



# G-LAW

A  
Publication  
for the Clients and  
Friends of  
GoldenbergLaw,  
PLLC

*"Promoting Safety Through Accountability"*

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## OVER-THE-COUNTER ISSUE

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A message from

## STUART GOLDENBERG

### OVER-THE-COUNTER DANGERS

**H**ave you ever walked into a Walgreens and been amazed at the number of over-the-counter (OTC) drugs on the shelves? Believe it or not, the FDA is not only responsible for regulating all prescription drugs, but they also are charged with regulating the safety and labelling of all the OTC medications.

OTC medications are big business for drug companies. According to the most recent survey of Consumer Healthcare Products Association (CHPA) the U.S. market for OTC drugs was \$17.4 billion dollars in a single year. Worldwide, the market for OTC drugs could exceed \$70 billion in 2015.

These numbers are staggering, and the number of products the FDA is supposed to regulate is equally overwhelming. Dr. Janet Woodcock, the director of FDA research, recently told the Wall Street Journal that the entire system needs to be

"overhauled" and "the agency is looking for creative ideas on how to improve the process."

As we have learned from the subprime mortgage crisis, the combination of inadequate regulation and big profits often leads to safety issues for consumers. Many severe and life-threatening side effects of OTC drugs can slip through the cracks. This leaves the manufacturer as the regulator of safety. Essentially, the "fox" is watching over the "henhouse."

We have featured two OTC products in this issue that have potentially life-threatening side effects: Talcum powder (ovarian cancer) and Tylenol (liver failure) (see pages 4-5). These are prime examples of this flawed system.

So the next time you walk into a pharmacy, remember that just because you can buy a product over-the-counter, doesn't mean it is 100% safe.

#### Stay in the Loop with GoldenbergLaw!

Our social media sites are a great way to keep up on safety news and updates, as well as any updates we have on our mass tort cases.

You can also show your support for what we do by becoming involved. Next time you're logged on, make sure to visit us at:

**Facebook:** [facebook.com/GoldenbergLaw](https://facebook.com/GoldenbergLaw)

**Medtronic BMP:** [facebook.com/BMPinjury](https://facebook.com/BMPinjury)

**Twitter:** @Goldenberg\_Law

**LinkedIn:** [linkedin.com/company/goldenberglaw-llc](https://linkedin.com/company/goldenberglaw-llc)

**Google Plus:** [GoldenbergLaw, PLLC](https://google.com/+GoldenbergLaw)

**Blog:** [defectivedruganddeviceresourcecenter.com](https://defectivedruganddeviceresourcecenter.com)



#### What Can You Do?

- Research your OTC products online by searching "safety," "adverse events," and "lawsuits."
- Follow label directions for the product.
- Ask your doctor about interactions with your other medications.
- Take OTC medications sparingly. They all have some side effects.
- Contact your doctor promptly if you begin having symptoms you have never experienced before.

## DANGEROUS DRUGS AND DEVICES

GoldenbergLaw is currently investigating claims involving these products and has 29 years of experience handling dangerous drug and device cases. Contact us at 612-333-4662 or 1-855-333-4662

### Medtronic Infuse BMP:

Used in spinal fusion surgeries - linked to unwanted bone growth, inflammatory reaction, severe arm and leg pain and possibly cancer.



### Medtronic Paradigm Pump:

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



### Tylenol/Acetaminophen:

Over-the-counter or prescription pain reliever - linked to liver damage and liver failure.



### Talcum Powder/Baby Powder

Talc-based powder used for many purposes - linked to ovarian cancer when used for female hygiene in genital area.



### GranuFlo/Naturalyte:

Dialysate solutions - linked to metabolic alkalosis, cardiopulmonary arrest, sudden cardiac death, and other cardiac-related events.



### Benicar

Blood pressure medication - linked to severe intestinal problems that cause chronic diarrhea and weight loss



### Yaz/Yasmin/Ocella; NuvaRing:

Female contraceptives - linked to dangerous blood clots (i.e. deep vein thrombosis/DVT, pulmonary embolism, stroke).



### Metal-on-Metal Hips:

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



### 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 need for revision surgery.



### Actos:

A blood sugar control medication for type II diabetics - linked to bladder cancer.



### Propecia/Proscar:

(finasteride) a hair loss and BPH drug - linked to severe and persistent sexual dysfunction in men and is also linked to prostate cancer.



### Testosterone Therapy Drugs:

Male hormone drugs - linked to increased risk of heart attack, stroke, or death.





# OVER-THE-COUNTER

## Tylenol (Acetaminophen)

Overconsumption of acetaminophen, the active ingredient in Tylenol and many other pain-relieving drugs, is known to cause **liver damage**. However, few people realize that it is dangerously easy to ingest more than the recommended daily dose and severely damage their liver.

Over-the-counter Tylenol, especially the “extra-strength” variety, instructs users to take doses that are only slightly below what safety experts consider to be a safe daily amount of acetaminophen. This leaves an extremely narrow margin for safety, according to experts. Taking just a few extra pills could lead to serious liver damage and/or liver failure.

In addition, acetaminophen can be found in more than 600 com-



## Talcum Powder/Baby Powder

Talcum Powder is best known for its effectiveness in preventing skin from chafing due to heat, moisture, or friction. Many women have made talcum-based “baby powder” or adult body powder part of their after-shower routine in order to prevent chafing and/or discomfort in their genital areas. Unfortunately, talcum powder has been found to increase these women’s risk of **ovarian cancer**.

An analysis combining data from 16 studies published before 2003 found about a 30% increase in ovarian cancer risk among talc users. In 2008, Harvard epidemiologist Dr. Margaret Gates reaffirmed that weekly use of talcum powder for



# DANGERS

mon over-the-counter products, including household brands like Nyquil, Excedrin, and Sudafed. Combining one or more of these drugs with Tylenol could easily send someone over the "safe" daily threshold.

About 56,000 ER visits, 26,000 hospitalizations, and 458 deaths are reported annually from acetaminophen overdose. McNeil, a subsidiary of Johnson & Johnson, has sold Tylenol for decades, often touting its "safety." Despite knowing the serious risks for liver damage and liver failure associated with acetaminophen, and the likelihood for someone to take an unsafe amount, they have taken only "half measures" to avoid further injuries.

The FDA has repeatedly called for more serious warnings, but some experts are saying the warnings that have been added are still inadequate. GoldenbergLaw is currently investigating liver damage claims against Johnson & Johnson and the manufacturers of other similar products. Manufacturers make billions off over-the-counter medications such as Tylenol, and it is time they be held accountable for their lack of action when it comes to safety.

perineal dusting increases the risk of ovarian cancer by 33% and that daily use of a talcum powder product increases the risk of ovarian cancer by 41%. In 2010, Dr. Gates, along with two other Harvard researchers, published a study in the journal Cancer Epidemiology, Biomarkers and Prevention. This study reinforced the notion that talc in baby powder is carcinogenic to humans.

Research is ongoing, and findings have been mixed. However, the possibility of talcum powder being carcinogenic is very concerning. Johnson & Johnson, a major manufacturer [of talc-based baby powder and body powder], has been accused of failing to warn consumers of the risks of talcum powder. If you or a loved one have developed ovarian cancer and have routinely used talc-based showers for perineal use, contact GoldenbergLaw to discuss your situation.

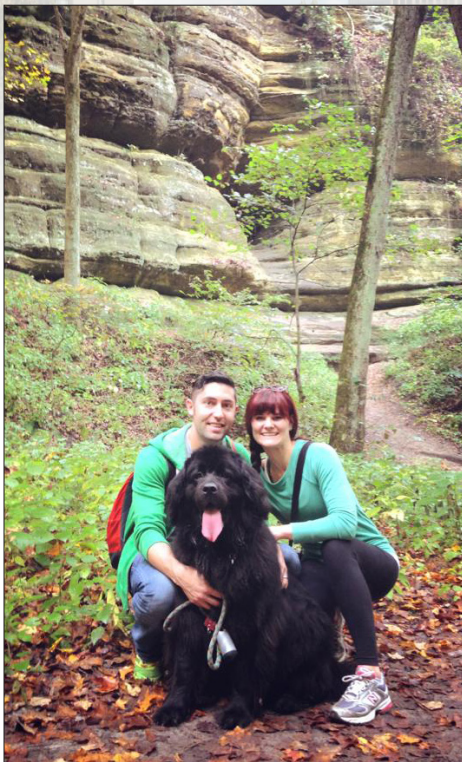


Sources: [ncbi.nlm.nih.gov/pubmed/16294364](http://ncbi.nlm.nih.gov/pubmed/16294364), Cancer.org

## INTRODUCING NOAH C. LAURICELLA

GoldenbergLaw is proud to announce a new addition to our team of attorneys. Noah C. Lauricella joined GoldenbergLaw in early July as an associate attorney, bringing with him valuable experience from defending product liability and mass tort claims.

Noah was a National Merit Scholar and graduated magna cum laude from Denison University. He then attended law school at Washington and Lee University in Virginia where he received the Spencer Graves Honor Scholarship.



Noah and his wife, Amy, along with one of their rescue dogs, Harper, on a hike through beautiful Starved Rock State Park in Utica, Illinois

Before law school Noah worked at the Faith Mission as a social worker for two years and helped homeless and disadvantaged people transition to sobriety, employment, and permanent housing. Noah is very civic-minded and served as a Loyola University Chicago School of Law Clinical Supervisor through a pro bono legal clinic he helped establish.

Prior to joining GoldenbergLaw, Noah was an almost 5-year associate with the defense firm Drinker, Biddle & Reath in Chicago. He defended corporations from initiation of suit to trial in products liability matters involving over-the-counter and prescription drugs, medical devices, and surgical implants. Noah also did extensive work representing defendants in asbestos litigation. His experience on the defense side of these issues makes him a valuable addition to our firm.



## CONTAMINATED STEROID BANKRUPTCY UPDATE

On September 26, 2012, New England Compounding Center (NECC) recalled three groups of its Methylprednisolone Acetate, an injectable steroid drug often used in patients with lower back pain. As a result of the contamination that led to this recall, fungal meningitis and other related infections have claimed over 50 lives, rendered over 700 extremely ill, and left thousands more with the anxiety that they had meningitis.

Since that time, we have been working diligently toward a resolution that will compensate victims of the negligent compounding practices of NECC. The process of compensating a large number of people is complex and was complicated even more when NECC filed for bankruptcy shortly after the recall.

There are multiple avenues through which we must pursue compensation. To recover any money from the NECC, we entered our clients into the bankruptcy court proceedings by April 1, 2014, using a proof of claim form. Through the efforts of all the attorneys around the country, the NECC settled the contaminated steroid claims for \$100 million dollars in bankruptcy court. The \$100 million will be distributed to claimants using a matrix system that will allocate certain amounts to specific categories of injuries. We will assist our clients in receiving the maximum compensation category (with the most seriously injured receiving higher rewards). This matrix should be approved soon.

Since NECC was not the only party involved in distributing the products, a multidistrict litigation (MDL) was established in order for injured parties to bring claims against NECC affiliates and clinics and hospitals. Alternatively, there is an option to pursue a claim against administering clinics and hospitals in the state court in which they operate. There is a very intricate analysis as to whether to bring in a claim in the MDL or state court. We will analyze each of our clients' situations carefully.

Regarding the \$100 million settlement, questions still remain regarding how much health insurers will be reimbursed out of the settlements for related treatment the insurer covered. Under the law, insurers have the right to seek and obtain compensation for the cost of related treatment rendered when a settlement results.

The road to justice is imperfect and will still take some time, but we remain committed to resolving claims for our clients who have needlessly suffered as a result of NECC and their clinics' negligence.



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Insurance Disputes