Alley ◆ Clark ◆ Greiwe
701 East Washington Street
Tampa, FL 33602

PRST STD
U.S. POSTAGE
PAID
TAMPA FL
PERMIT NO 3024

Client Newsletter

Alley ◆ Clark ◆ Greiwe

Spring 2012

In Brief

2011-2012 BEST LAW FIRMS U.S.News & World Report Best Lawyers®

In This Edition

Like

Become a fan on Facebook
Alley.Clark.Greiwe

SUBSTANTIAL BLEEDING RISKS ASSOCIATED WITH BLOOD THINNER DRUG PRADAXA

The attorneys at **Alley, Clark & Greiwe** are investigating claims of persons severely injured while taking the blood thinner Pradaxa. Pradaxa, also known as dabigatran, is prescribed to prevent strokes and blood clots in people who have atrial fibrillation without valvular heart disease. Pradaxa has only been available in the U.S. since the Fall of 2010, and is a new alternative to other anti-coagulants like Coumadin and Warfarin. While those medications require frequent lab monitoring on the patients ingesting them, Pradaxa does not. It is this advantage that has been a key selling point.

However, within weeks of its launch in the U.S., the FDA received an unusually high number of early adverse event reports about Pradaxa regarding its effects on bleeding or clotting events, including hemorrhages (too much anti-clotting effect) and thromboembolic events (too little clot inhibiting effect) such as pulmonary embolism and deep vein thrombosis. Some of the reports involved fatalities. Additionally, it has been determined that Pradaxa significantly increases a patient's risk of heart attack. An analysis of seven clinical trials published in January in the *Archives of Internal Medicine* found that Pradaxa was "significantly associated with a higher risk" of heart attacks and acute coronary syndrome, or ACS.

If you or a loved one have suffered a stroke, heart attack, brain bleed, gastrointestinal bleed, or death while taking Pradaxa, please contact the experienced trial attorneys at **Alley, Clark & Greiwe** for information about your legal rights.

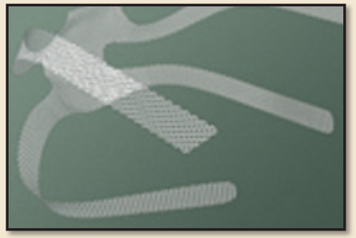
If you are presently taking Pradaxa, please call your health care provider immediately if you develop any of the following signs or symptoms of bleeding:

- Unusual bleeding from the gums
- Frequent nose bleeds
- Menstrual or vaginal bleeding that is heavier than normal
- Severe or unusual bleeding
- Pink or brown urine
- Red or black stools (looks like tar)
- Bruises that happen without a known cause or that get larger
- Coughing up blood or blood clots
- Vomiting blood or vomit that looks like coffee grounds

ALLEY ◆ CLARK ◆ GREIWE 701 E. WASHINGTON STREET, TAMPA, FL 33602 TEL: (813) 222-0977 FAX: (813) 224-0373 TOLL FREE (800) 840-0977

PELVIC MESH CLAIMS

JOHNSON & JOHNSON VAGINAL MESH PRODUCT SOLD FOR 3 YEARS WITHOUT U.S. APPROVAL



The alarming safety controversy regarding pelvic mesh products utilized during the surgical repair of certain female conditions continues to mount. The mesh products at the center of the litigation are made of a non-absorbable synthetic polypropylene and are implanted transvaginally to treat pelvic organ prolapse or urinary problems. On March 21, 2012, *Bloomberg* reported on the disturbing news that Johnson & Johnson's Ethicon unit sold a particular vaginal mesh product, the Gynecare Prolift, for three years before it actually obtained proper FDA approval in 2008.

There are numerous manufacturers of synthetic vaginal mesh products, and the adverse reports have been linked to multiple manufacturers/brands mesh. If you or a loved one have suffered a serious complication following mesh-repair surgery for pelvic organ prolapse or stress urinary incontinence, please contact the experienced trial attorneys at **Alley, Clark & Greiwe** for information about your legal rights.

Background on FDA Approval Process for Vaginal Mesh

Mesh products first came on the market in the 1950s for use in hernia repairs. In the 1970s, surgeons began using the mesh "off label" for abdominal procedures, and for vaginal procedures in the mid-1990s. Under the FDA's controversial 510(k) approval process, the agency granted approval for using the mesh in vaginal procedures in 2002. This approval process did not require new studies demonstrating safety or efficacy because mesh products were already in widespread use and were considered substantially equivalent to mesh products already on the market.

Complications Related to Vaginal Mesh

Studies indicate that nearly 10% of women who have the mesh placed transvaginally experience mesh erosion (also called exposure, extrusion, or protrusion) within 12 months of surgery. Mesh erosion can require multiple surgeries to repair and can be debilitating and life-altering for some women. The other most frequent complications include pain, dyspareunia (painful sexual intercourse), infection, urinary problems, bleeding, organ perforation, recurrent prolapse, neuromuscular problems, and vaginal scarring/shrinkage.

FIRM NEWS

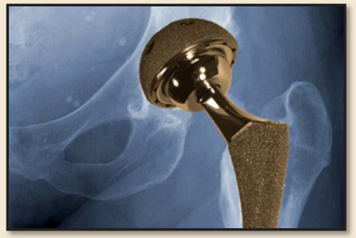
2011-2012 BEST LAW FIRMS U.S.News & WORLD REPORT Best Lawyers®

On November 1, 2011, U.S. News Media Group and Best Lawyers® released the 2011-2012 Best Law Firms rankings. For the second straight year, the law firm of **Alley, Clark & Greiwe** was honored with a First-Tier ranking in the Tampa metropolitan area in both **medical malpractice** and **personal injury litigation**. After years of representing thousands of clients all over the State of Florida, our firm has established a solid reputation of seeking justice for injured persons. We are committed to providing our clients with the best legal representation available. If you or a loved one has a question about a potential case or wish to inquire about our legal services, we hope that you will contact our office.

Moving Soon? Please be sure to keep us updated with any changes to your address or phone numbers.

METAL-ON-METAL HIPS

BRITISH EXPERTS: STOP USING METAL-ON-METAL HIP REPLACEMENTS



In March of 2012, a new study was published in the medical journal *Lancet* regarding the safety of metal-on-metal hip implants. Experts in Britain studied data from more than 400,000 hip replacements in the National Joint Registry of England and Wales, the world's largest joint registry. Researchers focused on the years 2003-2011 and found that metal-on-metal hips were repaired or replaced 2-3 times more often than traditional implants made of ceramic or plastic. Britain's health regulators urge its citizens to undergo annual examinations for as long as they have a metal-on-metal hip in place.

Previous studies have shown that metal-on-metal hip implant components wear down quickly and generate metallic debris. Such debris can cause pain, inflammation, swelling, tissue damage around the joint, and bone destruction in some patients. Last year in the U.S., the FDA ordered metal-on-metal hip manufacturers to conduct post-market surveillance studies due to serious safety concerns. To date, only one particular model called the "ASR" (manufactured by DePuy/Johnson & Johnson) has been recalled in the United States. The FDA announced on March 28, 2012, that it will convene an advisory committee in June regarding metal-on-metal hips.

The attorneys at **Alley, Clark & Greiwe** have extensive experience in representing persons injured by defective joint replacement products and other defective medical devices. Currently, our firm is litigating claims of persons implanted with metal-on-metal hip implants made by Zimmer, Smith & Nephew, and DePuy/Johnson & Johnson. If you or a loved one have been implanted with a metal-on-metal hip implant and have undergone revision surgery or suspect that you may need to undergo surgery in the future, please contact our firm for important information regarding your legal rights.

What medical effects might a metal-on-metal hip implant cause?

Metallic "wear debris" can cause a reaction around the hip joint, leading to deterioration of the tissue around the joint, loosening of the implant and failure of the device. In addition, metal ions from the implant may enter into the bloodstream. There have been case reports of patients with metal-on-metal hip implants developing a reaction to these ions which have the potential to lead to negative impacts on the nervous system, heart and thyroid gland.

What should you do if you are experiencing adverse events associated with a metal-on-metal hip implant?

If you are experiencing hip/groin pain, difficulty walking or a worsening of your previous symptoms, you should make an appointment to see your orthopedic surgeon for a physical exam and an evaluation based on your symptoms. Additionally, patients with metal-on-metal hip implants should have yearly blood tests to check chromium and cobalt metal ion levels to monitor dangerous metal levels in their bodies.

Reported problems with Metal-on-Metal Hip Implants Include:

- Severe pain in groin, hip, or leg
- Unusual "clicking" or "popping" of the joint
- Loosening of the product from the bone
- Loosening of the product causing fracture in surrounding bone
- Bone and tissue damage and/or necrosis from metallic wear debris
- Elevated levels of cobalt and chromium in patients' bloodstreams
- Serious injuries due to cobaltism, or cobalt poisoning
- High early failure rate

ALLEY ◆ CLARK ◆ GREIWE 701 E. WASHINGTON STREET, TAMPA, FL 33602 TEL: (813) 222-0977 FAX: (813) 224-0373 TOLL FREE (800) 840-0977