

Zantac and the NDMA Problem:

Isolated Event or Tip of the Iceberg?

In this fast-paced, fast-food world we inhabit, you don't have to go far to find someone who takes a prescription drug to treat hypertension or who regularly pops an over-the-counter product to alleviate heartburn. Among the most commonly prescribed drugs in the U.S., these medications account for millions of prescriptions and billions of dollars in sales annually.

Naturally, consumers and healthcare providers alike were alarmed over recent drug recalls triggered by the presence of the cancer-causing chemical N-Nitrosodimethylamine (NDMA). NDMA-associated recalls involving the blood pressure medication valsartan and the popular antacid drug Zantac®, have led to the filing of hundreds of lawsuits by those who claim to have developed cancer, or have been otherwise harmed from the use of these products. Given the severity of the alleged injuries, the question on the minds of many is whether these recalls are isolated incidents or a harbinger of more to come.

NDMA in Drug Products

NDMA is a semi-volatile organic chemical that forms in both industrial and natural processes. It is a member of a family of potent carcinogens called N-nitrosamines. Though NDMA is no longer used commercially in the U.S., it was formerly used in various applications including the production of liquid rocket fuel. Both the Environmental Protection Agency (EPA) and the International Agency for Research on Cancer (IARC) have classified NDMA as a probable human carcinogen.

The U.S. Food and Drug Administration (FDA) maintains that everyone is exposed



to some level of NDMA, a common contaminant in water and foods like cured and grilled meats. However, it acknowledges that nitrosamine impurities may increase the risk of cancer if exposure is above acceptable levels and over long periods of time. A drug found to contain NDMA above the FDA's acceptable daily intake limits may be subject to recall. According to the agency, the source of NDMA in a drug product can be related to the manufacturing process or its chemical structure or even the conditions in which it is stored or packaged.

Excessive Levels of NDMA in Zantac

Ranitidine, better known as Zantac, is an H2 (histamine-2) blocker that works by lowering the amount of acid created by the stomach. Available either over-the-counter (OTC) or by prescription, it has been used by millions of people to treat gastrointestinal issues including gastric ulcers, gastroesophageal reflux disease (GERD), and heartburn.

In a 2019 Citizen Petition, the online pharmacy Valisure called on the FDA to protect the public and request the immediate recall of all ranitidine

products from the market. Results from Valisure's own testing detected "extremely high levels" of NDMA in every lot of ranitidine it tested, across multiple manufacturers and dosage forms – far in excess of the FDA's permissible daily intake limit of 96 nanograms. It attributed the formation of NDMA to an "inherent instability of the ranitidine molecule." The drug itself may metabolize to form NDMA.

Zantac Off the Market

A September 2019 FDA warning about the potential risks of NDMA in Zantac products followed, setting off a cascade of voluntary recalls, culminating in the FDA's April 2020 request for the immediate market removal of all prescription and OTC ranitidine products. FDA had determined that NDMA levels in some ranitidine products "increase over time when stored at higher than room temperature," which may result in consumer exposure to unacceptable levels.

The agency was already investigating the presence of NDMA in valsartan, an Angiotensin II Receptor Blockers (ARBs) used to treat high blood pressure and heart failure. July 2018 marked the first of a number of voluntary recalls by generic drug makers for several ARB products due to NDMA contamination thought to be the result of a manufacturing issue.

Litigation Over NDMA Cancer Link

As Zantac recalls mounted, lawsuits accused drug makers of failing to warn millions of unsuspecting consumers

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Co-counsel SPOTlight

Heninger Garrison Davis – Birmingham, AL

The powerhouse that is the co-counsel firm of Heninger Garrison Davis, LLC was formed in early 2006, when two separate and distinct law firms joined forces, with each group bringing unique experience to the table. Lew Garrison's firm had a national practice focused primarily on pharmaceutical and medical device mass tort litigation as well as consumer class actions, and Steve Heninger and Tim Davis had a robust personal injury practice that covered the state of Alabama. Together, they brought a talented team skilled in high stakes litigation that could go toe to toe with any corporate or pharmaceutical defendant.

In its short history, HGD has built a reputation as one of the top litigation firms in the country having handled a multitude of cases successfully and having won over \$3 Billion in recoveries for their clients.

The firm's attorneys are leaders in their respective areas of expertise. Besides winning awards and earning accolades, they are routinely appointed to serve in leadership positions in MDL and state court litigations, including, most recently, the 3M Combat Arms Earplugs MDL and JUUL Product Liability litigation (California JCCP). Additionally, HGD has served



HGD attorneys (from l to r) Chris Hood, Taylor Bartlett, Honza Prchal, and Bill Bross

in leadership roles in other MDL/State Court actions such as Xarelto, Syngenta Corn Litigation, Actos, TVM, Vioxx, Zyprexa, Kugel Hernia mesh, and many others. Many HGD attorneys also serve as directors and officers in local, state, and national bar organizations.

Sokolove Law first partnered with HGD in 2009 and since then the firms have worked together on a number of campaigns, including Yaz, Actos, TVM, Xarelto, 3M Earplugs, Medical Malpractice and Nursing Home cases.

"Our success is directly related to the amazing firms we work with, and HGD is no exception," said Sokolove CEO Mike Skoler. "Besides being great attorneys, they are great people who represent our mutual clients with their best interest at heart.

We look forward to many more years of continued success with HGD."

"We have had a long-standing relationship with the folks at Sokolove Law. They are a great team to work with. They are responsive to what we need and always follow-up in a timely manner with questions we might have. They maintain an active presence in emerging litigations and reach out to us as new cases arise. Likewise, they are receptive to working on cases we are interested in developing. We look forward to many more years working together with this group." – Bill Bross

Besides their home office in Birmingham, HGD has offices in New York City and Atlanta. Today the firm has 25 attorneys collectively licensed to practice in more than a dozen states.

Campaign Highlight

Firefighting Foam

Although once thought of as a saving grace to put out flames, the occupational exposure to firefighting foam can unfortunately be dangerous. That is why the marketing team at Sokolove Law is trying its hardest to extinguish the pain that comes with a cancer diagnosis by fighting for those that have nowhere else to turn.

Known officially as aqueous film-forming foam (AFFF), chemical-based

firefighting foam has been used since the 1950s due to its effectiveness in extinguishing jet fuel and petroleum fires. However, before regulatory efforts were made, firefighting foam contained chemicals known as PFAS, which are linked to an increased risk of various types of cancer – pancreatic, kidney, testicular, bladder, breast, colon, liver and prostate cancer, as well as leukemia and lymphoma.

In 2019, we launched a fully integrated marketing campaign targeting those with occupational exposure to firefighting foam who later developed cancer. We've

utilized a wide variety of mediums from TV, Radio, and Paid Search, as well as numerous email and direct mail marketing campaigns, and social media efforts. This resulted in the generation of almost 8,000 qualified leads and over 2,000 signed cases. With over 1,000,000 firefighters in the U.S., the potential audience pool is large, and though the campaign has been continuously running for nearly 2 years, we've just started to scratch the surface in reaching potential claimants. Now is an excellent time to join the Firefighting Foam campaign. Contact us today to learn more.



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that use of ranitidine could expose them to unsafe levels of NDMA. Unlike valsartan, plaintiffs claim, the high levels of NDMA produced by ranitidine are not the result of a manufacturing defect, but rather a problem inherent to the molecular structure of the drug itself. This, coupled with the excessive levels of NDMA detected in the product, created a particularly high safety risk for users. Hundreds of plaintiffs now

link their cancer diagnoses to ranitidine use. Separate federal MDLs for Zantac and Valsartan NDMA litigation have been created to manage these growing dockets.

What Comes Next

Recently, the FDA found elevated levels of NDMA in some extended release metformin products, prompting many to wonder if we've only seen the tip of the NDMA problem. As Thornton Law

Firm's Marnie McGoldrick notes, "due to lax FDA safety oversight and the fact that the majority of all medications in the USA are made overseas, these impurities likely exist in many other medications consumers take on a regular basis daily." Whether they exist in amounts large enough to cause injury, or to prompt litigation remains to be seen. But it is certainly something worth watching.

Co-counsel Opportunity:

FLSA/Wage & Hour National Campaign

The Opportunity

Although many businesses shut down during the pandemic of 2020, court filings related to employment issues remained stable. FLSA collective actions were among the highest number of employment-related filings. In addition, the pandemic gave rise to other COVID-19-related litigation.

Workplace class actions are not only hot, but are likely to stay hot for the next several years. Stay at the forefront of this emerging area and drive growth to your employment practice by leveraging the power of our national television and web marketing campaign. As a co-counsel firm, you'll gain access to our proven experience and significant buying power, keeping you ahead of the competition. Enjoy all claims generated for your geographic area(s) and significant return on investment.

Targeted Claims Include both Collective Actions and Individual Claims for the following Violations:

- Unpaid or Improperly Calculated Overtime Pay
- Minimum Wage Violations
- Misclassification of Employees as "Exempt" Workers or Independent Contractors
- Tip pooling with Management
- On Call Time
- Expense Reimbursement and Mileage Claims
- Independent Contractor Status
- Comp. Time instead of Overtime Pay
- Unpaid Compensable time – putting on/taking off uniform; driving to work; lunch breaks, etc.

Call us today at 1-800-305-4009 or email us to learn more:

Christina Kritharas – ckritharas@sokolovelaw.com

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Take Advantage of Us

... Or more specifically, our vast network of co-counsel firms. If you have a case that you need to refer out and don't know where to turn, contact Sokolove Law for your one-stop shopping. We work with over 400 firms nationwide, and chances are, we can put you in

touch with the right firm to associate with on your case. Whether it's a pharmaceutical, defective device, or mesothelioma case, we have relationships with the top litigation firms in the country to ensure that your client gets the best representation.

Call us at 1-800-305-4009



SETTLEMENT	CASE TYPE	CO-COUNSEL FIRM
\$95,300,000	Mesothelioma and Other Asbestos-Related Diseases	Simmons Hanly Conroy, Alton, IL and other co-counsel firms
\$5,500,000	Cerebral Palsy	Goldberg & Schulkin Law Offices, Chicago, IL
\$5,000,000	Cerebral Palsy	Williams & Brown, LLP, Waco, TX
\$950,000	General Liability	Kralovec, Jambois & Schwartz, Chicago, IL
\$850,000	Nursing Home	Doolan Platt & Setareh, LLP, Irvington, NY
\$275,000	Nursing Home	Kralovec, Jambois & Schwartz, Chicago, IL
\$275,000	Auto Accident	Iannella & Mummolo, Boston, MA
\$250,000	Nursing Home	The Schupak Law Firm, Rockville, MD
\$225,000	Nursing Home	Shuttlesworth Law Firm, PC, Birmingham, AL

The Lights that Shone through the Storm: Our year of 2020

While many of us want to put 2020 out of sight and mind, there were some bright moments here at Sokolove Law that are worth highlighting. At the end of the day, pandemic or not, we're here to help those in need of legal help, and we were successful in doing just that.

- Our call center agents screened more than 100,000 leads in 2020.
- We logged more than 2 million call minutes, and utilized chat, text, and web forms as additional means of engaging with and qualifying potential claims.
- We connected more than 25,000 potential clients with a law firm last year.

At Sokolove Law, we continuously strive to be the best at what we do, therefore, we often set lofty goals for our Operations team. One of these goals was to improve our conversion rates for those case types where we handle client sign-up, which we accomplished by working with our Marketing team to refresh packet materials and our messaging. Our Call Center enhanced their packet follow-up methods after testing additional text and email communication strategies. We also increased our utilization of electronic sign-up by approximately 30%, allowing more people to receive the much-needed help that they need. As a result of these changes, we saw a 20% increase in our sign rate, and our e-signature return rate doubled in 2020. We've also seen improvements in both our time-to-sign and our single call sign-up rates.

But we never rest on our laurels. We continue to utilize technology to improve our communication with both potential clients and our co-counsel firms. As a result of

pandemic-related office closures, we made FTP (File Transfer Protocol) a standard method for providing signed case documents to co-counsel. This method provides co-counsel access to signed case documents 2-3 days sooner than mailing.

We are proud of the successes that we achieved in the dark year that was 2020, but look forward to continuing our improvement and better providing for those who do not have a voice. Here's to 2021!

2020 Sokolove Leads Funnel

