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CLIENT NEWSLETTER

FALL 2010

# IN BRIEF

*In  
This  
Edition*

New Medical  
Device Recall:  
DePuy ASR  
Hip Implant

Bard “Avaulta”  
Surgical Mesh  
Litigation  
Heats Up

Acne Drug  
Accutane  
Linked to  
Serious  
Digestive  
Disorders



*The Attorneys & Staff at Alley, Clark & Greiwe wish you  
and your family a very Happy Thanksgiving.*

## RECOGNIZED FOR LEGAL EXCELLENCE

On September 15, 2010, U.S. News Media Group and *Best Lawyers®* released the 2010 Best Law Firms rankings. The law firm of **Alley, Clark & Greiwe** has been honored with a First-Tier ranking in the Tampa metropolitan area in two specialties: medical malpractice law and personal injury litigation. Achieving a high ranking is a special distinction that signals a unique combination of excellence and breadth of expertise. Additionally, three lawyers from **Alley, Clark & Greiwe** have been selected for inclusion in *The Best Lawyers in America®* 2011: **C. Todd Alley** was selected in the field of personal injury litigation, **James D. Clark** was selected in the fields



of personal injury litigation and medical malpractice law, and **Don Greiwe** was selected in the field of medical malpractice law. *Best Lawyers* is universally regarded as the definitive guide to legal excellence, and inclusion in *Best Lawyers* is considered a remarkable honor. Attorneys are selected based on a peer-review survey in which more than 39,000 leading attorneys cast votes on the legal abilities of other lawyers in their practice areas.



Don Greiwe

James D. Clark

Todd Alley

## HRT LITIGATION STATUS UPDATE

In March of 2010, Judge William Wilson in Arkansas “activated” numerous MDL cases including several clients of **Alley, Clark & Greiwe**. The activation allowed for a limited amount of case-specific discovery to proceed, though the cases have yet to be remanded back to the State of Florida. Currently, three Arkansas breast cancer cases are scheduled for trial in October, and other federal trials are expected to proceed before the end of the year in Virginia and Puerto Rico.



Recently, a consolidated trial concluded in Philadelphia. Unfortunately, despite a valiant effort by the Plaintiffs’ attorneys, the jury returned a defense verdict. The attorneys polled the jury after the trial and all the jurors stated they agreed that hormone therapy promoted the growth of cancer in both women but still came back with a defense verdict. The Plaintiffs have filed a motion requesting that the Judge overturn the jury’s verdict, but it is extremely rare for this type of motion to be granted. Locally, our law firm’s *Esposito* case was scheduled for trial in May 2010 but was continued until April of 2011.

## NEW MEDICAL DEVICE RECALL: DEPUY ASR HIP IMPLANT

The DePuy Orthopaedics unit of Johnson & Johnson recalled two types of hip implants on August 26, 2010. Just one of the recalled products was sold here in the United States: the DePuy **ASR XL Acetabular System** hip implant. Earlier this year, *The New York Times* reported that the FDA has received hundreds of complaints since 2008 from patients who experienced pain and other symptoms that led to revision surgery within the first five years of receiving the ASR hip implant. New data indicates that approximately 13% of patients (or 1 in 8) who were implanted with the ASR hip implant were forced to undergo a second hip surgery to remove the defective implant.



### Reported problems with the DePuy ASR hip system include:

- Loosening of the product from the bone
- Bone around the implant may break
- Dislocation because parts of the implant that move against each other are no longer in alignment.

### How do you find out if you have an ASR hip implant?

Contact your orthopedic surgeon or the hospital where the surgery took place. If you are unable to determine the type of hip implant you received, we will provide you with a release form to sign so that we may obtain the brand name and model number of the hip implant that you received.

A hip joint is a “ball and socket” joint, and total hip replacement involves replacing both parts at once. The ASR hip implant system, launched in the U.S. in 2004, is comprised of three components: the ball (or femoral head) connects to a stem and then fits inside the bowl-shaped socket (or acetabulum). With an ASR hip, a concave metal piece is used to provide a smooth lining for the acetabulum. All components of the ASR hip implant are included in the recall. Late last year, DePuy indicated it was phasing out the implants because of “slowing sales.” However, in March of 2010, the company warned doctors that the implants might have a high failure rate in some patients.



A rendering of metallic debris generated by a metal-on-metal hip implant.

Several years ago, metal-on-metal hip implants became popular because the metal was thought to be more durable than traditional hip implants made of ceramic or plastic. More recently, some orthopedic surgeons have soured on metal-on-metal hip implants. Studies have shown that metal-on-metal hip implant components wear down quickly and generate metallic debris that can cause pain, inflammation, swelling, tissue damage around the joint, and bone destruction in some patients. In April of 2010, British regulators issued an advisory on the metal debris generated by hip implants. The FDA is said to be meeting soon with professional medical groups to discuss the British advisory on metal hip implants.

Symptoms of a failing hip implant include pain, swelling, or difficulty walking. If you are experiencing any symptoms of pain or discomfort, you should contact your orthopedic surgeon for an evaluation. The attorneys at **Alley, Clark & Greiwe** have extensive experience in representing persons injured by defective joint replacement products and other defective medical devices. If you or a loved one have been implanted with a DePuy ASR hip implant device and have undergone revision surgery or suspect that you may need to undergo surgery in the future, please contact the law firm of **Alley, Clark & Greiwe** for important information regarding your legal rights.

## LITIGATION UPDATE: BARD AVAULTA SURGICAL MESH

Many women suffer the unfortunate daily side effects from stress urinary incontinence (SUI) and pelvic organ prolapse (POP) due to the effects of childbirth and menopause. They may undergo trans-vaginal placement of surgical mesh products to correct and restore weakened vaginal muscles. During the past few years, thousands of complaints have been linked to these products. In October of 2008, the FDA issued a Public Health Notice warning the public about the unacceptably high number of complications with more than nine different vaginal surgical mesh products.

The **Avaulta™ BioSynthetic Support System**, is one of the mesh products included in the FDA's notice.

### Serious Complications Associated with Surgical Mesh Products include:

- Infection, Extreme Pain
- Urinary Problems
- Mesh Erosion into Vaginal Tissue
- Vaginal Scarring
- Hardening of Vaginal Mesh
- Recurrence of POP and/or Incontinence

The Avaulta Support System is a permanent implant that provides support of fascial structures of the pelvic floor, and has knit arms to provide tension-free fixation of the implant. The Avaulta product is made of synthetic polypropylene mesh and is designed to allow vaginal tissue infiltration (or ingrowth), which can make removal of eroded or infected Avaulta mesh very difficult. Many women have suffered devastating mental and physical pain and suffering due to defective vaginal mesh products. Some women must undergo multiple surgical procedures to remove the device and/or repair vaginal scarring. If you or a loved one have been implanted with a Bard Avaulta mesh device and suffered any serious complication or have undergone additional surgery, please contact the experienced trial attorneys at **Alley, Clark & Greiwe** for a free consultation regarding your legal rights.

## ACCUTANE LITIGATION



Accutane (Roche) is a prescription medication used to control breakouts in people suffering from severe forms of acne. Accutane, originally developed as a chemotherapy drug for certain types of cancer, was also discovered to be effective in treating severe cystic acne and the FDA approved Accutane for this use in 1982. The drug was marketed so aggressively by Roche that it was prescribed even for common acne and it quickly became a leading form of acne treatment. Accutane has been linked to a variety of severe and even life-threatening side effects including severe fetal abnormalities, depression and other psychiatric illnesses, kidney and liver problems, and cardiovascular and musculoskeletal problems. Studies have also shown

that Accutane may trigger the development of various forms of inflammatory bowel disease (IBD), including the digestive disorders Crohn's Disease and ulcerative colitis. After years of scrutiny and legal attack for its serious side effects, Roche pulled Accutane from the market in June of 2009.

In the last several years, Roche has lost several trials and has been ordered to pay more than \$56 million in damages for inadequate warnings about Accutane. If you or a loved one took Accutane and have developed inflammatory bowel disease, Crohn's Disease, or ulcerative colitis, please contact the law firm of **Alley, Clark & Greiwe** for important information regarding your legal rights.

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