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IN BRIEF

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TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LINKED TO INCREASED RISK OF HEART ATTACK, STROKE, AND DEATH

Sales of testosterone supplements in the form of gels, injections, pellets, pills, patches have skyrocketed in recent years leading to a multi-billion dollar industry with millions of prescriptions written each year in the U.S. Recent medical literature suggests that middle-aged and older men who take prescription testosterone supplements may be putting themselves at increased risk of heart attack, strokes or death.

On January 31, 2014, the FDA announced it would begin investigating whether there is an increased risk of heart attacks, stroke, and death in men using testosterone products. This decision came after a large new study found that prescription testosterone raised the risk of heart attacks in middle-aged and older men with a history of heart disease. The study tracked 56,000 men around the country who used testosterone products between 2008-2010. Study data showed the men had **double the rate of heart attacks** in the months after starting testosterone replacement therapy compared to the year before starting testosterone replacement.

This is not the first study in recent months that has highlighted a growing safety concern. A study published in November 2013 in the Journal of the American Medical Association followed 8,000 male veterans during the years 2005-2011 and found a **30% increased risk** of stroke, heart attack, and death in the group that had been prescribed testosterone replacement therapy compared to those not taking testosterone. The difference could be seen even after researchers factored in age, pre-existing heart disease, and other various factors. Another study published by the New England Journal of Medicine in June 2010 also found an increased risk of heart attacks and hypertension. Researchers discontinued the study due to health and safety concerns.

If you or someone you know suffered a heart attack, stroke, or death while using prescription testosterone products, please contact **Alley, Clark & Greiwe** to discuss your potential case.

Common Brand Name Testosterone Replacement Therapy Supplements		What is Testosterone Replacement Therapy?
Androgel	Androderm	Testosterone replacement therapy is approved specifically for the treatment of abnormally low testosterone levels, often referred to as "low T." The hormone helps build muscle, reduce body fat, and improves libido.
Axiron	Bio-T-Gel	
Depo-Testosterone	Delatestryl	
Fortesta	Striant	
Testim	Testopel	

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MASS TORT LITIGATION UPDATE: VAGINAL MESH

AJOG PUBLISHES ALARMING STUDY ON COMPLICATIONS OF SYNTHETIC MESH

In February 2014, the *American Journal of Obstetrics and Gynecology* published the results of a four year research study examining synthetic mesh-related complications after surgery for stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP).

Study data was based on 347 women who underwent pelvic reconstructive surgery between 2006-2010. 50% of the women underwent surgery for stress urinary incontinence (SUI) with a sling only, 25% underwent surgery for pelvic organ prolapse (POP), and the other 25% had a combination of SUI and POP. Of those who had a POP procedure, synthetic mesh was used in 85% of the procedures.

Study participants were examined at one of 4 facilities in the US approximately 6 months after their initial surgery. Study data showed over 25% of women had already sought help for complications by the six-month mark. The top complaints were mesh erosion (42%), pelvic pain (36%) or painful intercourse (30%). A staggering 77% of women were found to have suffered a "severe" complication (i.e. interventional procedure or reoperation with nearly one-quarter of the women requiring more than one surgical procedure). Findings showed patients who received synthetic mesh for POP were significantly more likely to have to return to the operating room compared to those women who had a bladder sling alone.

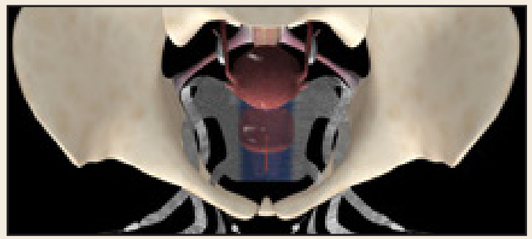

Illustration of synthetic mesh product.

FDA MOVES TO RECLASSIFY VAGINAL MESH AS HIGH-RISK DEVICE

In April 2014, the FDA finally submitted proposals to reclassify synthetic vaginal mesh implanted for the treatment of pelvic organ prolapse to a high risk device and would require manufacturers to apply for pre-market approval. Premarket approval is a process that requires a manufacturer to provide the FDA with clinical data to demonstrate the safety and effectiveness of a product before it can be sold. Currently, synthetic vaginal mesh is classified as a moderate risk device meaning that the products were cleared for sale based upon the manufacturers' assertion that the mesh was substantially similar to previously approved mesh products. However, some of the predicate products were removed from the market and/or recalled because they were defective and injured patients. Sadly for women, this move to reclassify comes almost three years after the FDA first addressed the serious complications with vaginal mesh being used in repair of pelvic organ prolapse and numerous years after these products were first marketed. In addition, the proposed reclassification does not include transvaginal mesh bladder sling products implanted for the treatment of stress urinary incontinence.

Serious Complications Associated with Surgical Mesh Products

- Chronic Infections
- Chronic Pelvic Pain
- Abnormal Bleeding
- Dyspareunia (Painful Intercourse)
- Erosion/Protrusion of Mesh through the Vaginal Wall
- Vaginal Scarring/Deformity
- Multiple Surgeries to Remove Imbedded Mesh
- Urinary Problems

MASS TORT LITIGATION UPDATE: ACTOS

$9 BILLION JURY VERDICT FOR PLAINTIFF IN FIRST ACTOS BLADDER CANCER MDL BELLWETHER TRIAL

In April 2014, a U.S. jury in Louisiana awarded a $9 billion punitive damages award - one of the largest in U.S. history. The case involved the diabetes drug Actos and the Plaintiff claimed that bladder cancer risks were concealed by the manufacturers. The verdict included a $3 billion award against Eli Lilly & Co., which jointly marketed Actos with Japan-based Takeda Pharmaceuticals. This was the first federal case to be tried in the Multi-District Litigation (MDL) proceedings comprising of nearly 3,000 lawsuits, and there are thousands of other cases pending in state court jurisdictions in Illinois, Nevada and California as well. Obviously, the verdict is being appealed and may ultimately be reduced. Critics of the amount of the award have also voiced concerns that the verdict in this case will not have the impact that many Plaintiffs may have hoped stating that the high dollar amount will not lead to meaningful settlement discussions or resolution of other Actos claims.

During the trial, it was revealed that Takeda breached a duty to preserve evidence and repeatedly (and intentionally) destroyed voluminous emails and other internal company documents proving that Takeda knew Actos could cause bladder cancer. This information was said to have been deleted during a litigation hold set by Takeda, in which "any and all documents and electronic data which discuss, mention, or relate to Actos," was forbidden to be destroyed. Given the amount of the punitive damages award, the jury was clearly outraged by the spoliation and destruction of evidence.

Germany and France suspended use of Actos, a multibillion-dollar seller, in 2011 because of concerns about a possible link to cancer. The drug remains on the market in the U.S. If you or a loved one has taken Actos, Actoplus Met, Actoplus Met XR, or Duetact and have been diagnosed with bladder cancer, please contact **Alley, Clark & Greiwe** for important information regarding your legal rights.

Summary of Actos Jury Verdicts to Date Across the U.S.

Cooper v. Takeda	California	Spring 2013	$6.5 million jury verdict thrown out by trial judge.
Ap v. Takeda	Maryland	Fall 2013	$1.7 million jury verdict thrown out by trial judge.
Alsabagh v. Takeda	Las Vegas	December 2013	Jury verdict for defense.
Allen v. Takeda	Louisiana (MDL case)	April 2014	$9 billion jury verdict. Defense vows to appeal.
Whitlatch v. Takeda	Illinois	May 2014	Jury verdict for defense.
Cipriano v. Takeda & Triana v. Takeda	Nevada	May 2014	Multi-plaintiff trial. Jury verdict for defense.

Moving Soon? Please call or email us with any changes to your address or phone numbers.