G-LAW

"Promoting Safety Through Accountability"

Fall 2017

Knee Replacements: Early Failures

What X-Rays & Radiographs Are Not Detecting

Farxiga

The dangerous risks of taking this drug

Table Saws

New product holds saw manufacturers accountable

Benicar

Celebrating a successful settlement

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a message from
Stuart Goldenberg

Why aren't problems with drugs and devices detected earlier?

Federal law requires drug and device companies to report all deaths and serious, adverse events with their products to the Food and Drug Administration (FDA). These reports are kept in a public database called MAUDE (Manufacturer and User Facility Device Experience) and are available to the public. Just Google "MAUDE database."

While the MAUDE system relies on hospitals, doctors, nursing homes, and treatment facilities to report these events, sadly it is not mandatory for them to do so. Consequently, unlike many European nations or Australia, according to the General Accounting Office, it is estimated that only one in ten adverse events is reported to the manufacturer. In turn, the manufacturer then "interprets" if an event is "serious" and only then is it reported to the FDA.

Only one in ten adverse events is reported to the manufacturer.

What this means to you is that the FDA is only receiving only about one tenth of the data they should be using to determine if a product's benefit is outweighed by its risk.

This is why, as a drug and device firm, we often discover the defects long before the FDA ever decides to recall or place a warning on a product. Since our flawed system isn't likely to change anytime soon, drug and device lawyers are often the only defense people have to protect them if a company is hiding a problem. We will continue to accept this challenge and work towards a better reporting system.

Accolades and Awards

Our law firm and our lawyers are privileged to do what we love: helping people. We are honored that others have recognized us for our work.

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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 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

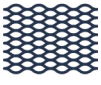
A knee replacement device - linked to loosening, instability, severe pain, and the need for revision surgery.

Farxiga

A drug used to treat type 2 diabetes, intended to block pathways that reach the bloodstream - linked to ketoacidosis.

Hernia Mesh

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



Inferior Vena Cava Filter

Blood clot filters 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 when used for female hygiene in genital area.

Testosterone Therapy Drugs

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

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.

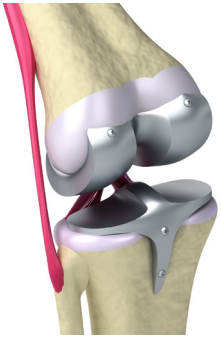
Knee Replacements

Early Failures Lead to Revision Surgeries

With a knee replacement comes the expectation of increased mobility and quality of life. Unfortunately, many people instead find their lives up-ended by a defective knee replacement device.

Overview

Individuals will undergo a total knee replacement when their knee is severely damaged by arthritis or injury. Often, they have limited mobility and ability to complete simple activities.



In most cases, there are metal femoral and tibial components that are sealed with cement to attach to the bone.

The Problem

The most common problem of knee replacement devices is the loosening of the tibial base, causing instability and severe pain in the knee. Additionally, the knee replacement devices were intended to last 15-20 years. However, many individuals have reported failure within two months to one year after surgery.

The Symptoms

Individuals with failed knee replacements often experience:

- instability
- severe pain
- swelling
- revision surgery

Another Problem

Unfortunately, X-Rays and radiographs are not detecting radiolucencies because they do not show the loosening in the device. For individuals with knee replacements experiencing severe pain and instability, it is vital to see a doctor immediately, so they can determine if the device is failing. A bone scan may be helpful to detect this problem.

Featured Litigation: DePuy Attune

This isn't the first time DePuy has had issues with its devices. The DePuy Attune Knee Replacement System is failing prematurely, causing painful, invasive revision surgery for individuals.

Farxiga

Dangerously High Levels of Ketones

Farxiga (dapagliflozain) is a type 2 medication that can cause dangerous side effects, including ketoacidosis. Ketoacidosis, or the overproduction of blood acids, is a serious and oftentimes life-threatening medical condition.

Overview

Farxiga is a drug that is taken orally by individuals with type 2 diabetes. It is designed to lower blood sugar levels by using SLGT2 inhibitors (sodium-glucose co-transporter 2), meant to help the kidneys eliminate extra glucose from the bloodstream. Farxiga sets itself apart from competing drugs by claiming to help individuals with type 2 diabetes lose weight.

The Problem

Farxiga can cause a build-up of acids (ketones) in the body. This results in dangerous injuries to the user of the medication. This build-up of acids is the leading cause of ketoacidosis.

Starting in 2015, the FDA began issuing warnings regarding the side effects of Farxiga, including ketoacidosis, after discovering several reports of such injuries in its adverse event report database. Before 2015, the side effect of ketoacidosis was not warned of by the makers of Farxiga. Further, in June 2016, the FDA required the makers of Farxiga and Xigduo XR to strengthen the warning regarding acute kidney injury, another dangerous side effect of the drug.

Our Leadership and Expertise

In 2017, a multidistrict litigation was formed in the Southern District of New York to address the injuries caused by Farxiga. Laura Pittner, Partner at GoldenbergLaw, has been appointed to be on the Plaintiff Steering Committee for this litigation.

The Symptoms

- fluid buildup in the brain
- kidney failure
- cardiac arrest
- coma or death (if left untreated)

Table Saw Injuries
Defective Guarding

The Invention of SawStop

It is no secret that table saws can be dangerous but there are safeguards that can protect against injury. After witnessing the dangers of table saws, Inventor Steven Gass created the SawStop. The SawStop blade is unique because it carries an electrical current that is continuously monitored. If the saw comes in contact with human skin, a change in current is detected and an automatic braking system is activated, stopping the saw's blade in about **three one-thousandths of a second.** In 2004, after power tool makers continuously refused to invest in their safety product, SawStop began making their own brand of saws. It has been suggested that large power tool manufacturing companies do not want a safety device like SawStop to prevail on the market. The availability of such a device could **place liability on conventional table saw manufacturers** should a user become injured while using a saw without the added stop technology.

The Expensive Cost of Injuries

With approximately 67,300 medically treated table saw injuries occurring each year, conventional table saw manufacturers could stand to lose large amounts of money due to injury settlement and litigation costs. The Consumer Product Safety Commission's (CPSC) Advanced Notice of Proposed Rulemaking estimated the average cost of a table saw injury to be around $35,000. In total, this amounts to an estimated $2.36 billion. The CPSC has been pushing for SawStop to be adopted.

Who is Liable?

In 2011, Carlos Osorio sued saw manufacturer Ryobi Technologies Inc., claiming that the saw he had purchased was defectively designed, in part because it did not incorporate the SawStop technology. SawStop Inventor Steven Gass testified at the trial that Ryobi was given the chance to incorporate the technology into its design in 2000 but opted against doing so. Osorio prevailed and was eventually awarded $1.5 million in damages. There are currently numerous cases filed relating to defective table saws, yet manufacturers continue to disregard the available safety technologies.

GoldenbergLaw has handled defective table saw cases since 1997. Please contact Senior Partner Stuart Goldenberg (slgoldenberg@goldenberglaw.com) regarding any questions about saw injuries.

Meet Ana O'Hara

Legal Assistant at GoldenbergLaw

What is a hidden talent of yours?

I make handmade greeting cards to send to my friends and relatives for birthdays and holidays.

What was your dream job as a kid?

I have, at least on and off, wanted to be a lawyer since I was fairly young. However, I have also, at various points, wanted to be a teacher, a novelist, and an illustrator.

What is your favorite fall activity?

Reading inside on a cold fall day, curled up with a warm blanket and a cup of hot cider.

What is the best trip you have taken?

I recently took a trip to Japan, and it was one of my favorite places to have visited. The food was amazing, the people were very kind and welcoming, and the cities and temples were beautiful and full of history.

Start Date: August 2016
Assigned Litigation: Abilify
Hometown: Sioux Falls, SD

The $300 Million Benicar Settlement

After several years of litigation, a $300 million Global Settlement has been reached with Daiichi Sankyo, the manufacturer of Benicar, for the gastrointestinal injuries caused by the drug. The settlement was announced in August 2017.

Benicar was approved in 2002 by the FDA. Since that time, thousands of gastrointestinal injuries have been associated with the drug. Studies have shown Benicar can cause damage to the small intestine. The injuries and conditions are very serious and caused hundreds to be hospitalized. Over 2,000 lawsuits were filed in a multidistrict litigation consolidated in the District of New Jersey. Senior Partner Stuart Goldenberg was appointed to the Plaintiff Steering Committee and Partner Laura Pittner was appointed to the discovery committee.

The $300 million settlement goes to individuals who experienced gastrointestinal problems, including chronic diarrhea, nausea, vomiting, weight loss, and/or villous atrophy due to the use of Benicar. An independent administrator has been appointed by the Judge to evaluate each case and assign an award. It will likely be another year before the settlement is completed and all cases are valued.

GoldenbergLaw is no longer taking Benicar claims, as the court-ordered deadline to participate in the Settlement was August 25, 2017. Thank you to all of our clients and referring attorneys for your trust and patience as we work to ensure all claimants are properly compensated.

GOLDENBERG LAW

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