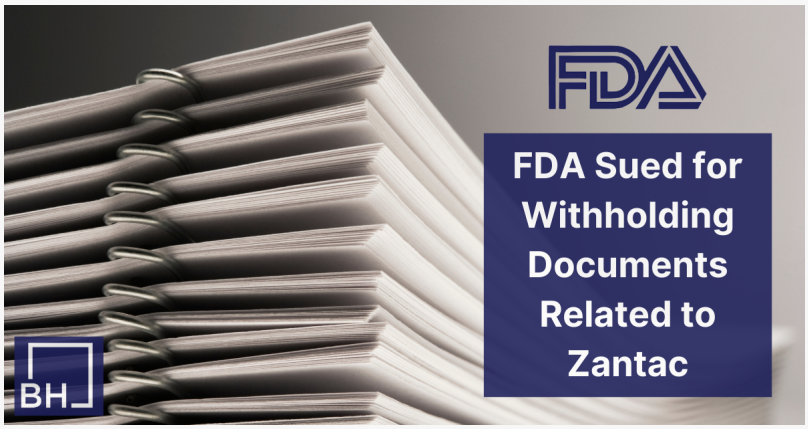
Baum Hedlund Sues FDA to Force Release of Agency Documents Related to ‘Flawed’ Zantac Study

Zantac lawyers sue the FDA to compel the agency to release documents regarding an FDA-sponsored Zantac study that "has a number of alarming and jarring flaws."



Zantac Plaintiff Lawyers Sue the FDA

SAN FRANCISCO, CA, UNITED STATES, August 26, 2022 /EINPresswire.com/ -- The Baum Hedlund Aristei & Goldman law firm filed a lawsuit against the U.S. Food and Drug Administration (FDA) last week under the Freedom of Information Act (FOIA) to compel the agency to release documents regarding an agency-sponsored study on Zantac that “has a number of alarming and jarring flaws,” attorneys say.

> The FDA has flouted the law and eschewed transparency and accountability by wrongfully withholding documents from my client.”
>
> *R. Brent Wisner, Baum Hedlund Senior Shareholder and Trial Lawyer*

The FDA study entitled, “Effect of Oral Ranitidine on Urinary Excretion of N-Nitrosodimethylamine (NDMA),” was published in the Journal of the American Medical Association on June 28, 2021. The study focused on the once highly popular but recalled antacid medication, Zantac (generic: ranitidine) and its possible link to cancer. A year prior to the FDA study’s publication, the agency recalled all ranitidine drugs because they were found to contain unsafe levels of the potent, probable human carcinogen, N-Nitrosodimethylamine (NDMA).

Zantac cancer lawyer R. Brent Wisner filed the complaint on August 19, 2022, on behalf of plaintiff James E. Goetz in U.S. District Court for the Northern District of California. Mr. Goetz’s case is scheduled to go to trial in Alameda County Superior Court on February 13, 2023. It is the first bellwether trial for many thousands of Zantac claims that are consolidated in a Judicial Council Coordinated Proceeding (JCCP), the California state court equivalent of Federal

Multidistrict Litigation (MDL).

The lawsuit against the FDA seeks agency emails and any other communications—internally amongst the authorship team as well as with any third parties—about the FDA study plus initial drafts of the work from June 2019 to June 2022.

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Attorneys say many thousands of people with Zantac claims "urgently need to understand the FDA study which has become an important part of the JCCP litigation." That is because the FDA study—funded with taxpayer dollars—is being used by the makers of Zantac, to argue that Zantac does not cause cancer. The defendants include GlaxoSmithKline (GSK), Pfizer, Sanofi, and Boehringer Ingelheim.

California Zantac cases are based on scientific questions of whether or not Zantac causes cancer, and whether Zantac caused a particular plaintiff's cancer. According to the complaint, the makers of Zantac are aggressively asserting that the FDA study stands for the proposition that ranitidine drugs are not carcinogenic—despite the FDA's NDMA-based recall—and therefore they have no liability in the Zantac litigation.

"The Drug Companies are leveraging the FDA's color of office and the agency's ostensible imprimatur of regulatory neutrality and expertise," per the complaint. "The Drug Companies will undoubtedly do so at trial as well; the FDA Study is central to their defense narrative."

"The FDA has a mandate to protect people from harmful drugs," says Zantac cancer attorney R. Brent Wisner. "We believe the FDA designed a flawed and potentially biased study. The agency's lack of transparency surrounding the release of these documents makes it clear that it is more interested in carrying water for drug companies than fulfilling its mandate. My client and the many thousands of other people stricken with cancer after taking Zantac have the right to know why the FDA injected itself into the scientific discussion of Zantac's carcinogenicity using taxpayer money on behalf of the drug companies they are supposed to regulate."

Wisner alleges in the complaint that the FDA Zantac study has several important flaws. First, the study makes bizarre comparisons, equating the amount of NDMA in Zantac to common foods like bacon. According to Wisner, while it is true that bacon tends to contain NDMA, the amount of NDMA in one pill of Zantac would be equal to the consumption of six pounds of bacon in a single day.

Additionally, attorneys say the FDA Zantac study used a protocol that was seemingly designed to obscure any formation of NDMA inside the body. For example, the FDA study required participants to ingest unusually high levels of vitamins C & E, which are known to stop NDMA

formation. Furthermore, the FDA study focused on urinary excretion of NDMA, even though it is well known that practically no NDMA is excreted in the urine.

These and other problems with the FDA Zantac study call into question its findings, per the complaint. “All of these issues must be explored, and that cannot be done without access to the underlying documents.”

Zantac cancer attorneys filed a FOIA request for documents related to the study’s “concept and design,” among other things. The FDA response to the request noted that the earliest the documents could be transmitted to the plaintiffs is June 2025. This would be years after the first Zantac bellwether trial is scheduled to take place in California state court. According to the complaint, the agency’s response to the documents request has been “deficient and in clear violation of its statutory deadlines for responding and producing documents or justifying their withholding.”

“The FDA has flouted the law and eschewed transparency and accountability by wrongfully withholding documents from my client,” says Wisner. “We need these documents to put this study in its proper, overall context. Did the study use a valid methodology? Was there any bias in the design? We believe there are answers in the documents we requested, which will be crucial to evaluate liability and causation in the Zantac litigation.”

The lawsuit asks for the FDA to “expeditiously provide copies of the requested records” within 30 days. The case is captioned James E. Goetz v. U.S. Food and Drug Administration (Case 3:22-cv-04768-TSH).

Read more about this case in our blog.

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