other state courts to follow.

**The Zantac Litigation.** For over 35 years, brand and generic pharmaceutical manufacturers sold ranitidine (Zantac) to treat heartburn among other intestinal disorders. In September 2019, Valisure, a private company and online pharmacy, claimed that ranitidine could degrade into N-Nitrosodimethylamine (NDMA), a likely carcinogen, and petitioned the FDA to require a recall. Valisure indicated that its testing detected NDMA levels exceeding three million nanograms (ng) per tablet, far above the 96 ng limit the FDA set for NDMA ingestion in an unrelated class of medications. The FDA raised concerns about Valisure’s methodology and findings after own its tests “did not produce the same results.”<sup>2</sup> FDA found levels of NDMA “you would expect to be exposed to if you ate common foods like grilled or smoked meats.”<sup>3</sup> Some batches, however, showed NDMA above 96 ng (though “a tiny fraction of the level reported by Valisure”).<sup>4</sup> In April 2020, the FDA asked manufacturers to recall the products due to concern that, if stored at higher than room temperatures, the impurity could increase over time.<sup>5</sup>

Immediately after Valisure submitted its Citizen Petition, lawsuits were filed.<sup>6</sup> Within months, the federal judiciary established a multidistrict litigation (MDL) process in the Southern District of Florida for all pretrial purposes. Fueled by an onslaught of attorney advertising,<sup>7</sup> the federal docket grew to include tens of thousands of claims.<sup>8</sup> In December 2022, however, the MDL court issued a 200-page opinion which found major flaws in the plaintiffs’ experts’ testimony, excluded their general

<sup>1</sup> *In re Zantac (Ranitidine) Litig.*, 2025 WL 1903760, at \*1, -- A.3d -- (Del. July 10, 2025).

<sup>2</sup> *Id.* at \*2.

<sup>3</sup> FDA, [Laboratory Test | Ranitidine](#), Nov. 1, 2019.

<sup>4</sup> *In re Zantac (Ranitidine) Litig.*, 2025 WL 1903760, at \*2 (quoting MDL decision).

<sup>5</sup> FDA, News Release, [FDA Requests Removal of All Ranitidine Products \(Zantac\) from the Market](#), Apr. 1, 2020.

<sup>6</sup> Editorial, [The Zantac Scare and Junk Science](#), Wall St. J., Dec. 8, 2022.

<sup>7</sup> [Zantac Remains Dominant Mass Tort Ad Target](#), X-Ante, June 9, 2021.

<sup>8</sup> Bonnie Eslinger, [Zantac Plaintiffs Must File Separate Complaints, Judge Says](#), Law360, Feb. 7, 2023.

causation opinions, and granted summary judgment for defendants.<sup>9</sup>

Following the MDL court’s Rule 702 hearing, nearly 75,000 Zantac suits were filed in Delaware state court.<sup>10</sup> Almost 80% of these plaintiffs originally registered their claims in the MDL.<sup>11</sup>

**Delaware Supreme Court Embraces Rule 702 Amendments.** In response to the Delaware defendants’ Rule 702 motions, the state trial court said that Delaware follows a “liberal thrust” standard “favoring admission” of expert testimony.<sup>12</sup> The trial court repeatedly dismissed arguments about the plaintiffs’ experts’ methodology “as going to weight rather than admissibility” of the testimony.<sup>13</sup>

The Delaware Supreme Court rejected this approach.<sup>14</sup> The court noted that FRE 702 was amended in 2023 “to clarify the rule without changing its substance” and to reaffirm that “trial courts are required to vigorously exercise their gatekeeping function.”<sup>15</sup> The federal Advisory Committee on Evidence Rules found that “judicial decisions treating expert opinions as presumptively admissible and dismissing challenges as questions of ‘weight’ rather than ‘admissibility’ consistently misapplied the rule and failed to perform the court’s gatekeeping function with fidelity.”<sup>16</sup> The amendment confirmed that the proponent of expert testimony must establish its admissibility by a preponderance of the evidence.<sup>17</sup>

Delaware’s Rule 702 has not been amended at the present time to mirror the updated federal rule, but the state high court viewed the federal Advisory Committee’s comments “as important material” in “providing guidance to litigants.”<sup>18</sup> The Delaware Supreme Court made clear that: (1) “trial courts should not approach a challenge to expert testimony with any presumption toward admissibility”; (2) a trial court “abdicate[s] its gatekeeping role by passing crucial questions of sufficiency and reliability to the jury”; and (3) “close calls go to the jury” is “not the correct standard under Delaware law.”<sup>19</sup> Because the trial court failed to address significant gaps in the plaintiffs’ expert opinions and erred in applying Rule 702, the Supreme Court reversed the trial court’s decision not to exclude the opinions and remanded for further proceedings.<sup>20</sup>

**Implications.** Since FRE 702 was amended, several states have aligned their standard with the federal approach, either by court rule (Arizona, Michigan, Kentucky, and Ohio) or by statute (Louisiana and Oklahoma). Through its Zantac decision, Delaware has confirmed that its courts follow the same principles. This ruling will help keep Delaware—the place of incorporation for many businesses—from becoming a magnet for speculative litigation based on flimsy science. The ruling also bodes well for ongoing efforts to address common misapplications of expert testimony standards in the states, and places renewed emphasis on the importance of the courts’ gatekeeping role.

<sup>9</sup> *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075 (S.D. Fla. 2022).

<sup>10</sup> *In re Zantac (Ranitidine) Litig.*, 2025 WL 1903760, at \*4.

<sup>11</sup> *Id.*; see also Amanda Bronstad, [After Federal Judge’s Dismissal, Zantac Legal Fight Reignites in State Courts](#), Law.com, June 14, 2024.

<sup>12</sup> *In re Zantac (Ranitidine) Litig.*, 2025 WL 1903760, at \*10.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at \*9.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* For a discussion of amended FRE 702, see Mark A. Behrens & Andrew J. Trask, *Federal Rule of Evidence 702: A History and Guide to the 2023 Amendments Governing Expert Evidence*, 12 Tex. A&M L. Rev. 43 (2024).

<sup>18</sup> *In re Zantac (Ranitidine) Litig.*, 2025 WL 1903760, at \*10.

<sup>19</sup> *Id.* at \*12-14.

<sup>20</sup> *Id.* at \*18.