October 21, 2019, Los Angeles, California - - The national law firm of Baum, Hedlund, Aristei & Goldman has filed lawsuits against the manufacturers of Zantac, alleging the popular heartburn drug leads to the formation of a potent cancer-causing chemical, NDMA, at levels over 3,000 times greater than the Food and Drug Administration's (FDA) legally allowable daily limit. These two lawsuits are among the first of many to come as thousands of people across the United States have developed cancer because of their exposure to the chemicals created in the human body by Zantac.

Attorneys R. Brent Wisner, Michael L. Baum, Bijan Esfandiari, Nicole K.H. Maldonado, Adam M. Foster and Pedram Esfandiary filed the Zantac lawsuits on behalf of two plaintiffs:

- Shawn L. Francis of Pennsylvania – U.S. District Court for the Eastern District of Pennsylvania (Case No: 5:19-cv-04824-JDW)
- Walter H. Hansen of California – U.S. District Court for the Eastern District of California, Sacramento Division (Case No: 2:19-at-00984)

Earlier this year, Wisner and his colleagues obtained a historic $2.055 billion jury verdict on behalf of clients who alleged their cancer was caused by Monsanto's Roundup weed killer. The verdict was the ninth-largest personal injury verdict in U.S. history. According to Mr. Wisner, "based on preliminary scientific findings, these lawsuits involving Zantac will dwarf what we are seeing for Roundup."

The complaints, filed in federal court in Sacramento and Philadelphia, seek punitive damages against the defendants:

- Boehringer Ingelheim Pharmaceuticals, Inc., a subsidiary of Boehringer Ingelheim Corporation of Germany
- Sanofi US Services Inc., a Delaware corporation with its principal place of business located in Bridgewater, New Jersey, a wholly owned subsidiary of Sanofi S.A.
- Chattem Inc., a Tennessee-based wholly owned subsidiary of Sanofi S.A.
- Pfizer Inc., a Delaware corporation based in New York, NY
- GlaxoSmithKline LLC, a Delaware corporation (named in complaint wherein plaintiff(s) took any brand-name prescription Zantac prior to 2009), based in Philadelphia, PA

GlaxoSmithKline (GSK) was the original creator of Zantac and controlled the New Drug Application (NDA) for prescription Zantac between 1983 and 2009. GSK, along with Warner Lambert (acquired by Pfizer in 2000), launched over-the-counter (OTC) Zantac in 1995, and after a few years, Warner Lambert (now Pfizer) took control over the OTC brand until 2006. After that, Boehringer Ingelheim acquired the OTC rights to Zantac from October 2006 to January 2017. Sanofi and its subsidiaries have controlled OTC Zantac since January 2017 with Chattem as its U.S. distributor.

The allegations against the defendants include:

- Count I: Strict Liability – Design Defect
- Count II: Strict Liability – Failure to Warn
- Count III: Negligence
- Count IV: Breach of Express Warranties
- Count V: Breach of Implied Warranties

“In my experience representing cancer victims against a corporate giant like Monsanto, I can say with 100% certainty that if these drug companies had warned my clients, if they were given the choice to avoid a dangerous product that could cause them to develop cancer, they never would never have taken Zantac,” says R. Brent Wisner, attorney and vice president of Baum, Hedlund, Aristei & Goldman.

“Based on recent scientific findings, the levels of NDMA in Zantac are staggering. Considering how many people took Zantac in the U.S. since 1983, we are staring into the face of a public health crisis, and these defendants—in particular GSK and Pfizer—are to blame.”

NDMA in Zantac

Zantac (ranitidine) is used to treat various gastrointestinal conditions, including acid reflux, heartburn, and sour stomach. The drug was brought to market in the United States in 1983. Three years later, Zantac became the first drug to reach $1 billion in sales.

According to the allegations, however, Zantac's groundbreaking sales figures were only possible because of a deception perpetrated by the drug's manufacturers, most recently Sanofi and Boehringer.

The complaints allege that the makers of Zantac products never disclosed to consumers that Zantac has a critical defect: when ingested, Zantac produces high quantities of N-Nitrosodimethylamine ("NDMA"), a potent carcinogen.

NDMA was initially discovered in the process of manufacturing rocket fuel. For more than 40 years, studies have shown that NDMA is dangerous. Today, the chemical only has one purpose—to induce cancer in laboratory experiments.

The FDA, the U.S. Environmental Protection Agency (EPA) and the World Health Organization (WHO) all classify NDMA as a cancer-causing chemical. NDMA belongs to "a family of potent carcinogens," according to the EPA. The WHO maintains that "NDMA is clearly carcinogenic. There is overwhelming evidence that NDMA is mutagenic and clastogenic."

Animal Studies Overwhelmingly Link NDMA to Cancer

According to the complaints, various animal studies on NDMA have found the following:

- In mouse studies examining the carcinogenicity of NDMA through oral administration, animals exposed to NDMA developed cancer in the kidney, bladder, liver, and lung.
- In comparable rat studies, similar cancers were observed in the liver, kidney, pancreas, and lung.
- In comparable hamster studies, similar cancers were observed in the liver, pancreas, and stomach.
- In comparable Guinea-pig studies, similar cancers were observed in the liver and lung.
- In comparable rabbit studies, similar cancers were observed in the liver and lung.

- In other long-term animal studies in mice and rats utilizing different routes of exposures — inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) — cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

Human Epidemiological Studies on NDMA and Cancer

In addition to the overwhelming animal data linking NDMA to cancer, the complaints note that there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers:

- In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng/day.
- In another 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng/day.
- In yet another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.
- In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "N-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.
- In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate and brain cancer.
- In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.
- In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.

Lawsuit Alleges Zantac Drug Makers Knew About NDMA Defect but Failed to Warn or Test

This summer, an online pharmacy company conducting FDA-approved testing of Zantac found more than 3,000,000 ng (nanograms) of NDMA in a Zantac 150mg tablet, a dosage that many people take every day. The FDA's daily allowable limit for NDMA is 96 ng, though according to the U.S. Agency for Toxic Substances and Disease Registry (ATSRD), this limit may be too high.

Valisure, the pharmacy company responsible for the testing, submitted a Citizen's Petition to the FDA on Sept. 13, 2019, noting that it found "extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products." The petition also included a request to recall and suspend the sale of Zantac.

According to the complaints, a person who takes a daily maintenance Zantac dosage of 150 mg is exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year. FDA's permissible intake limit of NDMA translates to just 0.000034 grams per year.

The drug is not solely indicated for adult use—teenagers, children, and pregnant mothers are also prescribed Zantac to treat a variety of gastrointestinal issues.

The lawsuit maintains that the makers of Zantac (ranitidine), knew or had reason to know that Zantac exposes consumers to unsafe levels of the cancer-causing chemical NDMA:

> "Under biologically relevant conditions, when nitrites are present, staggeringly high levels of NDMA are found in one dose of 150 Zantac, ranging between 245 and 3,100 times above the FDA-allowable limit. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 nM level (over 7,000 for the 50 nM level)…During the time that Defendants manufactured and sold Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—nor did Defendants report these risks to the FDA."

According to the complaints, the makers of Zantac deliberately refused to test Zantac products because they knew that the chemical posed serious health risks to humans. Nothing prevented the drug makers from being honest in their promotional activities for Zantac and, according to the lawsuits, had a duty to disclose the truth about the risks associated with Zantac in their promotional efforts, outside of the context of labeling.

The complaints further allege that if the drug makers had disclosed and disseminated the risks associated with their Zantac products, the plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication.

Background on the Plaintiffs

Shawn Francis, 46, took Zantac at least four times a week for more than a decade. In 2015, an MRI revealed that he had kidney cancer. Following his diagnosis, Mr. Francis was forced to undergo surgery to remove 55% of his kidney.

Walter Hansen, 49, took Zantac 150 mg daily as an antacid over the span of about nine years. In January of 2017, he was diagnosed with colorectal cancer, which soon spread to other parts of his body. He is currently undergoing weekly chemotherapy treatments.

About Baum, Hedlund, Aristei & Goldman

The law firm of Baum, Hedlund, Aristei & Goldman is representing individuals across the nation who have developed cancer after taking Zantac. The firm's award-winning personal injury attorneys have extensive experience holding big corporations accountable for concealing the dangers of consumer products.

For two years in a row, The National Law Journal and ALM Media awarded the firm as first place winners for 2018 and 2019 Elite Trial Lawyers for a groundbreaking pharmaceutical drug verdict and a landmark Roundup cancer verdict. The National Trial Lawyers Top 100 also awarded Baum, Hedlund, Aristei & Goldman's Roundup cancer trial team and co-counsel with "2019 Trial Team of the Year." In addition, The National Law Journal and Trial Lawyer Magazine named Baum Hedlund trial attorney R. Brent Wisner one of "America's Most Influential Trial Lawyers," and Law360 named him a "Titan of the Plaintiffs Bar."

Since 1973, Baum, Hedlund, Aristei & Goldman has obtained more than **$4 billion in verdicts and settlements** on behalf of clients across all areas of practice. This year, the firm co-tried a cancer case against Monsanto on behalf of a California couple who alleged exposure to Roundup weed killer caused them to develop non-Hodgkin lymphoma. The jury trial culminated in a $2.055 billion verdict for our clients, the ninth-largest personal injury jury verdict in U.S. history.