



# G-LAW

PROMOTING SAFETY THROUGH ACCOUNTABILITY

Fall 2018

## Contaminated Products *More Common Than You Think*



### Contamination

Stuart discusses  
recent product  
contamination lawsuits

### Valsartan Recall

Probable human  
carcinogen  
contamination

### Featured Case

Successful recovery  
for food  
contamination case

800 LaSalle Avenue  
Suite 2150  
Minneapolis, MN 55402

**GOLDENBERGLAW**  
PRODUCTS LIABILITY & PERSONAL INJURY ATTORNEYS



Phone: 612-333-4662  
Toll Free: 855-333-4662  
[www.goldenberglaw.com](http://www.goldenberglaw.com)

# *A Message From* **Stuart Goldenberg**

## *Contamination of Products - Are You Safe?*

### **Drug Contamination**

In a relatively small town in China lies a massive factory owned by Zhejiang Huahai Pharmaceutical. In this factory, they make a generic prescription drug called Valsartan. Last year alone, this Chinese company earned \$50 million dollars selling Valsartan to high blood pressure patients in the United States. While that seems fine, in July 2018, the FDA announced the recall of most of this product. Why? Because the drug had been contaminated with a cancer-causing substance called NDMA. The FDA claimed this contamination may have started as early as 2012! Now there could be untold numbers of people that have developed (or will develop) cancer (see pp. 3-4).

### **Food Contamination**

Picture a filet of salmon peeking out from cellophane wrapping in the grocery store. It looks great, but is it safe to eat? In December of 2017, Springfield Smoked Salmon was recalled when *Listeria monocytogenes* was found in the fish. This bacteria can be deadly. In fact, there were over 20 million pounds of food recalled by the FDA in the U.S. in 2017. The CDC estimates that 48 million people get sick, 128,000 are hospitalized, and 3,000 people die each year from foodborne illnesses. We recently handled a contaminated salmon case (see p. 5).

### **Cosmetic and Health Product Contamination**

Twenty-two women who used Johnson & Johnson Baby Powder almost daily over the past 30 years thought this product was pure and clean. The result was they all contracted ovarian cancer. In fact, they had never met each other until their cases were tried together in July, 2018 in St. Louis. A jury awarded them \$4.14 billion after learning the baby powder had been contaminated with asbestos. More than 9,000 cases are pending. We continue to pursue hundreds of these cases (see p. 2).

### **Water Contamination**

Last month, 50,000 students in the Detroit school system could no longer go to a drinking fountain or get a cup of water at school. The reason? After elevated levels of lead and copper were found in the water, Detroit authorities shut off all drinking water to the schools. An antiquated plumbing system was blamed but it has deteriorated over many years. Medical research has linked lead with stunting of children's neural development. Copper has been linked to liver or kidney damage.

We all have an expectation that our medicines, food, health products, air, and water will be reasonably safe from contamination. Unfortunately, because of a lack of accountability, there has been a recent increase in contaminants. When products become contaminated and the public is not told, then consumers are at serious risk. A product manufacturer is responsible for testing its products for contaminants, withdrawing an unsafe product, and warning of its dangers. There is never a reason to expose people to unnecessary risks. We will continue to hold those entities accountable for their actions.

# Dangerous Drugs and Devices

GoldenbergLaw is currently investigating claims involving these products and has over 30 years of experience handling dangerous drug and device cases. Contact us at (612) 436-5026 or (855) 333-4662.

## Abilify



An antipsychotic medication approved for the treatment of schizophrenia, bipolar disorder, and depression - linked to compulsive gambling behaviors.

## Bair Hugger



A warming blanket used during surgeries that can spread contaminated air over open wounds - linked to deep joint infections and the need for revision surgery.

## DePuy Attune Knee



A knee replacement device - linked to loosening, instability, severe pain, and the need for revision surgery.

## Hernia Mesh



A mesh implanted to strengthen muscles near a hernia - linked to migration, hernia recurrence, required removal surgery, bowel obstructions, and punctured organs.

## Inferior Vena Cava Filter



Blood clot filter placed in the large vein leading to the heart - shown to migrate or fracture after a period of time and can puncture parts of the vein or other internal organs.

## Medtronic Paradigm Pump



Insulin pump - linked to defects resulting in over or under-delivery of insulin, serious illness, and/or death.

## Metal-on-Metal Hips



Models include DePuy ASR, DePuy Pinnacle, Zimmer Durom Cup, and others - linked to implant loosening, pain, high metal levels in blood, and the need for revision surgery.

## Stryker Rejuvenate/ABG II Hip Stem



Modular hip stems - linked to corrosion at stem/neck juncture leading to elevated metal levels in bloodstream, necrosis, and revision surgery.

## Talcum Powder/Baby Powder



Talc-based powder used for many purposes - linked to ovarian cancer and mesothelioma.

## Tasigna



An oral chemotherapy treatment for Philadelphia chromosome-positive myeloid leukemia - linked to atherosclerosis, amputation, stroke, and death.

## Valsartan



A high blood pressure medication contaminated with N-Nitrosodimethylamine, a probable human carcinogen - linked to liver, kidney, pancreatic, colorectal, and stomach cancer.

## Zimmer Persona Knee



A knee device system that has been recalled by the manufacturer - has been known to loosen and cause bone damage when uncemented.

# Did You or a Loved One Receive

On July 13, 2018, the FDA recalled certain lots of the high blood pressure and congestive heart failure medication Valsartan. The recall was prompted after finding the probable human carcinogen N-nitrosodimethylamine (NDMA) had contaminated the drug in several supplier's facilities.

## What Is Valsartan?

Valsartan is an angiotensin receptor blocker (ARB), which means it helps the blood vessels to relax, lowering blood pressure and helping the heart to pump blood.<sup>1</sup> It was approved by the FDA in 1996. The FDA estimates that between 3 million and 3.7 million patients have been prescribed Valsartan over the last three years.

## Why Was Valsartan Recalled?

In July 2018, NDMA was found in the supplier's facility. At first, Zhejiang Huahai Pharmaceuticals in China was the only supplier with the contamination. After a few weeks of investigation, two other suppliers were added: Zhejiang Tianyu in China and Hetero Labs Limited in India.

The updated list of Valsartan products under the recall can be found at <https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf>.

## What Is NDMA?

According to the Environmental Protection Agency, NDMA is classified as a B2 carcinogen.<sup>2</sup> This classification means it is a probable human carcinogen. B2 carcinogens do not have enough data from human testing, but there is sufficient animal data to conclude that it's a potential carcinogen.

NDMA was used to make rocket fuel, but now it is used in laboratory research to induce tumors in animals. The tumors are found primarily in the liver, kidney, respiratory tract, and blood vessels.

## What Are the Injuries?

Short-term exposure to NDMA can cause liver damage. Long-term exposure, however, can cause tumors to develop in the liver, kidneys, stomach, intestines, lungs, and pancreas. Overexposure to NDMA can cause an enlarged liver and/or reduced function of the kidney, liver, and lungs. At high doses, NDMA is a "potent hepatotoxin that can cause fibrosis of the liver" in rats.<sup>3</sup> This means it is classified as a toxic substance that causes damage to the liver.

<sup>1</sup> *Angiotensin II receptor blockers*. Retrieved from Mayo Clinic. 2016.

<sup>2</sup> *Technical Fact Sheet - N-Nitroso-dimethylamine (NDMA)*. Retrieved from United States Environmental Protection Agency. 2017.

<sup>3</sup> *Dimethylnitrosamine-induced liver injury in rats: the early deposition of collagen*. Retrieved from Toxicology, ISSN: 0300-483X, Vol: 156, Issue: 2, Page: 129-138h. 2001.

# a Valsartan Recall Letter?

## Who Is the Defendant?

Novartis is the manufacturer of Valsartan. Novartis is a Swiss pharmaceutical company with products available in 155 countries. Last year, the company made \$49.1 billion in sales.

Novartis also manufactures a leukemia drug called Tasigna, which can cause serious circulatory conditions in patients that can lead to stroke, amputation, and death (see p. 2). GoldenbergLaw is investigating claims against Tasigna and Valsartan. Novartis needs to be held accountable for its negligence.



## GoldenbergLaw Can Help

If you or a loved one took Valsartan and was diagnosed with cancer, contact us. We are investigating claims in which an individual took Valsartan and contracted liver, kidney, pancreatic, stomach, and colorectal cancer. If you are concerned that your Valsartan medication is in the recall, please reach out to your doctor. The FDA recommends you do not discontinue taking your medication until your doctor prescribes a new one.

Novartis has made billions of dollars while leaving thousands of patients injured and suffering. We want to hold the pharmaceutical giant accountable for its manufacturing defects. Contact GoldenbergLaw to see if you have a potential claim, and leave the sleepless nights to us.



# Food Contamination

When consumers purchase food for themselves and their families, they trust that the companies manufacturing and selling that food have done everything within their power to provide a product safe for consumption. When that trust is betrayed, the results can be catastrophic.

“Ann” was a healthy woman enjoying life until she suffered from a terrible case of food poisoning. Food poisoning can be caused by any type of infectious organism or its toxins. Symptoms of food poisoning typically include nausea, vomiting, diarrhea, and pain. Contamination can occur at any point in the processing or production of the food in question, and the presentation of symptoms varies based on a number of factors, including the type of infectious organism and the pre-exposure health of the consuming individual. For Ann, the symptoms were severe and appeared within one day of exposure.

Ann often purchased fish from a local business in order to make nutritious meals for herself and her family. Sadly, one lot of fish she purchased turned out to be contaminated with *Listeria monocytogenes*. That contamination caused her to become extremely ill, spending more than a week in the hospital and suffering severe, life-threatening symptoms. Ann was eventually released from the hospital but continues to suffer significantly due to the lasting fear that anything she eats could cause her to suffer so terribly again. She also needs to take medication to help minimize her residual gastrointestinal symptoms.

Ann and her husband, “Peter,” hired GoldenbergLaw to represent them in their efforts to hold the manufacturer and seller of the contaminated fish accountable. GoldenbergLaw then hired a renowned epidemiologist who reviewed the case and authored an expert report supporting Ann’s allegation that her life-threatening symptoms were the result of exposure to *Listeria monocytogenes* in the contaminated fish. GoldenbergLaw also conducted multiple depositions of corporate representatives utilizing internal documents obtained from both the manufacturer and the seller of the contaminated fish. During those depositions, GoldenbergLaw was able to demonstrate that both the manufacturer and the seller of the contaminated fish disregarded FDA recommendations regarding the correct manner in which to warn and protect consumers once the companies knew of the dangerous contamination issue. Those depositions also evidenced the insufficient safety protocols in place which resulted in the contamination in the first place. Following the depositions, GoldenbergLaw was able to hold the companies that betrayed Ann’s trust accountable and obtain a substantial settlement for Ann and Peter.

Ann suffered tremendously from the companies’ breach of her trust in providing her food that was not safe to eat. Her life was turned upside down, and she has experienced physical and emotional damages that will likely never go away completely. However, their experience with GoldenbergLaw allowed Ann and Peter to put the terrible food poisoning incident behind them and move on with their lives. They expressed sincere appreciation for the supportive and sympathetic manner in which they were treated by GoldenbergLaw’s attorneys and staff.

# Meet Lindsay Golla

*Lindsay is our Marketing & Communications Specialist. She joined our team in September of 2017.*



Lindsay and her husband, Dylan

## **What do you like to do in your free time?**

I enjoy solving puzzles and playing board games. I also love interior design, so I'm often researching new trends and dreaming up ways to design my own spaces.

## **What is something most people don't know about you?**

I'm a talented whistler. I could whistle as a baby before I even learned to talk.

## **Where is your favorite place to visit?**

I love visiting my grandpa's lake house in western Michigan. It's my favorite place to be with family and relax. There's nothing better than the lake!

## **What's your favorite sports team?**

Having lived in a few different states in my life, I have a diverse mix of teams I follow. I'm a Green Bay Packers, Minnesota Gophers, and Detroit Tigers fan. But swimming is my favorite sport, making Katie Ledecky my favorite athlete.

# MAJ Members of the Year!

GoldenbergLaw would like to congratulate Partners Marlene Goldenberg and Laura Pittner for being awarded The Minnesota Association for Justice's (MAJ) Member(s) of the Year award!

MAJ's Member of the Year award is presented to a lawyer whose contributions to the organization advances MAJ's mission. Both Laura and Marlene were awarded for their leadership and persistence in creating the Women's Trial Lawyer Conference (WTLT). This event was created to help support female trial lawyers in Minnesota.



Marlene Goldenberg



Laura Pittner

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800 LaSalle Avenue  
Suite 2150  
Minneapolis, MN 55402

## **Contact:**

[www.goldenberglaw.com](http://www.goldenberglaw.com)

Phone: 612-333-4662

Toll Free: 855-333-4662

Fax: 612-367-8107

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