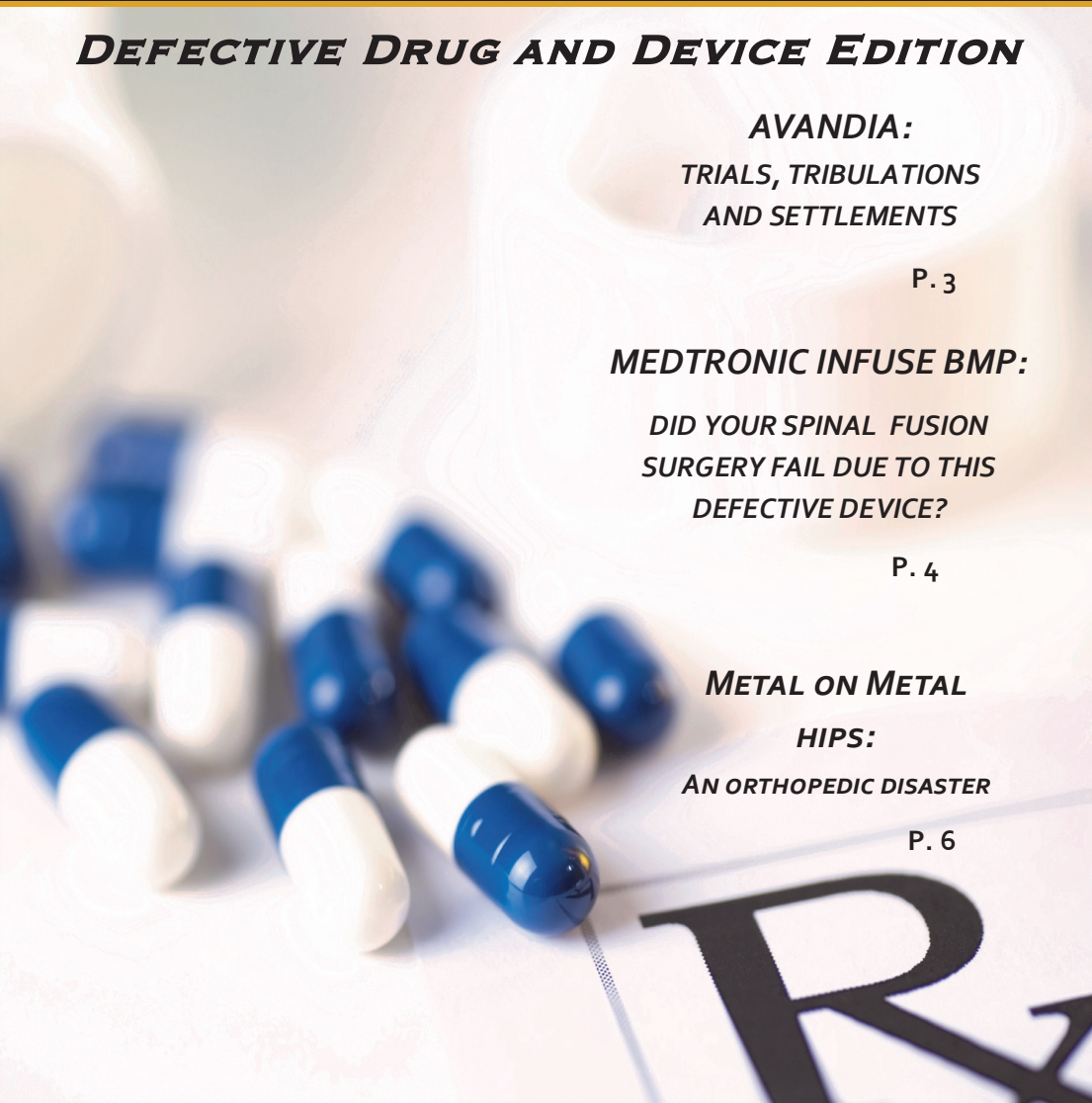
G-LAW

A publication for the clients and friends of GoldenbergLaw, PLLC

"Promoting Safety Through Accountability"

SUMMER 2012

Defective Drug and Device Edition



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Stuart Goldenberg

...On Pharmaceutical Companies Putting Patients at Risk

In the 1980's, the Dalkon Shield and Copper-7 IUD birth control devices were the first real "mass torts." These devices were poorly tested, hastily rushed to market and devoid of integral warnings concerning the risks of infection. Thousands of women were rendered infertile and billions of dollars had to be paid in verdicts and settlements. A.H. Robins was forced into bankruptcy for its reckless conduct.

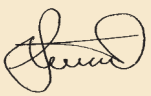
Despite these events, the lure of billion dollar profits has only increased over the past 27 years for the drug and device companies we refer to as "Big Pharma." As drugs and devices became increasingly profitable, Big Pharma has resorted to "ghost written articles," huge pay-outs to doctors to endorse or promote a product, industry funded "educational programs," drug sales representatives awarding gifts, cash and dinners to doctors for prescribing a drug or device, and even falsified studies.

In the last few years alone, drug and device manufacturers have paid billions in fines and settlements to the government for claims of fraud, off-label marketing, and regulatory violations. Yet, the rights of consumers have continued to be reduced by hostile legislation and Supreme Court decisions. If you are injured today by a dangerous generic drug or an FDA fully-approved medical device, your right to recover compensation is in jeopardy.

At GoldenbergLaw we have been involved in litigating mass tort cases since the Dalkon Shield in 1984. Since that time, we have held Big Pharma accountable for a long list of defective drugs and devices, including Fen Phen, Vioxx, Bextra, Celebrex, Mirapex, Avandia and many more. Tragically, Big Pharma doesn't appear phased by any of these disasters. The same conduct continues today. The civil justice system remains the only real deterrent.

On page 5 is a list of all the mass torts we are pursuing. **Behind each drug and device is basically the same story of poor testing, rush to market and failure to warn of some terrible side effect which has devastated or killed one of our clients.**

Although Big Pharma continues to place profits before safety, GoldenbergLaw will continue to fight for consumers' rights and to hold these companies accountable for putting patients at risk.



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

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Blogs catastrophicaccidentresourcecenter.com defectivedruganddeviceresourcecenter.com productrecallresourcecenter.com toxictortresourcecenter.com

AVANDIA:

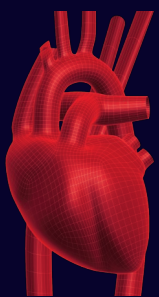
Trials, Tribulations and Settlements

After a decade of controversy over the safety of the drug Avandia, justice will finally come to the clients of GoldenbergLaw and their families in the form of a long-awaited settlement with the manufacturer, GlaxoSmithKline.

Cardiovascular Injuries Associated with Avandia

Released in 1999, Avandia is a medication administered to individuals with Type 2 diabetes.[1] The drug was developed to control blood sugar levels in diabetes patients.[2] However, after its release onto the pharmaceutical market, the drug was also associated with some serious and potentially fatal heart conditions.

A decade's worth of studies conclude Avandia causes heart problems. In 2003 the manufacturer itself conducted a study, which demonstrated using Avandia to treat diabetes caused far more heart problems than a placebo.[3] In that same year, the World Health Organization sent the manufacturer an alert indicating Avandia caused heart attacks.[4] In 2006 a multitude of companies created a meta-analysis, finding Avandia increased the risk of serious heart injuries by nearly one third.[5] Even after three years worth of studies continued to reveal more and more risks, GlaxoSmithKline continued to aggressively advertise their product.[6]



Injuries lead to Black Box Warning

A black box warning was added to the Avandia label in 2007.[7] By 2009, Avandia was linked to 304 deaths.[8] A study completed by editors of the American Medical Association released in 2010 concluded as many as 100,000 heart attacks, strokes, deaths and cases of heart failure may have been caused by the drug since its release onto the market.[9] Although Avandia is still available for doctors to prescribe, the seriousness of the black box warning has helped to protect consumers.

Settlement

Avandia-related injuries have affected thousands. GoldenbergLaw represents over 250 clients in the Avandia litigation. After two and a half years of case work, investigation, litigation and negotiation, the firm successfully reached a confidential settlement. We hope this will allow our clients to put this disaster behind them.

[1] *Rosiglatone*, PUBMEDHEALTH, last visited Aug. 15, 2011, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001051/

[2] PUBMEDHEALTH, see above.

[3] Garndiner Harris, *Research Ties Diabetes to Drug Woes*, NEW YORK TIMES, (Feb. 19, 2010,) http://www.nytimes.com/2010/02/20/health/policy/20avandia.html?pagewanted=all.

[4-8] New York Times, see above.

[9] Rachel B. Duke, *Drug Study Links Avandia to heart problems, strokes*, THE WASHINGTON TIMES, (June 28, 1010). http://www.washingtontimes.com/news/2010/jun/28/study-finds-diabetes-drug-risky-health/.

Fusion Confusion:

Medtronic Infuse © BMP

"Why don't I feel better after my spinal fusion surgery?"

Bone Morphogenetic Protein

Many of our clients are familiar with the "aha" moment that occurs when one first realizes that a medical or pharmaceutical product is likely responsible for their serious injury or the loss of their loved one. **Lately, many spinal fusion patients are now coming to the same type of realization—that their years of suffering following spinal fusion may have a common link.**

Last summer, *The Spine Journal* published an issue dedicated to the Infuse BMP (bone morphogenetic protein), a spinal fusion product manufactured by Medtronic. The issue boldly confronted and criticized the company-sponsored research and promotion of the product, emphasizing major safety and ethical concerns.

> *"Authors of nearly all those trials had financial ties with the manufacturer of rhBMP-2 with various compensations ranging to more than 26 million dollars/per study"*
> *-Spine Journal*

Downplaying Risks

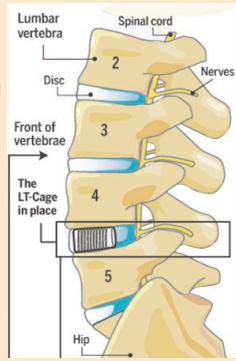
Complications are possible with many types of treatments, but according to experts published in the Spine Journal, the risks of this product have been downplayed for longer than the product has even been on the market. They believe financial conflicts of interest to be the main cause for the discrepancy.[2]

Promotion of Off-Label Use

Although Infuse BMP was approved in 2002 for spinal fusion surgeries, its FDA-approved use was limited. In spinal fusion surgeries, BMP was approved only for use in the lumbar (lower back) region and for an anterior (through the stomach) approach. Other restrictions also applied.[3]

Despite its limited authorized use, doctors have been using it for off-label purposes. Any use that deviates from the FDA-approved use is considered off-label, and it has been estimated that BMP is used off-label about 85% of the time.[4]

Experts share concerns that royalties paid to "opinion leading" doctors can have a domino effect—one that not only damages the integrity of clinical research but also infringes on doctors' abilities to make informed decisions about patient care. Doctors may choose to use a product off-label if they believe it will benefit the patient. However, it becomes difficult to make that decision when the risks are not accurately reported by the manufacturer who is promoting the off-label use.



Allegations that Medtronic directly promoted the off-label uses to bolster sales has prompted both congressional and federal investigations.[5] A shareholder's suit against Medtronic was recently settled for $85M[5]

INJURIES:

The causation of injuries associated with the product are still under review, but the following have been discussed in the context of BMP complications:

- **Ectopic (unwanted) bone growth near fusion site**
- **Inflammatory reactions involving radiating pain in arms/legs**
- **Cancer or recurrence of cancer**
- **Inflammatory cyst formation**
- **Bone loss**
- **Implant displacement**
- **Urogenital injuries**
- **Swelling of the neck or throat resulting in restricted airway or difficulty swallowing**

Sources: Photo: Medtronic, Inc. [1]Spine Journal 6/1/2011; [2]Med Page Today 6/28/2011; [3]Food and Drug Administration; [4]Milwaukee Journal Sentinel 8/28/2010; [5]Star Tribune 11/14/11; [5]Mpls/St.Paul Business Journal 5/30/12

There are a number of side effects associated with spinal fusion procedures. However, if Infuse BMP was the cause of your injuries, you may be entitled to compensation. GoldenbergLaw is currently investigating legal claims on behalf of people who have suffered serious adverse reactions to Medtronic Infuse BMP.

12 Dangerous Drugs and Devices

Avandia

A blood sugar control medication for type II diabetics– causes heart attack, CHF and stroke

**See page 3

Propecia

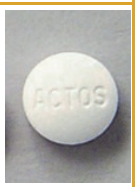
(finasteride)- hair growth medication and BPH treatment– causes severe and permanent sexual dysfunction to men

Topamax

An anti-seizure medication– causes birth defects such as cleft palate and cleft lip

Actos

A blood sugar control medication for Type II diabetics– causes bladder cancer



Accutane

An acne medication– causes Crohn's Disease or Ulcerative Colitis

Darvacet/ Darvon

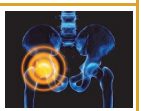
A narcotic for pain– causes heart arrhythmias

Yaz/Yasmin/ Ocella

A birth control pill– causes dangerous blood clots and gallbladder removals

Metal-on-Metal Hips

Causes loosening, pain, high metal levels in the blood and replacement surgery. Includes DePuy ASR, Pinnacle and other models



Stryker Rejuvenate Hip System

Modular hip system – can cause elevated metal levels in bloodstream and/or need for revision due to fretting/ corrosion of the neck joint

Transvaginal Mesh, Bladder slings, TVT Tape

Causes tissue erosion, device failure, need for additional surgery to remove or manipulate device

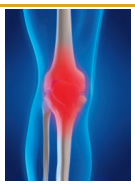
Medtronic Infuse BMP Bone Graft

Used in spinal fusion surgeries- Causes unwanted bone growth , severe arm and leg pain and cancer

**See Page 4

Zimmer NexGen Knee

Knee prosthetic that causes loosening, shifting, pain and need for surgical replacement



GoldenbergLaw is currently investigating claims involving these products and has 27 years of experience handling dangerous drug and device cases.
Contact us at 612-333-4662 or 855-333-4662.

Metal-on-Metal Hip Devices

Failing the Test of Time

Hip replacement surgery is the most common orthopedic operation in the United States. However, patient satisfaction and the success of the treatment are low relative to the number of procedures.[1] Metal-on-metal (MoM) hip implants, in particular, have presented a problem for patients. Though they were developed to be more durable than traditional implants, recent research has shown that MoM implants are hazardous, prompting the recall of multiple device systems and causing thousands of replacement surgeries.

Medical professionals and the FDA alike have questioned the safety of MoM devices after recipients suffered from adverse side effects. Several manufacturers have voluntarily recalled their MoM devices; others slowly scaled back their production. Furthermore, the FDA issued an order in May of 2011 for 21 manufacturers to investigate the safety of their implants.[2] Companies called to action include: DePuy, Zimmer, Biomet, Stryker, and Wright Medical.

The popularity of MoM systems has plummeted, now accounting for less than 5% of the hip replacement market[3] (down from nearly a third).[4] But for those who have already had the devices implanted, the risks—and the stakes—can be high.

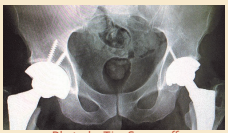


Photo by Tim Sammoff

The United States lacks a national database, oftentimes called a joint registry, to track patients with artificial hips. Though our nation is one of the top providers and users of implants, many European nations are leaps and bounds ahead in terms of tracking the device and promoting patient safety.

Our client, Cindy, knows this firsthand. After being implanted with a defective Zimmer Durom Cup metal-on-metal hip in 2007, which was eventually recalled, Cindy experienced a dramatic change in her lifestyle. The procedure hadn't alleviated the symptoms of her degenerative arthritis. After the normal recovery period had elapsed, she began noticing that she wasn't bouncing back as expected.

Cindy was unable to return to her active lifestyle from before the surgery – whether bowling, yoga, golfing, or walking with friends. She found she could no longer keep up with her seven grandchildren or manage routine household chores.

A second opinion from another doctor revealed the failure of the implant. The prosthesis had loosened, and Cindy was suffering from metallosis and debilitating pain, both tell-tale signs of a MoM implant. She would eventually need revision surgery.

GoldenbergLaw negotiated a confidential settlement for Cindy. Though it is difficult to put a price tag on justice and health, the settlement held the product manufacturer liable while dually compensating Cindy for all she went through. Today, after the replacement of this defective hip, Cindy is getting back to life as normal – whether it means grocery shopping or enjoying a summer baseball game with her family. We will continue to litigate and fight for our clients injured by MoM devices.

According to the New York Times,[5]
MoM implants can lead to the following negative results:

- ⇒ Metallosis (a high concentration of metal ions in the bloodstream or organs)
- ⇒ Implant failure at high rates
- ⇒ Need for costly revision surgeries
- ⇒ Tissue and muscle damage
- ⇒ Neurological problems

Sources: [1]West End Hospital [2]U.S. Food and Drug Administration [3]Med Page Today [4]USA Today [5]New York Times

NEWS AROUND GOLDENBERGLAW, PLLC

In our summer edition, we would like to turn the spotlight to one of our most talented legal assistants, Kris Triske. Kris has been a legal assistant at GoldenbergLaw for almost 15 years and has helped hundreds of seriously injured clients with their products liability and personal injury cases.

Kris Triske is one of our longest-serving employees at GoldenbergLaw. Initially, she went to school to become a court reporter but changed her career path to be more directly involved with clients as a legal assistant. She enjoys the uniqueness of every case, as it keeps her job interesting and allows her to learn new things.

At the end of the day, Kris loves knowing that she made a difference for our clients. With product liability cases in particular, she knows that every product or machine that we get modified or recalled could save another person from being injured in the future. Though she grew up in Duluth, Minnesota, Kris now lives with her husband, Dan, and three daughters in Minnetonka. She jokes that free time is a foreign concept to her, between working and taking her girls – Hannah (10), Hailey (8), and Kalli (6) – to their sporting events. Their weekdays and weekends are filled with fastpitch games and bowling tournaments (times three!).

Kris used to play a lot of softball herself, but what really makes her light up now is talking about her responsible kids and all their fun activities. Kris does it all—she is a terrific legal assistant and a caring mom.

STUART GOLDENBERG WAS AGAIN NAMED ONE OF THE TOP 100 TRIAL LAWYERS BY THE AMERICAN TRIAL LAWYERS ASSOCIATION

Member of THE AMERICAN TRIAL LAWYERS ASSOCIATION TOP 100 TRIAL LAWYERS

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