



G-LAW

A
Publication for
the Clients and
Friends of
GoldenbergLaw,
PLLC

"Promoting Safety Through Accountability"

Summer 2013

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A message from

STUART GOLDENBERG

Karen Bartlett, a young, active woman, suffered from shoulder pain and was prescribed the generic drug, Sulindac. Tragically, Ms. Bartlett developed a horrible side effect called Stevens-Johnson Syndrome (SJS) which chemically burned 60% of her skin off from the inside and left her nearly blind (see our Winter 2012 article on SJS).

Ms. Bartlett spent a month in a coma and a year being fed through a tube. Mutual Pharmaceutical, the generic manufacturer, *knew* of this horrible side effect but did not warn about it on the product label. A lawsuit was brought in New Hampshire by Ms. Bartlett, and a federal jury awarded her 21 million dollars. The Court of Appeals affirmed.

This week, the U.S. Supreme Court issued a 5-4 decision in *Mutual Pharmaceutical v. Bartlett*, which struck down this verdict on federal preemption grounds. The Court decided generic manufacturers cannot be held responsible for failing to warn of side effects regarding the design of the drug since they are only making “a copy.” Therefore, no one could be held responsible.

This is the second Supreme Court decision giving generic manufacturers immunity. As you may recall, our prior firm, Goldenberg & Johnson, took the generic drug case of *Pliva v. Mensing* to the U.S. Supreme Court and lost on similar “logic.”

The concept of drug and device preemption compromises the rights of every person who has ever used a medical device or taken a prescription drug. According to NPR, 75% of all drugs used in the U.S. are generic.

That means, despite the egregious conduct of these generic manufacturers, they cannot be held accountable by any of us if we are harmed by their products. However, if you are taking a brand name drug, under the U.S. Supreme Court case of *Wyeth v. Levine*, you can hold a manufacturer responsible. This is frankly ridiculous and offensive to the millions of Americans who have no idea their rights have been taken away from them.

This absurd result must now be addressed by Congress. We urge you to contact your senators and congressmen to ensure that your rights are protected in the future. If you would like assistance in doing so, our office would be happy to assist you in advocating for your rights.

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

Twitter:

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defectivedruganddeviceresourcecenter.com



GRANUFLO/NATURALYTE DIALYSATE

A Serious and Deadly Chemistry Problem in Dialysis

Last March, a whistleblower leaked an internal memo to the FDA, exposing a dangerous dosing problem in two dialysates (solutions used in dialysis), GranuFlo and Naturalyte. Both contained hidden extra units of acetate. Consequently, many patients were overdosed, causing sudden cardiac death, cardiac arrest, and arrhythmias. Fresenius Medical Care (FMC), the manufacturer, chose to warn only their own company-run centers of this problem when they circulated the internal memo in November of 2011. Soon after the memo was leaked to the FDA, however, FMC was forced to recall the product and warn all dialysis centers who purchased the product from them.

FMC's pattern of misconduct: FMC is the largest operator of dialysis centers and treats more than one third of the estimated 400,000 Americans on dialysis. Internal documents dating back almost 10 years discussed routine and frequent miscalculations in bicarbonate levels leading to cardiac-related injuries and deaths. Although FMC was aware of those risks over the span of 10 years, March 2012 was the first time many clinics were made aware of any problems.

UNDERSTANDING THE SCIENCE Behind GranuFlo and Naturalyte

As you may know, dialysis replaces renal functions for patients whose kidneys are no longer able to work properly. One of these functions is the maintenance of bicarbonate, the solute that balances pH levels in the bloodstream. A nephrologist prescribes the amount of bicarbonate in a patient's dialysis treatment and bicarbonate levels are then maintained through regular treatments.

Bicarbonate comes from two sources during dialysis. One is the bicarbonate concentrate, and the other is the acetate in the acid concentrate. Acetate is quickly converted to bicarbonate in the liver; therefore, it is counted as part of the bicarbonate that the patient receives. The total amount of bicarbonate through these two sources is the "total buffer." FMC failed to properly warn nephrologists and clinic staff that the sodium acetate in GranuFlo and Naturalyte converts at a higher rate than other dialysates, meaning patients were getting too much bicarbonate in dialysis.

Conversion rate from acetate to bicarbonate, combined with the confusing and limited user interface of FMC machines, would have made it nearly impossible for physicians to calculate and administer the intended bicarbonate levels. Instead, patients were routinely overdosed with excessive bicarbonate levels. Patients with those bicarbonate levels are subjected to a 6-fold increase in sudden cardiac death and cardiopulmonary arrest.

FMC's failure to adequately train their own staff, as well as to warn all of the doctors using their products, has placed thousands of dialysis patients at risk and has resulted in numerous unnecessary deaths around the country. Many families have lost their loved ones too soon due to the negligence exhibited by this company. GoldenbergLaw has taken a leadership role in pursuing these cases throughout the country. We look forward to helping our clients get the justice they deserve.

SETTLEMENTS & HOLDBACKS

The Ins & Outs of a Successful Resolution of Mass Tort Claims

We are always excited to see settlement funds distributed to our clients. Because the settlement process is often complex, we wanted to take time to answer some of your most frequently asked questions.

The settlement process requires many steps before funds can be distributed. Liens must be verified and negotiated, and all necessary paperwork must be carefully read and signed. In many settlements, the defense requires a holdback of a certain percentage or amount to satisfy any medical liens. Sometimes, insurance providers (or Medicare or Medicaid) require a 100% holdback until their lien is resolved. Wrongful death cases get even more complicated, as we are responsible for identifying and contacting proper heirs. Because we know how complex settlement can be, we guide our clients through every step of the process.

What is a medical lien?

If an insurance company or a government program like Medicare or Medicaid pays for your medical treatment, these entities have a right to recoup their expenses out of your settlement. We work with all of our clients' medical providers to resolve these liens when we settle a case and to maximize the amount of money that ends up in our clients' pockets.

What is a holdback?

If the defense pays you and later finds out that a lien wasn't satisfied, they can be responsible for paying the lienholder. A holdback is when the defense sets some of the funds aside until liens have been resolved. GoldenbergLaw works to resolve all our clients' liens as quickly as possible so that any amount which is held back can be released to our clients.

How long does it take to resolve liens & holdbacks?

Only about half of this process is within our control. The best way to speed up the process is to make sure that all liens are properly identified and that we submit all of the necessary paperwork promptly. We work with companies to help us identify all lienholders. Unfortunately, we cannot control how quickly the lienholders will respond. Once we obtain the lien information and submit the proper paperwork, it's a matter of the defense responding.

I am bringing a claim as an heir.

**How much will I get?
How is it divided?**

If you are receiving a settlement on behalf of a relative who passed away, the answer to this question depends upon the state in which the case was brought. Each state has its own laws on how wrongful death settlements are distributed. We always encourage the family to reach an agreement on distribution. If no agreement is reached, the court has ultimate authority to determine which heirs are entitled to money and the amount each heir receives.

Is my settlement taxable?

Generally, personal injury settlements are not taxable. However, please be aware that other components of a settlement (like punitive damages) may be taxable. We always recommend that you speak to an accountant before filing your taxes.

DANGEROUS DRUGS AND DEVICES

GoldenbergLaw is currently investigating claims involving these products and has 28 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.



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.



Topamax:

An anti-seizure medication - linked to birth defects such as cleft palate and cleft lip.



Actos:

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



GranuFlo/Naturalyte:

Dialysis solutions - linked to metabolic alkalosis, cardiopulmonary arrest, sudden cardiac death, and other cardiac-related events. **See page 3



Byetta/Janeuva:

Diabetes medications - linked to an increased risk of pancreatitis and pancreatic cancer.



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.



Transvaginal Mesh (TVM/TVT):

Linked to tissue erosion, device failure, need for correctional or removal surgeries.



Fosamax:

An osteoporosis drug - linked to femur fractures and a possible link to esophageal cancer.



Mirena IUD:

Contraceptive that can cause abscesses, pelvic inflammatory disease, embedment in or perforation of uterus, erosion of adjacent areas, and other related problems.



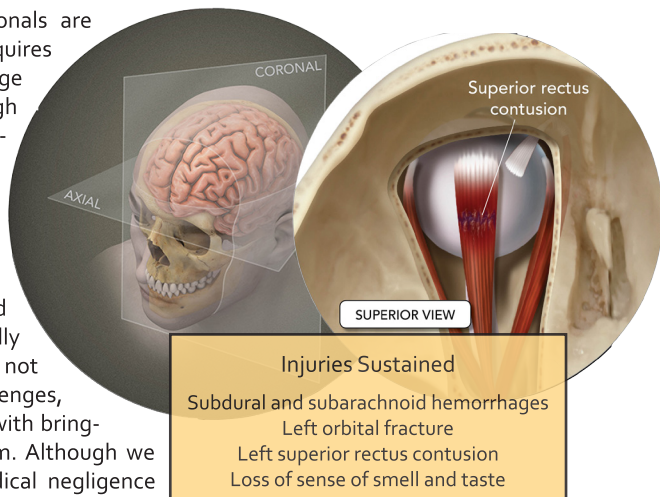
MEDICAL NEGLIGENCE

Because medical professionals are engaged in work that requires a high degree of knowledge and skill, they are held to a high standard in the care they provide. However, doctors are trying to help people, and just because a doctor makes a mistake does not mean the mistake constitutes negligence. A doctor must violate a standard of medical care to be held legally responsible. Many people are not aware of the complexity, challenges, and financial risks associated with bringing a medical negligence claim. Although we are very selective in the medical negligence cases we take on, one of our recently settled cases is a great example of why we pursue these cases.

Nicolas (name changed) underwent pulmonary function testing for his work at a clinic in the Twin Cities. During the procedure, he was required to blow "as hard as he could" for 12 seconds while standing. He suffered a syncope (fainting) episode and violently struck his head on the floor.

The risk of syncope, while rare, is the predominant hazard in administering a lung function test. For this reason, there is specific protocol established to minimize risk. If the standing position is used to perform the test, both *The European Respiratory Journal* and OSHA express the need for a chair without wheels to be placed behind the patient. The nurse should be trained to identify signs of syncope and maneuver the patient quickly and easily to the sitting position to prevent injury.

Despite the clinic's representations that its staff was certified to perform these tests, it violated the standard of care by (1) **failing to keep Nicolas positioned with a chair behind him**, (2) **failing to restrain or reposition**



Nicolas and (3) failing to train the nurse administering the test to recognize and observe the obvious signs of syncope.

Nicolas suffered a significant brain injury and, as a result, has permanently lost his senses of taste and smell. This incident changed his life completely, as he used to love to cook and had a sophisticated appreciation for food. In addition, Nicolas lost over \$300,000 in wages over a 5-year recovery period. Our expert analyzed his wage loss pattern and estimated that he will eventually lose even more than that. His medical bills totaled almost six figures.

There are inherent risks associated with medical treatment of any type. One of the differences between an unfortunate outcome and one that merits legal action is whether those risks were mitigated correctly and whether the medical provider and clinic acted within the standard of care. Here they did not. After extensive litigation, we are happy to have secured a favorable settlement for him. We also hope our involvement yields broader results in the form of more responsible practices for future patient care.

NEWS AROUND GOLDENBERGLAW, PLLC



We are pleased to announce Marlene Goldenberg as our newest associate attorney! Marlene began working at GoldenbergLaw (then Goldenberg & Johnson) when she was twelve years old. She began as a file clerk and has since served as an intake specialist, law clerk, and now an attorney. Marlene graduated from Syracuse University, magna cum laude, receiving her Bachelor's degree in International Relations, Political Philosophy, and Spanish. She attended law school at William Mitchell College of Law in St. Paul, Minnesota and at BPP Law School in London, England, earning her J.D. (cum laude) and Graduate Diploma in Law (GDL), respectively.

Marlene presently works on Medtronic Infuse, GranuFlo, and Propecia cases. Marlene has previously worked on a variety of mass tort cases including Mirapex, Avandia, Kugel, Trasylol, Sprint Fidelis, and Reglan. She also handles individual personal injury and product liability cases.

Marlene serves as a volunteer for Big Brothers Big Sisters Minnesota and Children's Law Center and is a Board Member of Jewish Family and Children's Services NextGen group. She also enjoys traveling, spin class, cooking, and spending time with family and friends.

Get To Know Marlene

Do you have any pets?

Pumpkin and Cecil (cats- they both play fetch!)

What is your favorite month of the year?

June. It's my birthday month and when rhubarb and tulips are in season.

If you could choose one type of food to eat for the rest of your life, what would it be?

That's an unfair question. My life revolves around food, so having to pick just one is impossible.

What is the best part about being an attorney?

I love knowing that I will learn something new every single day when I go to work. I also enjoy being able to make a difference in the lives of my clients.

When did you decide you wanted to be an attorney?

A long time ago, but I announced my intentions to be an attorney when I was 13 at my bat mitzvah.

What is your favorite sports team?

It's a toss-up between the Minnesota Vikings and the Syracuse Orange basketball team.

What is your biggest pet peeve?

Lack of organization and poor grammar



Pictured: Marlene and her husband, Bobby, at their wedding in Fall 2012

IN OTHER NEWS:

In June, the Medtronic-sponsored YODA study was released. Medtronic had hoped these results would counter the criticisms of its INFUSE device which appeared in the June 2011 issue of the Spine Journal. Instead, this study found Infuse to be no more effective than other treatments and lacked the necessary investigation of the risks.

Stuart has served as one of the media contacts in the Infuse litigation.

Visit our Facebook page for a link to the study!

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