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

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IN BRIEF

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In This Edition

SURGEONS WARNED AGAINST USING SURGICAL MESH IN PELVIC SURGERIES

On July 13, 2011, the FDA issued a new advisory warning about plastic surgical mesh utilized during transvaginal surgeries to correct common female gynecological problems. The surgical mesh is made from porous synthetic material and is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat stress urinary incontinence. U.S. physicians perform about 75,000 surgeries utilizing these mesh products each year. From 2008 to 2010, the FDA received more than 1,500 Adverse Event Reports related to complications associated with the plastic mesh.

Thousands of women suffering pelvic organ prolapse are treated with plastic mesh each year, but reports indicate surgery can often be performed safely and effectively without the need for mesh. Recent studies indicate that about 10% of women who have the mesh placed transvaginally experience mesh erosion within 12 months of surgery and more than half of those women require additional surgeries to remove the mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complications.

Serious Complications Associated with Surgical Mesh Products Include:

- Infection
- Extreme pelvic pain
- Bleeding
- Dyspareunia (painful intercourse)
- Erosion/Protrusion of mesh through the vaginal wall
- Vaginal scarring
- Multiple surgeries to remove imbedded mesh

Under the FDA's controversial 510(k) approval process, the agency granted approval for use of the mesh in vaginal procedures in 2002 without requiring new studies demonstrating their safety or effectiveness since mesh products were already in widespread use and were "substantially equivalent" to mesh products already on the market. The FDA plans to convene an advisory committee of experts this Fall to determine whether to ban the mesh.

If you are considering this type of surgery in the near future, be certain to ask your doctor if mesh will be used during your surgery. Also, talk to your surgeon about all available treatment options, including surgical repair without mesh and non-surgical options.

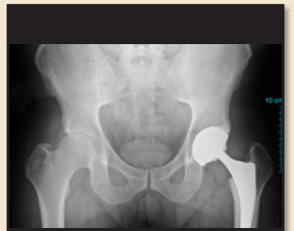
If you or a loved one have suffered a serious complication following mesh-repair surgery for pelvic organ prolapse or stress urinary incontinence, please contact the experienced trial attorneys at **Alley, Clark & Greiwe** for information about your legal rights.

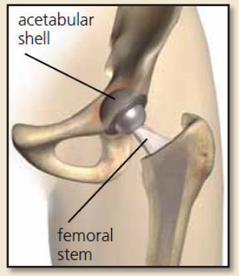
ALLEY ◆ CLARK ◆ GREIWE 701 E. WASHINGTON STREET, TAMPA, FL 33602 TEL: (813) 222-0977 FAX: (813) 224-0373 TOLL FREE (800) 840-0977

METAL HIP IMPLANT LITIGATION

FDA ORDERS HIP MANUFACTURERS TO CONDUCT POST-MARKET STUDIES ON CHROMIUM AND COBALT ELEVATIONS IN PATIENTS WITH METAL-ON-METAL HIP IMPLANTS

The law firm of **Alley, Clark & Greiwe** continues to aggressively pursue claims on behalf of persons who have suffered serious injury and disability directly related to metal-on-metal hip implants manufactured by several orthopedic companies including DePuy Orthopedics, Johnson & Johnson, Zimmer Orthopedics, and Smith & Nephew. Finally, the FDA is taking a closer look at all metal-on-metal hip implants and has ordered 21 manufacturers to conduct post-market safety studies due to concerns that metal hip implants create a dangerous level of heavy metals in patients' bloodstreams.





Sadly, metal implants are another product approved under the FDA's controversial 510(k) approval process which did not require submission of any studies demonstrating their safety or effectiveness. Until recently, more than one-third of all hip replacements performed annually in the U.S. were performed with metal-on-metal implants where the ball-and-socket are made from metals like cobalt and chromium. All metal prosthetic hip implants generate metallic "wear debris" as the weight-bearing surfaces of the metal components rub together. The metallic debris generated can lead to a unique complication called metallosis, which is the build-up of metallic debris in the surrounding soft tissues that can contribute to early implant failure and other significant complications in some patients.

If you or a loved one have been implanted with a metal hip implant device within the last few years and have undergone early revision surgery, please contact the law firm of **Alley, Clark & Greiwe** for important information regarding your legal rights.

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

Cobalt Frequently Asked Health Questions:

What is cobalt?

Cobalt is a naturally occurring element found in rocks, soil, water, plants, and animals. Cobalt is used to produce alloys used in the manufacture of aircraft engines, magnets, grinding and cutting tools, artificial hip and knee joints. Cobalt compounds are also used to color glass, ceramics and paints, and used as a drier for porcelain enamel and paints.

How can cobalt affect my health?

Cobalt can benefit or harm human health. Cobalt is beneficial for humans because it is part of vitamin B12. Exposure to high levels of cobalt can result in lung and heart complications and dermatitis. Liver and kidney issues have also been observed in animals exposed to high levels of cobalt.

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

HOT TOPICS

PLIVA v. MENSING: BAD NEWS FOR CONSUMERS OF GENERIC DRUGS

On June 23, 2011, the U.S. Supreme Court ruling in the case of *Pliva v. Mensing* was a victory for the pharmaceutical industry. Under this decision, generic drug manufacturers are shielded from liability for failure to adequately warn consumers of possible side effects associated with their products. Unfortunately, as a result of this one ruling, an untold number of pending lawsuits for citizens injured by generic drugs will be dismissed and numerous other claims will never be filed in state courts. This is especially disturbing since an estimated 75% of the prescriptions written in the United States are for the generic versions of more costly brand name drugs. Without regulatory and/or legislative intervention, this decision has a devastating effect on an injured consumer's ability to bring a claim against the manufacturers of generic drugs. State law failure-to-warn claims will continue against brand name manufacturers but, for the time being, the same exact claims against generic manufacturers are preempted by federal law.

ACTOS LINKED TO BLADDER CANCER

In September of 2010, the FDA began a formal safety review of the Type-2 diabetes drug Actos (pioglitazone), after receiving disturbing preliminary data mid-way through a 10-year clinical trial which showed a significant increase in bladder cancer among patients taking the drug. The data did not indicate an across-the-board increased risk of bladder cancer among all patients; rather, the risk of bladder cancer went up with cumulative dose and duration of pioglitazone use. The study data showed a 40% increased risk of bladder cancer in patients taking the drug for more than one year.

Recently, on June 16, 2011, the FDA officially announced that patients who use Actos for more than one year have an increased risk of developing bladder cancer, and product warning labels will be added to include this risk. People currently taking Actos should continue taking it until advised otherwise by their health professional. Those who are concerned about the possible risk of bladder cancer should talk to their health care provider. If you or a loved one has taken Actos and have been diagnosed with bladder cancer, please contact the law firm of **Alley, Clark & Greiwe** for important information regarding your legal rights.

Facts About Actos (pioglitazone):

- Actos is used along with diet and exercise to improve control of blood sugar in adults with Type-2 diabetes.
- From January 2010 through October 2010, approximately 2.3 million patients filled a prescription for a pioglitazone-containing drug.
- Actos had sales of $4.8 billion in the last fiscal year making it Japan-based Takeda Pharmaceuticals's best selling drug.

Pioglitazone-containing drugs impacted by the new FDA warnings include:

- Actos
- Actoplus Met
- Actoplus Met XR
- Duetact