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Will *Zantac* Lawsuit Turn Delaware Into Plaintiffs' First Choice?

by Glenn G. Lammi

Delaware—the first of the 13 colonies to ratify the U.S. Constitution—also prides itself on being the state of incorporation for "more than 66% of the Fortune 500." The Delaware Supreme Court recently granted interlocutory review in a case which, depending how the court decides, could solidify the state's reputation or erect a virtual "open for business" sign on Route 95 for mass-tort lawyers and other members of the plaintiffs' bar.

Over 75,000 plaintiffs filed suit in Delaware Superior Court alleging that ranitidine, which several manufacturers market under the trade name Zantac, caused their cancer. More specifically, they claim that when ingested, ranitidine breaks down into a substance known as NDMA that is believed to be carcinogenic. In such mass-tort cases, the court routinely conducts a hearing to determine if the allegedly offending substance can cause the claimed harm, i.e. whether "general causation" exists. The Superior Court considered both sides' expert evidence under Delaware Rule of Evidence 702, which is nearly identical to the federal Rule 702.

On May 31, 2024, the Superior Court issued a ruling that denied each of defendants' challenges to the plaintiffs' experts and their evidence. The defendants urged the trial judge to follow the lead of a December 2022 general-causation ruling in a nearly identical multidistrict litigation before a federal court in the Southern District of Florida. Former HHS General Counsel Robert Charrow[1] succinctly described how the federal court viewed the plaintiffs' experts in an August 27 *Wall Street Journal* editorial:

> [O]ne must demonstrate the drug exhibits consistent positive associations with certain cancers across a series of human studies. No such relationship existed. The human studies didn't show a consistent statistically significant and valid association between ranitidine use and cancer, let alone causation. Based on these, along with another study from the Food and Drug Administration, the agency and its European counterpart concluded that ranitidine poses no risk of cancer. The judge followed these assessments and excluded the plaintiffs' expert testimony.

The Delaware Superior Court judge acknowledged the December 2022 federal court ruling and the similarities between the state and federal rules of evidence, but, as Susanna Moldoveanu wrote in the *Drug and Device Law* blog:

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[1] Mr. Charrow co-authored a 1994 WLF *Monograph* with Professor David E. Bernstein, *Scientific Evidence in the Courtroom: Admissibility and Statistical Significance after* Daubert.

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> The Delaware court also took great pains to distinguish the issues before it from the MDL court's ruling, noting that the experts were not the same, and that Plaintiffs included a slightly broader list of cancers than those pursued in the MDL court (presumably because they have even weaker support). But even though the experts were not the same, their logic was.

The court made two legal errors in setting the ground rules for its Rule 702 hearing, Ms. Moldoveanu further wrote. First, the court concluded that it would accept evidence not only on ranitidine, but also on NDMA, when deciding on general causation. Second, the court did not require the plaintiffs to prove a "threshold dose," which is the minimum amount of exposure to the substance in question that would cause the disease at issue. Without a threshold dose requirement, the defendants could be held liable for plaintiffs' background exposure to NDMA, which is present in, among other things, smoked meats and fish as well as malt beverages such as whiskey and beer.

In its August 27, 2024 order accepting the defendants' motion for interlocutory appeal, the Delaware Supreme Court identified the trial court's conclusions on NDMA studies and threshold dose as "substantial issues regarding the *Daubert* standard generally and mass tort litigation specifically." The *In re Zantac (Ranitidine) Litigation* appeal provides the First State's high court a prime opportunity to clarify Delaware law on those two issues and remind trial judges that in most instances it's their duty, not the jury's, to evaluate defendants' evidentiary challenges.

