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Fla. Court Axes Zantac MDL Claims, Citing Lack Of Experts

By **Hailey Konnath**

Law360 (December 6, 2022, 11:22 PM EST) -- A Florida federal judge on Tuesday handed a major win to drugmakers battling multidistrict litigation over the heartburn medication Zantac, dismissing all claims against Pfizer, GlaxoSmithKline, Boehringer Ingelheim and Sanofi and finding that "no scientist outside this litigation" has concluded that the drug's active ingredient causes cancer.

In a 341-page ruling, U.S. District Judge Robin L. Rosenberg granted summary judgment in favor of the companies and tossed plaintiffs' expert evidence in the sprawling litigation, finding that the plaintiffs' scientists "systemically utilized unreliable methodologies" in determining that ranitidine causes cancer.

The decision dismisses a substantial percentage of pending claims over Zantac nationally, according to a statement from Pfizer. Plaintiffs have also lodged a number of related claims in state courts, and those aren't affected by Tuesday's decision. Since the MDL's creation in 2020, more than 2,450 plaintiffs have filed lawsuits in — or had them transferred to — the U.S. District Court for the Southern District of Florida, according to Judge Rosenberg's order. On top of that, 150,000 potential claimants have registered their claims in the registry.

The judge said that plaintiffs' experts lacked documentation on how experiments were conducted, substantiation for "analytical leaps," statistically significant data and "internally consistent, objective, science-based standards for the evenhanded evaluation of data." Ultimately, this leaves the plaintiffs without the evidence needed to establish general causation, she said.

"As a result, if the plaintiff does not have this evidence, then there is no genuine dispute of material fact, and the defendant is entitled to judgment as a matter of law," Judge Rosenberg said.

Pfizer said in Tuesday's statement that while it has "great sympathy for plaintiffs in these cases, Pfizer agrees with the MDL court's determination that the lawsuits are not supported by reliable scientific evidence that Zantac causes cancer."

The company said that in the remaining cases in state courts, plaintiffs either allege claims relating to the same cancers that have now been dismissed by the MDL court or claims relating to cancers that MDL leadership chose not to pursue.

"Pfizer has not sold a Zantac product in more than 15 years and did so only for a limited period of time," it added.

Co-lead counsel for the plaintiffs said in a joint statement provided to Law360 on Wednesday that they are "extremely surprised by this decision given that our scientific and medical experts clearly met the legal standard required under Daubert."

The attorneys — Tracy A. Finken, Robert C. Gilbert, Michael L. McGlamry and Adam Pulaski — said they fully expect the Eleventh Circuit to reverse the ruling. They said it is well-established by scientists, regulators and the pharmaceutical companies' own studies that ranitidine degrades into a carcinogen.

"Defendants, contrary to scientific evidence and the repeated acknowledgement of their own employees, seek to ignore that fact as part of their decades-long scheme to conceal the inherent dangers and risks associated with this cancer-causing drug," the lawyers said.

GSK said in a statement Wednesday that it welcomes the decision, which "reflects the state of that science and ensured that unreliable and litigation-driven science did not enter the federal courtroom."

It added that it will "continue to defend itself vigorously, including against all claims brought at the state level."

The other drugmakers and counsel for the MDL plaintiffs didn't immediately respond to a request for comment late Tuesday.

In September 2019, the U.S. Food and Drug Administration issued a warning that trace amounts of a carcinogen known as NDMA were found in Zantac and ranitidine, resulting in a recall of the over-the-counter medications in April 2020. The FDA has set an allowable daily limit of 96 nanograms of NDMA, but researchers have found more than 3 million nanograms in a dose of Zantac. NDMA is also found in red meat, tobacco and beer.

In her decision Tuesday, Judge Rosenberg noted that the FDA's voluntary recall of Zantac — with which all manufacturers complied — goes back to evidence presented by Valisure, a private company that theorized that ranitidine has the potential to degrade into NDMA. The judge flagged a number of issues with Valisure's tests involving ranitidine in various conditions.

She also said the FDA's own tests revealed NDMA levels far below Valisure's, but the agency ultimately initiated the voluntary recall because some of its tests showed ranitidine samples higher than the 96-nanogram daily limit.

Judge Rosenberg also pointed out that one could expect to consume that amount of NDMA from eating a meal of grilled or smoked meats, yet those foods remain legal to sell.

Because of this, the plaintiffs in the MDL opted not to rely upon Valisure's test results to prove their case, she said, adding that much of the science that predated the litigation no longer helps their case.

"As for ranitidine-based science that developed during the pendency of this MDL, that science also did not assist the plaintiffs," Judge Rosenberg said.

The plaintiffs instead opted to prove their case by retaining a chemist to rest ranitidine for NDMA and retaining epidemiologists who based their opinions, "not on the conclusions of any ranitidine-based study author, but instead (for the most part) upon the raw data found in studies that analyzed NDMA-rich food and NDMA-rich air," the judge said.

The methods used by the chemist were unreliable and resemble the testing conducted by Valisure, Judge Rosenberg said.

"As the court's ruling reflects, the only reliable testing of ranitidine puts the average amount of NDMA in ranitidine at roughly equivalent or slightly higher than the FDA's daily limit which, as discussed, equates to an infinitesimal, unprovable risk of cancer," she said.

And the studies on NDMA-rich foods and air were similarly unreliable and too far removed from the ingestion of ranitidine to be applied to the MDL, she said.

"Thus, at first blush it may appear surprising that, notwithstanding the FDA's voluntary recall of ranitidine, the court grants the defendants' Daubert motions in full and strikes the plaintiffs' experts," Judge Rosenberg said. "Once the court's ruling is viewed in conjunction with the totality of the evidence on ranitidine, however, the court's ruling is somewhat unremarkable."

Litigation over Zantac has ensnared pharmacies, Zantac generics makers, repackagers, retailers and distributors, among a long list of other defendants. Today, the MDL encompasses roughly 50,000 claims involving five cancers: bladder, esophageal, gastric, liver and pancreatic, according to the plaintiffs' attorneys.

Last year, Judge Rosenberg held that state labeling and design defect claims, dismissing state product liability claims against 32 Zantac generics makers, retailers and distributors.

And last month, the Eleventh Circuit affirmed dismissal of proposed multidistrict class claims brought by a plumbers union against generics makers. In a per curiam opinion, a two-judge panel held that although Judge Rosenberg erred in finding that the plumbers union lacked standing, the union failed to challenge on appeal the trial court's finding that the case must be tossed due to the union's shotgun pleadings, in which there were too many defendants and vague claims.

R. Brent Wisner, an attorney with Baum Hedlund Aristei & Goldman PC representing plaintiffs in state court, said in a statement Tuesday that, early on, he learned that the direction of the MDL "was not looking out for the best interests of the victims."

"I am glad my firm realized this and focused on filing in state court," he said.

The first trial is set to kick off in February in California state court, according to Wisner, who said he feels "very confident about the science in our favor."

"Our clients are suffering from all types of cancers and deserve justice," he said.

The plaintiffs are represented by Tracy A. Finken of Anapol Weiss, Robert C. Gilbert of Kopelowitz Ostrow Ferguson Weiselberg Gilbert, Michael L. McGlamry of Pope McGlamry PC and Adam Pulaski of Pulaski Kherkher PLLC.

Boehringer Ingelheim is represented by Andrew Thomas Bayman, Rob Friedman, Julia Zousmer and Eva Canaan of King & Spalding LLP.

Pfizer is represented by Joe Petrosinelli of Williams & Connolly LLP.

GlaxoSmithKline is represented by Mark Cheffo of Dechert LLP and attorneys with Shook Hardy & Bacon LLP.

Sanofi is represented by Anand Agneshwar, Daniel S. Pariser and Loren Brown of Arnold & Porter Kaye Scholer LLP.

The case is In Re: Zantac (Ranitidine) Products Liability Litigation, case number 9:20-md-02924, in the U.S. District Court for the Southern District of Florida.

--Additional reporting by Carolina Bolado, Dorothy Atkins, Emily Field and David Minsky. Editing by Jay Jackson Jr.
