

Defective Medical Devices and Bad Drugs

Abilify

Abilify is an anti-psychotic drug developed and prescribed for schizophrenia, bipolar disorder, depression, Autism disorders and Parkinson's disease. Despite knowing of the risks linked to pathological gambling, hyper-sexuality, binge eating and compulsive shopping, the manufacturers chose not to warn users in the US of these possible side-effects. Despite this knowledge, the manufactures continued to aggressively promote Abilify until April 2015 when the FDA found Abilify promotional materials to be "...false or misleading because it makes claims and representations....and implies that Abilify offers advantages over other currently approved treatments....which have not been demonstrated".

IVC Filters

An IVC filter is a small strainer type of device used to filter out blood clots and assist in preventing them from forming and becoming pulmonary embolisms (a blood clot that travels to the lungs). IVC stands for Inferior Vena Cava, which is the large vein that enters the upper right chamber of the heart and delivers oxygen depleted blood from the legs, pelvis and abdomen back to the heart. The filters were designed for people who cannot take anticoagulants (blood thinners) and are at risk for pulmonary embolisms. Injuries can be in the form of: chest pain, confusion, heart rhythm irregularities, hypotension, lightheadedness, nausea, neck pain, shortness of breath, hemorrhaging, internal bleeding, pulmonary embolism, stroke and even death.

TransVaginal Mesh

Women suffering from pelvic organ prolapse (POP) and/or stress urinary incontinence (SUI) who sought help from a TransVaginal Mesh ("TVM") implant or pelvic/bladder support system may have been victims of a defective medical device. After the shocking results of a clinical study, victims are filing suit against the TVM manufacturers. Some of the side effects with TVM include: pain radiating into lower back or extremities, and/or during urination and intercourse, infection, migration, erosion and the need for corrective surgeries. These problems can develop shortly after implantation, but may also take years to develop.

Hernia Mesh

A hernia occurs when organs, intestines or connective tissue, breach a weak point or a hole in a muscle. This is often caused by some type of pressure such as heavy lifting or pulling. In order to repair a hernia, doctors often recommend a mesh patch to reinforce the muscle, close the hole and to reduce the likelihood of a reoccurring hernia. Hernia repair surgery is among the most common medical procedure done annually. Common complications after a mesh implant include: ongoing chronic pain, infections or abscesses, adhesive scar tissue, intestinal blockage/obstruction, organ perforation, allergic reaction, rejection of implant, foreign body reaction, mesh migration or erosion mesh shrinkage/contraction, dental problems, joint aches and pains, severe headaches, liver abnormalities and rashes. In May of 2016, Ethicon (a division of Johnson & Johnson) issued a voluntary recall of its Physiomesh Flexible Composite Mesa for laparoscopic use from the global market. The recall was initiated after two (2) studies revealed higher rates of hernias reopening and the need for more operations with the Ethicon mesh compared to similar hernia meshes. Other hernia mesh products named as defective include: Atrium C-Qur Mesa, Kugel Hernia Mesa, 3D Max Hernia Mesa, Perfix Plug Mesa, Ventralex ST Mesh patch, Sepramesh Patch, Surgipro Hernis Mesh and Paritex Plug and Patch System.

Xarelto

Xarelto is an anti-clotting, blood thinning medication similar to Coumadin (warfain) and Lovenox (enoxaparin). Xarelto is prescribed to reduce the risk of stroke and blood clots, as well as to treat deep vein thrombosis (DVT) and pulmonary embolisms (PE); especially after knee or hip replacement surgery. Possible side effects from Xarelto are: uncontrollable or unusual bleeding, discolored urine (blood in the urine), red or black-colored stools, vomiting or coughing blood, retinal hemorrhage, stroke and even death.

Benicar

Benicar is a prescription medication used to control high blood-pressure, but comes with the risk of developing serious intestinal problems such as: chronic diarrhea, nausea, vomiting, severe weight loss and malnutrition. In 2012 the Mayo Clinic published an article concluding that Benicar is associated with a serious intestinal

condition called "Severe Spruelike Enteropathy". Other clinical trials have found that taking Benicar can increase the risk of cancer, heart disease and diabetes in some patients.

Power Morcellators

In April of 2014, the FDA issued a warning advising surgeons not to use laparoscopic power morcellators during hysterectomy or myomectomy surgeries due to the risk they may spread undiagnosed cancerous uterine tissue to other parts of the body. The FDA estimated that approximately 1 in every 350 women who require a hysterectomy or myomectomy surgery for uterine fibroids have undiagnosed Uterine Sarcoma Leiomyosarcoma ("USLM"). USLM is a rare but highly aggressive form of cancer that occurs in smooth muscular part of the uterus. It typically occurs in women between the ages of 40 and 60 and is highly metastatic with nearly 70% of patients who had their tumors removed seeing a recurrence within 8 to 16 months.

Risperdal

Risperdal is the brand name for the drug Risperidone to treat schizophrenia in teenagers and adults, Bipolar I Disorder in those ages 10 and older, and irritability associated with autistic disorder in children age 5-16 years. According to FDA, elderly dementia patients who took Risperdal are 1.6 - 1.7 times more likely to die of various ailments, including heart disease and pneumonia. Medical research has also found a connection between Risperdal and adolescent male breast enlargement (Gynecomastia) and production of milk from breasts (Galacomastia). It is also believed that Risperdal may cause heart disease, diabetes, Neuroleptic Malignant Syndrom (NMS), Tardive Dyskinesia (TD) and a decreased white blood cell count.

Zofran

Zofran is manufactured by GlaxoSmithKline ("GSK") and was approved by the FDA for preventing nausea and vomiting due to chemotherapy and surgery. Although Zofran is not approved for any other indication, it is often prescribed "off-label" by physicians to treat morning sickness in pregnant women. Studies published in 2013 and 2014 found that Zofran is associated with an increased risk of heart defects and oral clefts in newborns if taken by women during the first trimester. In 2012 the U.S. Department of Justice reached a \$3 billion settlement with GSK after the government alleged it illegally promoted the off-label uses of several drugs, including promoting Zofran for use by pregnant women to treat morning sickness.

Asbestos Exposure

Asbestos fibers are microscopic and durable and were therefore used in a variety of industries for many years. Workplace exposure to asbestos materials was extremely common in naval shipyards, power plants, railroad infrastructure and other industrial jobsites including many of the construction trades. Asbestos related diseases can lay latent or dormant for many years and has been diagnosed in family members of those exposed to asbestos because these dangerous fibers were transported on the clothing, hair or the body, exposing others with to the same dangerous asbestos fibers. Asbestos exposure can be deadly.

Orthopedic Devices

DePuy hip and knees, Striker hip, Wright hip and Zimmer hip.

Air Bags

On June 11, 2014, the NHTSA opened a formal defect investigation (Preliminary Evaluation, P# 14-016) into Takata air bag inflators that may become over-pressurized and puncture during air bag deployment, resulting in injury to the driver and/or passenger. On February 24, 2015, the NHTSA upgraded and expanded its investigation to include various model year 2001-2011 motor vehicles, which contain air bag inflators manufactured by Takata. During the course of the NHTSA's investigation and its review of documents produced by Takata, the agency discovered facts and circumstances indicating that Takata may have violated the Safety Act and its regulations. Takata failed to comply fully with the NHTSA instructions and thus were ordered to pay a \$200 million dollar civil penalty over the course of five years to the federal government. The air bag recall is now a full-blown crisis with nearly 70 million vehicles in the US and 100 million worldwide recalled. The recall includes vehicles from Honda, Toyota, Mazda, BMW and Audi just to name a few. To see a complete list of vehicles with air bag recalls visit <https://www.nhtsa.gov/recall-spotlight/takata-airbags>

For more information on these, or any other defective medical device or bad drug, please contact **Billie-Marie Morrison, Esq. at bmorrison@cpklaw.com or 702-380-2800.**