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BLOG

Zantac MDL Decision Reinforces Principle that Lack of General Acceptance of an Expert's Conclusions Raises a Red Flag

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The *Zantac* MDL Court recently reinforced the important role of general acceptance of an expert's conclusions to a court's Rule 702 admissibility analysis.

The U.S. District Court for the Southern District of Florida granted summary judgment against more than 2,450 plaintiffs who had cases pending in the MDL, ruling that they had failed to produce reliable expert testimony necessary to support their claims under Rule 702. *In re Zantac (Ranitidine) Prod. Liab. Litig.*, No. 20-MD-2924, ---F. Supp. 3d---, 2022 WL 17480906, at *4, *6, *167 (S.D. Fla. Dec. 6, 2022).

The litigation involves claims against manufacturers of ranitidine, a heartburn medication sold under the brand name of Zantac. After Zantac had been on the market for several decades, a testing laboratory filed a Citizen Petition with the FDA and called for a recall of ranitidine. *Id.* at *2, *5. The petition explained that the private company's testing found high levels of a carcinogen in the drug. *Id.* at *5. Simultaneously, plaintiffs filed cases alleging Zantac caused several types of cancer. *Id.* The FDA subsequently issued a voluntary recall of ranitidine from the market. *Id.*

The court excluded Plaintiffs' general causation experts under Rule 702 because "there is no scientist outside this litigation who concluded ranitidine causes cancer, and the Plaintiffs' scientists within this litigation systemically utilized unreliable methodologies with a lack of documentation on how experiments were conducted, a lack of substantiation for analytical leaps, a lack of statistically significant data, and a lack of internally consistent, objective, science-based standards for the evenhanded evaluation of data." *Id.* at *4. The court made clear that "if an expert makes an analytical leap from available data that no other scientist outside of the litigation has made, a court may consider that fact." *Id.* at *83.

The court emphasized the distinction between litigation experts' conclusions and those of impartial scientists. *See id.* While acknowledging that Rule 702 is focused on evaluating an expert's methodology to determine whether their opinions are reliable, the court clarified that "when an expert's theory 'lacks any acceptance, let alone general acceptance, in the scientific community' it is an indication of an unreliable methodology." *Id.* at *124 (quoting *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II) (Mirena II)*, 341 F. Supp. 3d 213, 268 (S.D.N.Y. 2018)); *see also Mirena II*, 341 F. Supp. 3d at 247 (lack of general acceptance of expert's theory requires court to take a "hard look" at methodology).

Plaintiffs often assert that a Rule 702 analysis focuses on methodology, not conclusions. The *Zantac* decision reaffirms the principle first articulated in *General Electric Company v. Joiner*, 522 U.S. 136, 146 (1997), that "conclusions and methodology are not entirely distinct from one another." The Advisory Committee Notes to the 2000 Amendment to Rule 702 noted that when an expert "reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied." *See also Coning v. Bayer Pharma AG et al.*, 982 F. 3d 113, 124 (2d Cir 2020) ("the court was well within its discretion to consider whether plaintiffs' experts' conclusions were generally accepted by the scientific community"); *Lust v. Merrell Dow Pharms., Inc*., 89 F.3d 594, 598 (9th Cir. 1996) (when an expert "claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist," the court "should be wary").

These holdings are important to companies defending product liability and mass tort lawsuits because they give teeth to the *Daubert* adage that "law lags science." As the court noted here, "the courtroom is not the appropriate forum for new scientific methodologies and theories to be tested; laboratories and published journals are the appropriate forum." *In re Zantac*, 2022 WL 17480906, at *3. The *Zantac* MDL decision provides a powerful tool for companies to challenge an expert's reliability when the expert's conclusions and theories are not generally accepted in the field.

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