The BOYK BULLETIN Special Edition

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Is Your Prescription Drug or Medical Device Causing Your Health Problems?

Not sure if your health problems are related to a recent surgery, implant, or drug? Boyk Law's Pharmaceutical and Medical Device Litigation Group has extensive experience researching, investigating, and litigating cases involving defective drugs, dangerous medical devices and other products, resulting in millions of dollars in compensation. As a result of our experience and our team's expertise, we have created an internal database of drugs that have been recalled, are in litigation, under investigation, or on our watch list. We are also constantly monitoring complaints, scientific research, and recalls of drugs and medical devices both here in the United States as well as internationally.

How much does it cost?

Our team of skilled lawyers, researchers, and medical staff routinely review cases - for free - and would be happy to investigate any concerns you may have with a medication or medical device. Simply visit www.isitalawsuit.com and fill out the confidential on the site so an attorney in our office can let you know if you have a potential claim. In the meantime, feel free to read in this newsletter current claims that are being investigated and how you can protect yourself if you feel that you may be suffering from a similar problem.

Attorneys! Do You Have A Client Facing Any of These Issues?

Call Us!

If your clients or callers are dealing with any of the medical issues mentioned in this newsletter, we would be happy to review the case for them. Our goal is to team with lawyers and provide our joint clients with the peace of mind that they will be receiving from our team a steady case flow and constant communication, while the referring attorney rests assured that the leg work is being handled with the utmost care. If you or a staff member would like to sit down with the attorneys at Boyk Law to discuss how you can be a part of our extensive Referral Network, **please call us at 888-888-2110.**

We look forward to working with you.

3M Bair Hugger

The 3M Bair Hugger is a warming blanket used to maintain a patient's body temperature during surgery. The surgical warming blanket is connected to a portable heater that blows warm air on a patient's skin. Studies have shown that keeping the body at proper temperature during surgery has many benefits including the reduction of recovery time. However, there has been an outbreak of patients developing serious infections following the use of these warming blankets. The issue seems to be that the medical device, which recirculates ambient air during surgery, takes up contaminated air, warms it and blows it on to the patient during surgery. This leaves patients with a greater risk of MRSA and other serious infections. Many patients who underwent hip or knee replacement surgery have suffered serious deep joint infections requiring revision surgery.

Who may have a lawsuit? Anyone suffering a serious infection after surgery who was also put under a 3M Bair Hugger during their procedure.

How do I know if a 3M Bair Hugger was used on me? If you can't remember a nurse placing one on you before surgery, the device would be mentioned in the operative report of a patient's medical records, patients can ask their surgeons, or Boyk Law would be happy to find out on your behalf. To receive immediate assistance and to learn more about the 3M Bair Hugger lawsuit, call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

Diabetes drugs - SGLT2 Inhibitors: Invokana, Invokamet, Farxiga, Xigduo XR, Glyxambi, Jardiance

Those with diabetes may be familiar with a class of drugs known as sodium-glucose co-transporter 2 (SGLT2) inhibiters. With the combination of diet and exercise, SGLT2 inhibitors are designed to lower blood sugar and improve glycemic control. However, the FDA has warned that these drugs may inhibit kidney function and lead to "ketoacidosis". Ketoacidosis is a severe condition in which the body is unable to get sugar needed for energy so it begins to break down fat and muscle for energy and releases "ketones" into the blood. The release of ketones into the blood produces abnormally high amounts of blood acid. Left untreated, ketoacidosis can lead to a diabetic coma or even death. The FDA as also issued an alert about an increased risk of bone fractures and bone loss associated with these drugs. Specifically, patients taking these drugs were nearly 50% more likely to suffer a fracture. Many individuals are stepping forward, accusing pharmaceutical companies of knowing about the risks of these drugs and not warning patients. If you take any SGLT2 inhibitor and, you should speak pharmaceutical team about your legal options.

Who may have a lawsuit? Anyone on diabetes medication who has developed ketoacidosis, kidney failure, or a suffered a fracture.

I'm a diabetic with one of these problems, but I don't know if I am taking one of those medications. Can you help me? If you are not sure which medication you are taking, talk to your physician or pharmacist, or Boyk Law would be happy to find out on your behalf. Simply call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

forxiga (dapagliflozin)

Invokamet canagliflozin/metformin HCl tablets

Surgical Mesh

The concept of using a mesh to reinforce week tissue has been around for decades. Surgeons use mesh to repair hernias, pelvic organ prolapse, and urinary stress incontinence. As the popularity of these surgical procedures grew, so did the development of new mesh products. Currently, there is a wide variety of mesh products. Products can be made of synthetic or biomaterial. They can be light-weight or heavy-weight, and have small pores or large pores. Different mesh products vary in their construction, elasticity, and the degree to which they shrink post-surgery. But what they all have in common is that they are a foreign body and likely will cause your body to react. Most of the time, reactions may be minor and tolerable. However, we are seeing an increase in serious reactions in several mesh products. Some reactions include fibrosis (thickening and scarring of connective tissue), blood clotting, serious infection, mesh migration, erosion, or organ perforation. The prevalence of these serious reactions and injuries has caught the eye of the FDA. The FDA recognized that complications from mesh products can be painful and life-altering, even after mesh is removed. In 2016, the FDA reclassified some mesh products as "high risk" and increased regulations based on thousands of reported complications. More than 100,000 surgical mesh lawsuits have been filed against manufactures. It appears that manufacturer knew about serious risks of using certain mesh products before their devices hit the market, but withheld this information from the public.

To date, manufacturers have collectively paid more than $2 billion to settle existing mesh claims, and continue to have multi-million dollar verdicts rendered against them.

Who may have a lawsuit? Anyone who has had surgical mesh implanted in their body and now experiencing health problems.

How do I know if it's the mesh that is causing my problems? Sometimes it can be hard for doctors to pinpoint what is wrong, which is why it is important to have experts familiar with the mesh litigation review your records with the help of our medical professionals trained to spot problems. To have Boyk Law do this on your behalf, call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

Risperdal

Risperdal (risperdone) is a prescription drug used to treat patients that suffer with varying forms of behavioral problems, including bipolar disorders and schizophrenia. The manufacturer of the drug, Jassen Pharmaceuticals, is a subsidiary of Johnson & Johnson. Although the drug has proven to be effective at treating a number of medical conditions, it is frequently prescribed for "off-label" use (a use for which it was neither tested or approved by the FDA).

It appears that part of Johnson & Johnson's marketing campaign for the drug was to give doctors thousands of free samples and encourage or even pay for them to market and prescribe the drug for off-label use to increase prescriptions. Following a federal criminal investigation into its conduct, J&J paid over $2.2 billion in penalties for misbranding the drug, promoting unapproved uses, as well as for paying kickbacks to physicians and nursing homes. Civil lawsuits continue with thousands being filed this year. It is believed that J&J misrepresented the potential benefits and risks of Risperdal for use in children. The drug, in many children or young adolescents taking it, causes elevated levels of prolactin, a hormone that causes breast tissue to grow. Many males go on to then develop gynecomastia, an abnormal growth of breasts tissue, or hyperprolactinemia, which cause males to produce breast milk. Often surgery is required to correct the painful and embarrassing condition. As is the case with all pharmaceutical and medical device injury cases, there are time limits to making a legal claim.

Who may have a lawsuit? Any male who has taken Risperdal for any reason and has since developed breast tissue.

How can I tell a difference between breast tissue growth from Risperdal versus weight gain? The attorneys in our office have helped patients dealing with that same question and we would be happy to explain the difference. Simply call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

Testosterone Replacement Therapy

The U.S. Food and Drug Administration recently announced they are investigating the safety of Testosterone treatments, such as Androgel, Testim and Axiron, after two studies have linked the drug to increased risks of cardiovascular injury. Among men younger than 65 who had pre-existing history of cardiac issues, a study found the risk of heart attack in the first 90 days following the first prescription of Testosterone nearly tripled. This drug is primarily used for men who have a deficiency of the male hormone and need assistance to improve their testosterone levels.

Who may have a lawsuit? Any male with any cardiac problem who has used testosterone therapies including Androgel, Testim, or Axiron.

What is the best way to prove that my heart problem is related to my testosterone drug use? The attorneys at Boyk Law will construct a plan for you to show eligibility for the lawsuit and the path to compensation. The first step is to call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

Taxotere

Taxotere, manufactured by Sanofi-Aventis, is a widely-used chemotherapy drug to treat breast cancer and other forms of cancer. The drug is administered intravenously to prevent cancer cells from spreading. While Taxotere can be effective in treating patients diagnosed with cancer, lawsuits are being filed against Sanofi-Aventis regarding Taxotere's link to permanent hair loss. Reports reveal that that manufacturer knew about the dangers of Taxotere but failed to mention it to patients and the medical community.

Who may have a lawsuit? Cancer patients who are dealing with permanent hair loss after undergoing chemotherapy.

I recently underwent chemo but my hair hasn't grown back yet. How long should I wait? While each individual is different, it is important to start the medical review as soon as possible as important deadlines are always arising in drug and device litigation. The attorneys at Boyk Law can create a reasonable timeline for you. Call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com to have an attorney begin the process for you.

Zofran

Zofran is an FDA-approved prescription medication used to treat nausea during chemotherapy. In recent years, the drug has developed popularity as an off-label treatment for nearly 1 million pregnant women who struggle with morning sickness. Unfortunately, the drug has recently been linked to serious birth defects such as cleft palate, and heart defects. Lawsuits are being filled claiming that the manufacturer, GlaxoSmithKline, was aware of the potential side effects but intentionally decided not to disclose the dangers to the public. To receive immediate assistance and to learn more about Zofran, call our office at 888-888-2110.

Who may have a lawsuit? Any mother who was taking Zofran or nausea medication during pregnancy whose child was born with a birth defect or health problems.

My child was born with health problems and I remember being given medication for morning sickness, but I'm not sure if it was Zofran. Can you still help me? Yes! Boyk Law can review your medical records and your child's medical records to pinpoint exactly what you were taking during pregnancy and if it is linked to what your child is facing now. Simply call our office at 888-888-2110 or confidentially ask additional questions by visiting www.isitalawsuit.com.

Hip Replacements

Hip replacement surgery is one of the most commonly performed joint replacement surgeries. Often, these surgeries provide people relief and increase their mobility. However, sometimes these procedures cause debilitating side effects and leave people worse off.

All artificial hip implants carry a variety of risks, but certain products have caught the attention of governmental agencies due to their failure rate or hazards associated with the materials they are made from. For example, metal-on-metal implants (MoM) have been shown to have additional risks associated with them. A MoM hip has a metal ball and a metal socket. When the metal components rub against each other tiny metal particles begin to wear off. Metal toxins can enter the bloodstream, cause damage to bone and/or tissue surrounding the implant. This tissue damage can lead to pain, implant loosening, and device failure. Many patients are required to undergo a painful revision surgery and often suffer post-revision complications.

Our office is investigating MoM hip cases as well as cases involving Stryker Orthopedics LFITTM CoCr V40TM hip replacement components. There have been higher than expected complaints of taper lock failures on these Stryker devices. Warnings and/or recalls have already been instituted in Canada, Australia, and the United Kingdom. Stryker issued a voluntary recall stating that it believed that all affected products have either already been implanted or removed from the market. Potential hazards associated with device failure include:

- **Disassociation of femoral head from hip stem**
- **Fractured hip stem trunnion**
- **Excessive metallic debris**
- **Insufficient range of motion**
- **Insufficient soft tissue tension**

Again, many patients that require revision surgery due to defective hip devices not only must endure the pain and healing time of undergoing a second surgery, but often suffer significant post-revision complications. If you or someone you provide care for has had a hip replacement you should be aware of any issues related to the specific hip product used. Talk to your health professional, particularly if you experience any unexpected pain, loss of mobility, inflammation, instability or other problems you think may be related to the implant.

Who may have a lawsuit? Anyone who has undergone a hip replacement and is either facing additional problems or had a revision surgery.

How do I know my surgeon implanted a metal-on-metal hip? If your physician or surgeon did not tell you if your hip replacement was metal-on-metal, the device name would be mentioned in the operative report of a patient's medical records or Boyk Law would be happy to find out on your behalf. To start the process, call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

PDE5 Inhibitors: Viagra & Cialis

Millions of men take Viagra or Cialis or similar drugs, for erectile dysfunction. If you are one of many who take these prescription drugs, you should be aware that these medications have been associated with an increased risk of developing skin cancer. While it may seem like these drugs and the risk of skin cancer are completely unrelated, it is the way these drugs work that link them to the increased risk. Specifically, these medications work in part by preventing the release of PDE5, an enzyme, which in turn helps blood flow and erectile function. However, research has shown that the blocking of PDE5 can lease to the creation of melanoma cells. It appears that drug makers knew about this risk, but did not advise the FDA and include it in its warning label or advertising materials. These dangerous side effects include:

- **Heart attacks**
- **Vision loss**
- **Hearing loss**
- **Melanoma**

Who may have a lawsuit? Any male Viagra or Cialis user who suspects that their health problems could be linked to taking the drug.

What if my doctor says that there is no link between Viagra or Cialis and the problems I've been having? Though no fault of their own, many doctors are completely unaware that the medications they have prescribed have dangerous side effects – they have simply taken the word of the drug manufacturer and the company's pharmaceutical sales rep. That is why it is important to have an experienced dangerous drug lawyer like the ones at Boyk Law review your case from a legal perspective. To speak with an attorney, call 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

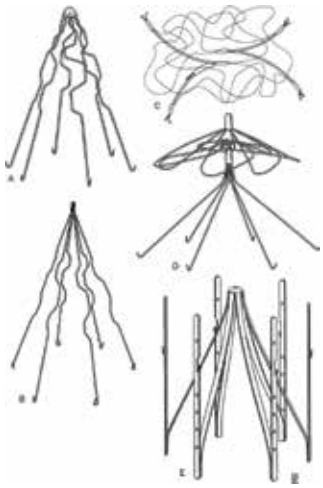
Xarelto

Xarelto, the number one prescribed blood thinner in America, is facing multiple lawsuits over an array of significant side effects including irreversible bleeding, stroke, and death. Xarelto, manufactured by Bayer, Janssen and Johnson & Johnson, is widely prescribed to help reduce the risk of blood clots and to treat deep vein thrombosis and pulmonary embolism. Despite being linked to thousands of injuries, no recall has been issued, and the drug continues to be prescribed to individuals across the country.

Who may have a lawsuit? Patients who are taking or have taken Xarelto and have suffered serious cardiac health issues.

Should I be worried if I am already taking Xarelto? Boyk Law would be happy to share with you the research linked to Xarelto so that you can discuss them with your doctor. You can call us at 888-888-2110 or confidentially ask additional questions by visiting www.isitalawsuit.com.

IVC Filters



Retrievable IVC (Inferior Vena Cava) filters are small spider-like devices built catch and dissolve blood clots. They are implanted into the vena cava in patients who are at high risk of pulmonary embolism, but cannot take blood thinners. The filter works by trapping or filtering blood clots before they travel to vital organs such as the heart or the lungs and cause serious, even life-threatening injuries. Retrievable IVD filters are designed for short-term use. Once a patient's risk for a pulmonary embolism has passed, the device should be promptly retrieved. Unfortunately, a greater than expected number of patients suffer adverse events associated with these devices. Two of the most serious complications occur when the filter comes loose or breaks apart. The device and/or the blood clots it was trapping may be carried to the heart or lungs;

- **Perforation: The IVC filter punctures and causes serious damage to the heart, lungs or vena cava**
- **Blockage;**
- **the filter**

The device contains struts that expand inside the vein to prevent blood clots from entering the heart, lungs or brain. However, reports indicate that filters have a design defect that can cause them to break apart and migrate through the body. Lawsuits have been filed against manufacturers of IVC filters claiming that the devices are defective and that manufacturers intentionally decided not to disclose the dangers to the public.

Who may have a lawsuit? Anyone who is experiencing complications after having a small device implanted into their vein to treat blood clots.

How do I know if my problem was caused by an IVC filter? Let Boyk Law do the research for you. To speak with an attorney, call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

Proton Pump Inhibitors

Proton pump inhibitor (PPI) medications are commonly prescribed to individuals with heartburn and acid reflux disease. They include products such as Nexium, Prilosec, Prevacid, and other similar drugs. Although these drugs may be the most powerful acid inhibitors, long-term use of PPI medications can potentially lead to complications with the body's ability to consume magnesium, calcium and other vital nutrients. As a result, this can put patients at a higher risk of suffering from:

- **Kidney damage**
- **Cardiac disorders**
- **Bone fractures**
- **Other serious medical problems**

A recent study in the Journal of the American Geriatrics Society found that dementia patients who take PPIs have an 89% increased risk of developing pneumonia compared to non-dementia patients taking the drugs.

Who may have a lawsuit? Anyone on heartburn or acid reflux medication that is facing other serious health issues that doctors cannot explain.

Is my medication on the list of drugs that lawsuits are being filed about? Boyk Law has access to a database of all drugs and medical devices that are currently under recall or being watched for problems and would be happy to find out on your behalf. Simply call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

Biomet Shoulder

Although less common than conventional total shoulder replacement, thousands of reverse total shoulder replacements are performed in the U.S. every year. Reverse total shoulder replacements are often performed on patients who have large rotator cuff tears that have caused them to develop arthritis. On December 20, 2016, Zimmer Biomet sent an Urgent Medical Device Recall of its Comprehensive Reverse Shoulder replacement system because specific devices were fracturing at a higher than expected rate. The recall is categorized by the FDA as a Class 1 – the highest recall level possible – meaning there's "a reasonable probability that use of these products will cause serious adverse health consequences or death." Patients whose reverse shoulder implants have fractured have had to go through additional surgery to fix the problem. This exposes patients to not only pain and suffering, but also increased risks of infection, permanent loss of shoulder movement, or even death. The device under the current recall was distributed between August 2008 and September 2015.

Who may have a lawsuit? Anyone who is dealing with any type of complication after having a shoulder replacement surgery.

How do I know my surgeon implanted a Biomet shoulder? If your physician or surgeon did not mention the Biomet by name, the device would be mentioned in the operative report of a patient's medical records or Boyk Law would be happy to find out on your behalf. To start the process, call our office at 888-888-2110 or confidentially provide your information by visiting www.isitalawsuit.com.

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Talcum Powder & Ovarian Cancer

Talcum powder is a mineral made up of elements containing silicon, magnesium, and oxygen. This powder can absorb moisture, oils and odor, making it a widely-used product among women. Although a popular cosmetic product, frequent talcum powder use on the female genital area increases the risk of ovarian cancer by more than 30%. In fact, reports indicate that thousands of women get ovarian cancer from talcum use each year. The discovery of internal records from Johnson & Johnson show that J&J knew about these dangers for decades, but intentionally decided not to disclose the dangers to consumers. To receive immediate assistance and to learn more about talc powder, call our office at 888-888-2110.

Who may have a lawsuit? Women who have used talc powder for more than five years and have been diagnosed with ovarian cancer.

I am a longtime talc powder user and have been diagnosed with another type of reproductive cancer, just not ovarian cancer. Do I still have a lawsuit? Since the talc powder litigation is constantly changing, Boyk Law wants to protect all women fighting reproductive cancers and would be happy to review the records of any talc user who has been diagnosed with other cancers, including:

- **Cervical**
- **Uterine**
- **Ovarian**
- **Vaginal**
- **Vulvar**

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