Alley ✦ Clark ✦ Greiwe ✦ Fulmer

701 East Washington Street
Tampa, FL 33602

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A&C&G&F

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**Alley, Clark,
Greiwe & Fulmer**
701 E. Washington St.
Tampa, FL 33602
(800) 840-0977
(813) 222-0977

Hearsay

Accolades

Recently, the law firm of **Alley, Clark, Greiwe & Fulmer** was selected for inclusion in the 2006 edition of the *Bar Register of Preeminent Lawyers.* Fewer than 5% of all law firms qualify for this distinction after undergoing a peer review process to ensure that the firm has the highest ethical standards and legal ability. Mike Ingram, Todd Alley, Jim Clark, and Don Greiwe are all "AV-rated" by Martindale-Hubbell, the facilitator of a peer review rating process. Ratings reflect the confidential opinions of members of the Bar and the Judiciary. Martindale-Hubbell ratings fall into two categories – legal ability and general ethical standards. Attorneys must be in practice for at least ten years in order to be eligible for an "AV rating." Don Greiwe was recently selected by his peers for inclusion in *The Best Lawyers in America® 2007* in the area of medical malpractice. Jim Clark was selected for the second time for inclusion in the areas of personal injury and medical malpractice. The 2007 edition is the thirteenth edition of *The Best Lawyers in America.* Since its inception in 1983, *Best Lawyers* has become universally regarded as the definitive guide to legal experience in the United States. Because *Best Lawyers* is based on an exhaustive peer-review survey in which 24,000 leading attorneys throughout the country cast more than a half million votes on the legal abilities of other lawyers in their specialties, and because lawyers are not required or allowed to pay a fee to be listed, inclusion in *Best Lawyers* is considered a singular honor.

Don Greiwe

Jim Clark

Season's Greetings from the attorneys and staff of Alley, Clark, Greiwe & Fulmer

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Alley, Clark, Greiwe & Fulmer is accepting clients who were diagnosed or first developed symptoms of any of the following smoking- related conditions prior to 11/21/96:

Peripheral Vascular Disease
Aortic Aneurysm
Bladder Cancer
Strokes
Cervical Cancer
Emphysema
Esophageal Cancer

Tobacco Claims

Pregnancy Complications
Laryngeal Cancer
Lung Cancer
Stomach Cancer
Oral Cancer
Kidney Cancer
Pancreatic Cancer

A recent Florida Supreme Court decision has made the pursuit of these claims feasible, but there is a limited amount of time for filing claims.

Concerns About Drug-Coated Heart Stents

An FDA Panel recently convened to discuss safety concerns regarding drug-eluting stents. These expensive stents were heralded as a medical breakthrough when they were introduced several years ago by Johnson & Johnson and Boston Scientific. Sales have mushroomed to more than $5 billion in a short period of time, but are now falling off dramatically due to safety issues. Recent studies have noted that the stents themselves may be responsible for more than 2,000 heart attacks each year. Studies from Europe indicate that the risk may be much higher, although no one really knows for certain. Stents are tiny pieces of wire mesh that have been used for years to keep arteries open. The devices are effective, but patients have a 20-30% risk of restenosis of their vessels. Drug-eluting stents were thought to be an improved design, as they are coated with a drug that prevents cell growth. The rate of restenosis fell to 5% with this new design, but different problems then started to emerge. Some patients developed hypersensitivity reactions to the drug coating requiring risky operations to remove them. Also, the body is unable to create a cellular barrier around the new stent, and the presence of the bare metal actually becomes a source for the formation of clots that can cause heart attacks. The FDA Panel felt that the benefits of the stents outweighed their risks, but recommended that patients take medication to minimize their risks of clots (and long-term risks of these drugs are unknown). Patients with drug-eluting stents should consult with their cardiologists to determine whether any changes are needed to their current regimen.

Averting Medical Malpractice Claims

A recent study confirmed a fact that medical malpractice lawyers have long known to be true – doctors are more likely to get sued for medical malpractice when they are arrogant or deceptive when mistakes have occurred. The studies found that doctors were likely to acknowledge mistakes only when they were obvious (such as overdoses and foreign objects left in patients) and were not forthcoming with respect to errors that would be less obvious to patients. A stunning 56% of the physicians responding to a survey noted that they would divulge that an adverse event had occurred but would purposely fail to inform the patient that medical negligence was the cause of the adverse event. The study laments that physicians in this country have been schooled to put up a "wall of silence" with regard to medical errors, and that our system as a whole would benefit from frank disclosure and prompt compensation to victims.

Bisphosphonate Litigation

From 2001 through 2003, there were sixty-three reports of patients who were diagnosed with jaw necrosis as a result of their ingestion of bisphosphonates. Most of these patients were cancer survivors who were taking high-dose formulations. This class of drugs is used for the treatment of osteoporosis and bone loss and includes Zometa, Aredia, Fosamax, Actonel, and Didronel. More recent studies estimate that thousands of patients may have developed jaw necrosis, leading to changes in the protocol for the treatment of patients who have ingested these drugs. There is particular concern since these drugs remain active in the body for years after ingestion. It is believed that it may take up to three years for injuries to surface after the drugs are discontinued. The new treatment guidelines recommend that patients avoid invasive dental procedures and undergo a dental examination before initiation of therapy with a bisphosphonate drug. Also, scientists are now questioning whether long-term therapy with these drugs presents greater risks than benefits to patients. Currently, there are several class actions and individual lawsuits pending involving this class of drugs. Please contact **Alley, Clark, Greiwe & Fulmer** for more information about these claims.

Breast Implant News

The FDA recently decided to permit silicone gel-filled implants to return to the market in the United States with limitations on their use. Their decision was based upon information provided by the two current manufacturers (Mentor and McGhan/Allergan) who had studied women who had gel-filled implants for up to four years. This decision is terribly upsetting given the long history of problems associated with these devices, and the fact that many of these problems may not surface for a decade or more. The FDA has ordered that the devices will not be permitted to be used in women younger than twenty-two years of age. Also, the FDA will reportedly monitor approximately 40,000 women for ten years after implantation to determine whether the new devices pose any unexpected safety risks. The warning label for the new implants includes many warnings not provided to our breast implant clients who were implanted decades ago: that implants are not lifetime products, that a woman is likely to require multiple breast implant-related surgeries during her lifetime, that the devices can rupture without warning, and that costly, long-term monitoring by MRI for silent ruptures is required (the FDA recommends the first MRI be performed three years after implantation and then repeat MRIs every two years after that).

Efforts to Increase Drug Safety

The controversy regarding the delay in removing Vioxx from the market may ultimately result in meaningful changes in the regulation of drug companies. The FDA's handling of Vioxx has been widely criticized (by drug safety experts and even FDA employees such as Dr. David Graham). The Government Accountability Office and a panel for the Institute of Medicine have both recently issued reports and recommendations for the overhaul of the FDA.

Recommendations

- Give the FDA more power to require drug companies to conduct testing of products after approval.
- Permit revenue from new drug application fees paid by drug companies to be used to fund regulation of drugs after FDA approval.
- Ban direct-to-consumer advertising for new drugs for the first two years that they are on the market.
- Limit the tenure of an FDA director to a single six-year term (currently, the FDA director is appointed by the President) in order to minimize the influence of politics on such appointments.

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