FIRM NEWS

FIRM RECOGNIZED FOR LEGAL EXCELLENCE

On November 2, 2015, *U.S. News Media Group* and *Best Lawyers®* released the 2016 "Best Law Firms" rankings by state. We are proud to announce that for the sixth consecutive year **Alley, Clark & Greiwe** has been recognized with a "First Tier" ranking in the Tampa metropolitan area in **Medical Malpractice Law, Products Liability Litigation,** and **Personal Injury Litigation.** Achieving a high ranking is a special distinction that signals a unique combination of excellence and breadth of expertise. After years of representing thousands of clients throughout the State of Florida, our firm has established a solid reputation of seeking justice for injured persons. If you or a loved one has a question about a potential personal injury case or wish to inquire about our legal services, we hope that you will contact our office for a free legal consultation.

CURRENT LITIGATION PROJECTS

Auto Accidents Car, truck, motorcycle, bicycle and pedestrian accidents; accidents/injuries caused by distracted drivers	**Medical Malpractice** Serious permanent injuries caused by error of a medical provider	**Wrongful Death** Accidental death caused by the action of another (drug company, reckless driver, medical mistake)
Vaginal Mesh Synthetic mesh used in females to correct pelvic organ prolapse and/or urinary incontinence	**Xarelto** An alternative to Coumadin, this blood thinner has been linked to serious bleeding events and fatalities	**Metal-on-Metal Hips** Hip implants linked to high failure rates, metallosis, pseudo-tumors, chronic pain
Testosterone Replacement Testosterone supplements linked to increased risk of stroke, heart attack and death	**Benicar** Blood pressure medication linked to serious gastrointestinal complications	**Zofran** Nausea medication prescribed during pregnancy linked to serious birth defects
IVC Filters Certain implantable IVC filters linked to higher rate of filter migration, fracture, or embolization	**Invokana** Type-2 diabetes drug linked to ketoacidosis, heart attacks, kidney damage	**"Bair Hugger" Warming Blanket Claims** Forced-air warming device used in orthopedic surgery linked to post-operative joint infections
Taxotere Chemo drug linked to permanent hair loss	**Talc Powder** Common household product linked with ovarian cancer	**Actos** Type-2 diabetes medication linked to bladder cancer

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CLIENT NEWSLETTER Alley ◆ Clark ◆ Greiwe SPRING 2016

IN BRIEF

Best Lawyers® BEST LAW FIRMS U.S.News & World Report 2016

In This Edition

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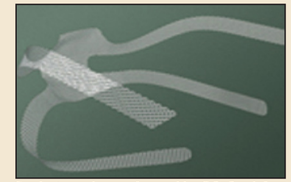
FDA FINALLY RECLASSIFIES CERTAIN VAGINAL MESH PRODUCTS AS HIGH-RISK

At last, the FDA has finalized its proposals from April of 2014 to reclassify certain transvaginal mesh products from Class II medical devices to Class III devices. Class III medical products are considered high-risk devices that must undergo the agency's most stringent safety evaluation before being put on the market. In other words, manufacturers must provide the FDA with clinical data to demonstrate the safety and efficacy of a product before it can be sold. The reclassification only applies to transvaginal mesh used to treat pelvic organ prolapse (POP) and does not include transvaginal mesh sling products implanted for the treatment of stress urinary incontinence. Companies *already* selling the vaginal mesh products (Johnson & Johnson/Ethicon, Boston Scientific Corp., C.R. Bard, Inc., etc.) will still have two years to submit their premarket approval applications.

Companies making new transvaginal mesh devices for POP repair must submit a premarket approval application before the new products can be sold.



Synthetic mesh manufactured by C.R. Bard, Inc.

If you or a loved one has suffered a serious complication following vaginal mesh-repair surgery, please contact the experienced trial attorneys at **Alley, Clark & Greiwe** for information about your legal rights.

Serious Complications Associated with Vaginal Mesh Products:	Manufacturers of Vaginal Mesh Include:
• Chronic Infections • Chronic Pelvic Pain • Abnormal Bleeding • Dyspareunia (Painful Intercourse) • Erosion/Protrusion of Mesh Vaginal Scarring/Deformity • Multiple Surgeries to Remove Embedded Mesh • Urinary Problems	• American Medical Systems (AMS) • Boston Scientific Corp. • C.R. Bard, Inc. • Ethicon/Johnson & Johnson • Coloplast/Mentor • Caldera Medical • Cook Medical • Covidien/Tyco Healthcare

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EMERGING MASS TORTS

CHEMOTHERAPY DRUG TAXOTERE LINKED TO PERMANENT HAIR LOSS

Our law firm has recently begun investigating claims for patients who underwent chemotherapy with the drug Taxotere (docetaxel) and developed permanent hair loss. Taxotere is a chemo drug used for treatment of breast cancer and other types of cancers. The drug manufacturer was forced to update the drug label for Taxotere in December 2015 to add a warning regarding the risk of **permanent alopecia** due to a significant number of cases of permanent hair loss being reported to the FDA.

It is alleged that the drug manufacturer (Sanofi-Aventis) knew about the risk of permanent hair loss, but failed to warn patients and physicians in the United States of this risk. As early as 2005, Sanofi-Aventis made a report to the European Medicines Agency warning about the potential for permanent hair loss after treatment with Taxotere. In Canada, a similar warning was issued in 2012 regarding the potential side effect of permanent hair loss after the use of Taxotere. Inexplicably, doctors and patients in the U.S. did not receive warnings of potential permanent alopecia until December 2015.

If you or a loved one experienced permanent hair loss after being treated with Taxotere for breast cancer, please contact **Alley, Clark & Greiwe** for a free consultation regarding your legal rights. It is possible that thousands of women across the U.S. have been negatively impacted after being treated with Taxotere.

J&J SLAMMED WITH $72M VERDICT IN TALCUM POWDER CANCER CASE

Last month a jury in a St. Louis ordered Johnson & Johnson to pay $72 million ($10 million compensatory; $62 million punitive) to the family of a woman who died from ovarian cancer after using J&J's Baby Powder and Shower to Shower for 35 years for feminine hygiene. This is the first jury verdict in a baby powder case to result in monetary damages to a Plaintiff.

To date, about 1,000 cases have been filed in Missouri, and an additional 200 in New Jersey against J&J. Trials in several other talc lawsuits have been set for later this year and thousands of cases are being investigated. It is alleged that J&J conducted little or no research even though over 20 epidemiologic studies revealed an association between talcum powder and ovarian cancer. Allegedly, regular, long-term use of talc powder in the genital or perineal areas may double or triple the risk of developing ovarian cancer.

For nearly 30 years, the attorneys at our firm have represented people seriously injured by pharmaceutical and medical devices. If you or a loved one has developed ovarian cancer after regularly using talcum powder for feminine hygiene, please contact **Alley, Clark & Greiwe** for a free case evaluation.

LITIGATION UPDATES

SECOND TRIAL INVOLVING DEPUY "PINNACLE" METAL-ON-METAL HIPS RESULTS IN HUGE WIN FOR PLANTIFFS

After a two-month trial and 6 days of deliberations, DePuy Orthopedics (a division of Johnson & Johnson) was hit with huge $497.6 million verdict ($360 million in punitive damages) by a jury. This is the second bellwether trial to take place in the U.S. in the multi-district litigation proceedings in Dallas, Texas. The consolidated trial involved five different plaintiffs, all of whom alleged similar problems from their Pinnacle hip devices, and the jury found in favor of all five plaintiffs in the trial. The first bellwether trial in the MDL proceedings in 2014 resulted in a defense verdict by the jury. There are more than 8,000 cases Pinnacle hip devices pending in the MDL federal court proceedings.

Our firm continues to litigate claims involving persons injured by defective joint replacement products and other defective medical devices. 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 **Alley, Clark & Greiwe** for important information regarding your legal rights.

INFERIOR VENA CAVA FILTER (IVC) FILTER CLAIMS

Our firm is investigating claims for patients seriously injured after having inferior vena cava (IVC) filters surgically implanted. IVC filters are implanted in patients who have a history of or are at risk of developing blood clots and cannot take blood thinners. Now, serious complications have been associated with IVC filters including the following:

- Embolization or detachment of the device components
- Device migration
- IVC perforations
- IVC filter fracture

Any of the above complications can lead to internal bleeding, penetration into the spine, protrusion of internal organs, additional surgery to remove the filter, and even death. If you or a loved one experienced complications after having an IVC filter implanted, please contact the defective medical device attorneys at **Alley, Clark & Greiwe** for a free legal consultation.

What is an IVC Filter?

The inferior vena cava is the main vessel that transports blood to the heart from the lower portion of the body. IVC filters are small, cage-like devices that are implanted into the inferior vena cava to capture blood clots and prevent them from reaching the lungs. IVC filters are implanted permanently or temporarily in patients who are at high risk for blood clots and for whom blood thinners are not an option.

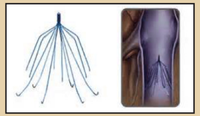

Illustration of IVC filter implanted in the interior vena cava

LITIGATION UPDATES

BLOOD THINNER XARELTO LINKED TO SERIOUS BLEEDING EVENT

Our firm is investigating claims of persons seriously injured while taking the prescription blood thinner Xarelto (rivaroxaban). Xarelto is a relatively new blood thinner approved by the FDA in 2011. It is prescribed to treat or prevent blood clots including deep vein thrombosis (DVT) and pulmonary embolism. Xarelto is also prescribed to patients with atrial fibrillation to lower to the risk of stroke.

Xarelto is an alternative to Coumadin (warfarin). While patients on Coumadin require frequent lab monitoring and dose adjustments, patients on Xarelto do not. It is this advantage that has been a key selling point. However, Xarelto has been linked to serious bleeding events including hemorrhage, GI bleeds, and even death. Additionally problematic with Xarelto is the absence of an approved reversal agent or antidote that can stop uncontrollable, sometimes fatal, bleeding.

If you or a loved one has been prescribed Xarelto and suffered a serious bleeding event, please contact **Alley, Clark & Greiwe** for a free case evaluation. For nearly 30 years, the dangerous drug lawyers at our firm have represented people seriously injured by pharmaceutical and medical devices.

XARELTO CLINICAL TRIAL UNDER FIRE

Clinical trials are used to gain approval from the FDA in order to place a drug on the market. A faulty medical device used in one of the clinical trials leading to the FDA's approval of Xarelto (rivaroxaban) has called those results into question. Recently, the *British Medical Journal* published a report alleging that faulty devices were used to test blood clotting levels in one particular Xarelto clinical trial. The results of the "ROCKET-AF" clinical study concluded that Xarelto and warfarin had comparable effectiveness, and comparable rates of excessive bleeding. However, the clinical trial data may have been unreliable and misled researchers and the FDA as to the effectiveness and safety of Xarelto. The ROCKET-AF clinical trial is now under investigation and review by the European Medicines Agency (EMA) while Bayer continues to stand by the Xarelto clinical trial results.

Important Information about Xarelto

- Xarelto was approved for sale in the U.S. by the FDA in 2011. Xarelto is prescribed to treat or prevent blood clots including deep vein thrombosis (DVT) and pulmonary embolism. The drug can also be prescribed to patients with atrial fibrillation (a heart rhythm disorder) to lower the risk of stroke.
- Xarelto is particularly dangerous because it does not have an emergency antidote to stop uncontrollable bleeding.
- Xarelto has been linked to serious bleeding events, including: Strokes, Brain Hemorrhage, Sudden Aneurisms, Fatal Bleeding Episodes.