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SPRING 2020

What is NDMA?

The carcinogen that has contaminated the U.S. drug supply.

IN THIS ISSUE

GOLDENBERGLAW
PRODUCTS LIABILITY AND PERSONAL INJURY ATTORNEYS

Why we care. *We want to help people. There is nothing more important to us than obtaining justice for our clients that have been harmed. We firmly believe that the best way to promote safer practices is to hold negligent parties accountable when they cause harm to others.*

LITIGATIONS DISCUSSED IN THIS ISSUE

TALCUM POWDER

→ Talc-based baby powder with history of asbestos contamination, linked to ovarian cancer and mesothelioma.

VALSARTAN

→ Blood pressure medication recalled due to contamination with NDMA, a probable human carcinogen.

ROUNDUP

Weed killer with active ingredient, glyphosate, linked to non-Hodgkin's lymphoma.

METFORMIN

→ Type-2 diabetes drug found to have high levels of NDMA contamination by Valisure, some lots recalled in Canada and Singapore.

ZANTAC

→ Heartburn medication with molecular defect that causes NDMA contamination, linked to cancers of the blood and digestive tract.

BELVIQ

→ Prescription weight-loss drug recently recalled after study found high cancer rates among users.

STUART GOLDENBERG
SENIOR PARTNER

"We know the power of good science and positive solutions to solve serious health issues."

We will persevere.

WHAT HISTORY HAS TAUGHT US IN MOMENTS OF PERIL.

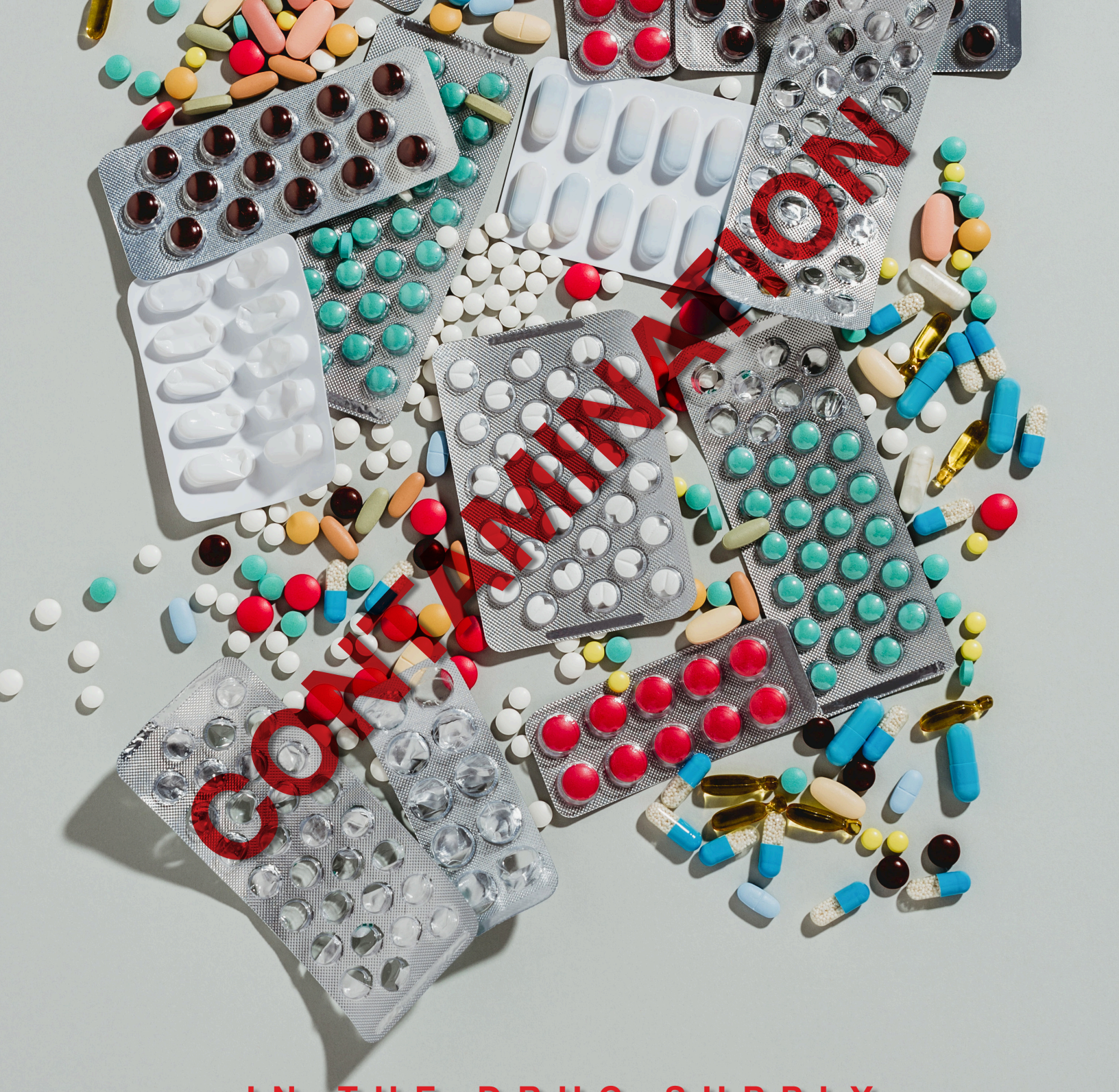
"Just when the caterpillar thought his world was ending he turned into a butterfly"

PROVERB

Last night, against my better judgment, I watched the movie, *Contagion*. This movie, made in 2011 and starring Matt Damon, mirrors an outbreak of a virus similar to the COVID-19 virus that we are struggling with today. And now a spoiler alert: After terrible events, the movie ends with the discovery of a vaccine that ends the pandemic.

There are two very important lessons here. The first is that we should not be surprised about the occurrence of a virus like COVID-19. While certainly uncommon, this was predictable. In fact, the Spanish Flu (H1N1 virus) in 1918 killed 1% of all people on the planet (50 million people including 675,000 Americans). The second lesson is that people persevered, and it spurred a solution: the scientific study of pandemics. We now must hope the continued advancement of that study will result in a plan, medication, or vaccine to protect us from COVID-19.

At our firm, we must regularly evaluate the science behind products and the predictability of injury. While we often see the most dangerous examples of these products, we know the power of good science and positive solutions to solve serious health issues. I have faith and gratitude for the wonderful people working tirelessly to try to treat and cure COVID-19. History tells us we will persevere through these difficult times. Hopefully, just as in 1918 and in *Contagion*, this will not only spur a cure but will also create new science that will prevent future outbreaks. This will be our "butterfly."



IN THE DRUG SUPPLY

Over 4,800 Americans are diagnosed with cancer every day. While great strides have been made in the detection and treatment of cancer, the causes of many types of cancer remain relatively unknown. Some cancers can be caused by human behavior like smoking, and others can be passed down through genetics. However, a number of cancers have recently been linked to exposure to harmful chemicals that are increasingly found in consumer products and medications.

Over the past two years, the Food and Drug Administration (FDA) has announced dozens of recalls of the heartburn medication Zantac and the blood pressure medication Valsartan from the U.S. Market. These recalls represent two of the largest Class I recalls in FDA history. The reason for the recalls was similar: contamination with the probable human carcinogen NDMA [N-Nitrosodimethylamine]. NDMA is classified as a probable human carcinogen and has been linked to a variety of digestive cancers, including stomach, colorectal, and liver, among others. NDMA was previously produced to make rocket fuel, but this production ceased after unusually high levels were found in the air, water, and soil samples collected near a rocket fuel manufacturing plant. Notably, scientists running cancer studies on animals typically use NDMA to induce cancer in the animals involved in those studies.

Unfortunately, NDMA can unintentionally be formed during the manufacturing process, from reactions involving other chemicals, or even from heat while medications are being stored. These sorts of unintended NDMA formations are the likely reason it has been identified in such commonly used products like Zantac and Valsartan. While NDMA can be found in very low, but acceptable quantities in everyday products, the levels found in Zantac and Valsartan substantially exceed known safe levels.

Since July of 2018, various lots of Valsartan have been recalled due to the finding of unacceptable levels of NDMA in some lots of the drug. In September 2019, researchers identified higher than acceptable amounts of NDMA in Zantac. Several manufacturers of the drug pulled it from the market shortly thereafter. On April 1, 2020, the FDA recalled all versions of Zantac from the U.S. Market citing concerns that NDMA can reach unacceptable levels when the pills are exposed to excessive heat during storage.

Research into how such high levels of NDMA ended up in these products is ongoing. There is ample evidence that the manufacturing process to produce Valsartan created higher than acceptable levels of NDMA in the drug. Researchers believe that NDMA in Zantac may form as a result of the way the medication is broken down in the stomach or as a result of the pills being exposed to heat during storage.

Recently, researchers also discovered unacceptably high levels of NDMA in metformin, a diabetes drug and one of the most widely prescribed medications in the country. This finding follows several recalls of metformin in other countries, including, Singapore and Canada. While the FDA has found trace amounts of NDMA in metformin products, those amounts have not exceeded FDA regulatory limits. The FDA's findings conflict with testing performed by Valisure, a small pharmacy that tests all of the drugs it sells. Valisure identified levels of NDMA in metformin that well-exceed FDA regulatory limits.

The research linking NDMA to cancer is well-established, and this link has been known for some time. Unfortunately, what has only been recently discovered is that this dangerous and toxic compound lurks at unsafe levels in the daily products millions of U.S. consumers digest. ■

CONSUMER PRODUCT CONTAMINATION

NDMA is not the only carcinogen found in popular consumer goods. Despite scientific evidence of contamination and safer alternative products widely available, some of these products continue to be sold today.

ROUNDUP

The International Agency for Research on Cancer declared in 2015 that glyphosate, the active ingredient in the weed killer Roundup, is “probably carcinogenic to humans.” Further research has found that as little as three to five exposures to Roundup over a two year period can increase cancer risks by over 40 percent.

TALC

In October 2019, J&J issued its first ever recall of talcum powder after FDA testing found asbestos in the product. The recall came after a Reuters investigation revealed that J&J’s raw talc and finished powders sometimes tested positive for small amounts of asbestos. Talc is often mined from deposits that contain asbestos, a known human carcinogen.

BELVIQ

In March 2020, the FDA announced the recall of the weight-loss drug Belviq after a study showed an increase in certain cancers over long term use. The agency has yet to release an explanation for why Belviq users experienced higher cancer rates, but the drastic step to recall the drug off the market suggests the risks to taking the drug outweigh the benefits.

INDUSTRY NEWS & STATS

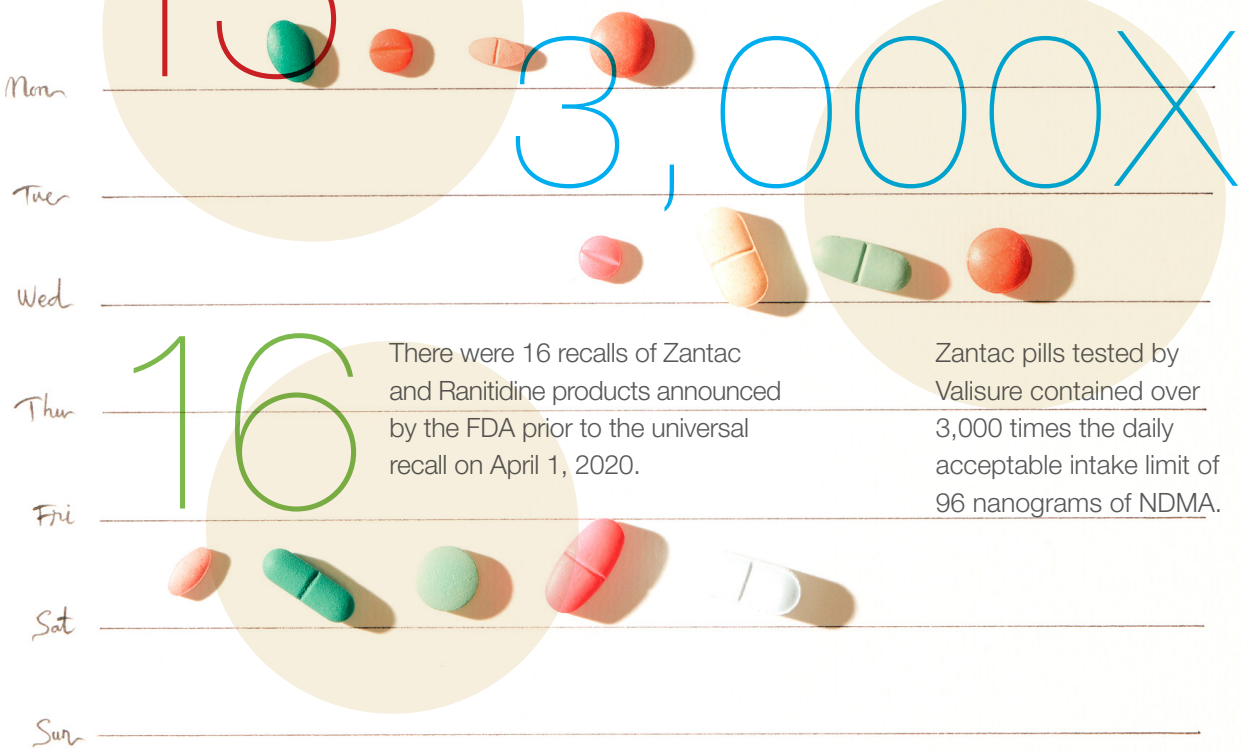
BY THE NUMBERS

$180 MILLION

Over $180 Million has been awarded by juries and courts relating to Roundup cancer trials. In 2018, a groundskeeper diagnosed with non-Hodgkin's Lymphoma after years of Roundup use was awarded $78 million. In 2019, a plaintiff who used Roundup regularly on his property and was later diagnosed with non-Hodgkin's Lymphoma was awarded $27 million. That same year, a couple was awarded $86.7 million. They both used Roundup at home and were diagnosed with non-Hodgkin's Lymphoma. A substantial portion of these awards are categorized as punitive damages, established to punish the makers of Roundup for their bad behavior.

15 MILLION

15 million Americans are prescribed ranitidine products every year. Millions more consume over-the-counter Zantac.



3,000X

Zantac pills tested by Valisure contained over 3,000 times the daily acceptable intake limit of 96 nanograms of NDMA.

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There were 16 recalls of Zantac and Ranitidine products announced by the FDA prior to the universal recall on April 1, 2020.

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Are your drugs safe?

SPRING 2020

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AREAS OF EXPERTISE

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Medical Malpractice
Wrongful Death
Construction Accidents
Structural Collapses
Gas Explosions
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Defective Medical Devices
Toxic Tort
Catastrophic Injury
Insurance Disputes