UPDATE ON CURRENT LITIGATION PROJECTS:

Avandia – Brief Timeline of Significant Events

May 1999	Avandia approved for sale in U.S.
Jan. 2001	Reports emerge suggesting Avandia may induce heart failure.
Dec. 2002	FDA orders revision of Avandia label to include "rare reports of unusually rapid increases in weight" and recommends patients be monitored for congestive heart failure.
Sept. 2005	GSK performs analysis of 37 randomized Avandia drug trials which confirm increased risk of heart attacks. Trial results are shared with FDA but not made public.
Sept. 2006	DREAM study trial published, shows higher number of cardiovascular events and increase in congestive heart failure among Avandia control group.
Oct. 2006	GSK performs updated analysis of 45 randomized Avandia drug trials which confirm stronger evidence of increased cardiovascular events. Trial results are shared with FDA but not made public.
Dec. 2006	ADOPT study trial published showing an excess of heart attacks among Avandia control group.
Dec. 2006	Approximately 13 million prescriptions written for Avandia in 2006 (generating sales in excess of $3.3 billion).
May 2007	*New England Journal of Medicine* published study showing there was 43% increased risk of cardiovascular events for those taking Avandia compared with other diabetes medications. Study consisted of 28,000 people who had taken the drug. A bipartisan U.S. Senate committee inquiry is launched shortly after this study.
2007	FDA advisory board voted 8-7 that Avandia should remain on the market.
Aug. 2007	FDA adds "black box" warning – the most serious type of warning - about increased risk of congestive heart failure.
Nov. 2007	FDA adds new information on the "black box" already in place that includes warnings that Avandia may cause heart attacks.
2007	FDA staffers found Avandia to be linked to over 83,000 heart attacks between 1999 and 2007.
Oct. 2008	American Diabetes Association (ADA) and the European Association for the Study of Diabetes to unanimously advise against using Avandia.
Dec. 2008	Approximately 3 million prescriptions written for Avandia.
Fall 2009	Avandia is ranked first among all prescribed drugs with the highest number of serious, disabling, and fatal problems and linked to over 300 patient deaths.

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

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

In Brief

In This Edition

Diabetes Drug Avandia Harms the Heart, Manufacturer Knew for Years

Avandia is a prescription drug marketed by GlaxoSmithKline (GSK). Released in the U.S. in 1999, Avandia has been used by millions of Americans to treat Type-2 diabetes. The controversy over the drug's safety has been looming for years as the drug has been linked with serious and potentially fatal side effects including increased risks of heart attacks and congestive heart failure.

On February 20, 2010, the shocking results of a two-year U.S. Senate inquiry were released that criticized GlaxoSmithKline, and by extension the FDA, for failing to warn patients for years that Avandia was potentially deadly. Senate committee investigators reviewed more than 250,000 pages of internal documents provided by GSK, the FDA, several research institutes, and conducted interviews of GSK and FDA employees and anonymous whistleblowers.

FDA officials inexplicably decided not to pull the drug in 2007 when it was up for review, yet FDA staffers had already concluded that Avandia had caused 83,000 heart attacks between 1999 and 2007.

Key findings by the Senate committee concluded:

"The totality of evidence suggests that GSK was aware of the possible cardiac risks associated with Avandia years before such evidence became public... Based on this knowledge, GSK had a duty to sufficiently warn patients and the FDA of its concerns in a timely manner. Instead, GSK executives intimidated independent physicians, focused on strategies to minimize findings that Avandia may increase cardiovascular risk, and sought ways to downplay findings that the rival drug Actos (pioglitazone) might reduce cardiovascular risks."

The Senate report suggests that the FDA has become too cozy with drug companies to effectively perform its regulatory obligations to the public, which includes safeguarding the drug supply. The FDA plans to convene an Advisory Panel hearing to consider the issues surrounding Avandia, but not until July of 2010.

As this battle unfolds in the weeks ahead, it highlights broader issues of patient safety. A pharmaceutical company, especially one which is publicly traded like GSK, has one overriding goal: profit. When safety concerns impact profit, time and again we see companies choose to skew or even hide evidence, downplay side effects, risk patient safety, and sometimes defy the law, all in the name of profit.

The law firm of **Alley, Clark & Greiwe** has been investigating Avandia for many months. If you or a loved one has taken Avandia and suffered liver failure, heart attack, congestive heart failure, vision loss, or death, please contact one of our attorneys for important 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

HOT TOPICS

Neurological Damage Linked to Denture Creams Containing Zinc

It is estimated that approximately 20 million people in the U.S. wear dentures and use denture adhesive products like Poligrip or Fixodent. On February 18, 2010, the manufacturer of Poligrip denture cream, GlaxoSmithKline, issued a Press Release warning consumers of potential health risks associated with long-term excessive use of over-the-counter denture adhesives containing zinc. The company announced it was taking "voluntary, precautionary" action and will stop making and marketing variations of Super Poligrip products in the U.S. GlaxoSmithKline stressed that the products are safe when used as directed, but that some people with ill-fitting dentures use more cream than directed by the instructions.

This public announcement was made amid hundreds of pending lawsuits against GlaxoSmithKline. Lawsuits have also been filed against Procter & Gamble, which sells Fixodent. In the lawsuits, Plaintiffs claim that years of excessive use of the zinc-containing denture cream caused neurological damage. Attorneys for Plaintiffs argue there was no warning for people regarding excessive use of the denture cream.

Denture creams containing zinc were linked to neurologic disease back in 2008 in a study published in the medical journal *Neurology*. Researchers documented that excessive zinc purged the body of copper, a chemical needed for normal brain and nervous system function. Interestingly, GlaxoSmithKline and Proctor & Gamble only began disclosing the zinc in their denture creams after this study was published. More than $520 million in denture adhesive sales were reported in 2009 by GlaxoSmithKline alone.

Symptoms of Neurological Damage from Zinc Poisoning May Include:

- Nerve damage
- Loss of sensation in the hands and feet
- Weakness and numbness in arms and legs
- Difficulty walking and loss of balance
- Permanent paralysis

If you or a loved one have suffered zinc poisoning resulting in permanent neurological damage after using Super Poligrip or Fixodent, please contact the law firm of **Alley, Clark & Greiwe** today to learn more about your legal rights.

Useful Consumer Information on Drug Recalls

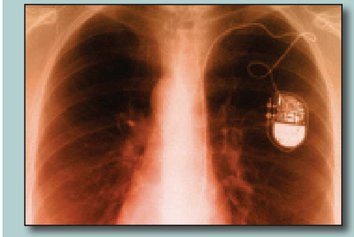
There are many new methods now available online for consumers that provide email alerts about medication errors, drug recalls, and provide general guidance to consumers about ways to prevent medication errors. One website is **ConsumerMedSafety.org**, which contains a portal of information provided by the Institute for Safe Medicine Practices (ISMP). You can sign up for customized alerts about the medications you take and report any problems you encounter with the medications. Another website is **MedWatch**, a FDA-sponsored site for safety information on prescription drugs and other medical products where patients can submit reports of medication errors and other serious adverse reactions directly to the FDA.

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

UPDATE ON CURRENT LITIGATION PROJECTS

Failure Rate of Medtronic Sprint Fidelis Defibrillator Leads Increasing

In October of 2007, Medtronic suspended sales of its Sprint Fidelis leads, the wires that connect a defibrillator to a patient's heart, due to a defect that could cause the leads to fracture. When the Sprint Fidelis leads fracture, the defibrillator can fail to send a needed electrical jolt, and the patient can die. Or, the defibrillator can send repeated, massive jolts, which themselves can be fatal. Approximately 150,000 patients across the U.S. still have the Sprint Fidelis leads implanted in their body. Patients who require the removal of a fractured device face a dangerous surgical procedure to replace the defective leads.



In March of 2009, Medtronic attributed 13 patient deaths to the defective leads, yet the company website says the likely risk to patients remains "small" at about 4.6%. A *Wall Street Journal* article published on February 4, 2010 disputes these findings and suggests the actual failure rates of the Sprint Fidelis leads are significantly higher than what Medtronic is publicly reporting. A Mayo Clinic study cited by *The Wall Street Journal* estimated that failure rates were as high as 20.4% in patients under 50 years of age, but Medtronic disputes the test data. *The Wall Street Journal* investigation also identified at least 12 additional patient deaths reported to the FDA since March of 2009 that were allegedly linked to the Sprint Fidelis leads.

Currently, Medtronic is shielded from liability by various court rulings. The Medical Device Safety Act of 2009 (MDSA; H.R.1346/S. 540) was introduced in an attempt to reverse the U.S. Supreme Court's decision in *Riegel v. Medtronic, Inc.* where it was ruled that a medical device manufacturer cannot be sued under state law by patients alleging harm from a device that was approved by the FDA. Since the *Riegel* decision, thousands of lawsuits against medical device manufacturers have been dismissed by courts around the country, including more than 1,000 cases filed in Minnesota against Medtronic over Sprint Fidelis leads. We hope once the Medical Device Safety Act becomes law that lawsuits can proceed against Medtronic on behalf of patients who received a defective Medtronic lead.

If you wish to voice your support to this important legislation, contact your members of Congress. You can write a letter, make a phone call or send an email. Contact information can be found at **www.Congress.org** or call the Congressional switchboard at 202-224-2131 and ask for your Congress members' office.

Alley, Clark & Greiwe is one of only a handful of firms that are involved in the Medtronic lead litigation. Please contact our office immediately if you or someone you love has received a Medtronic lead.

Recalled Medtronic Sprint Fidelis® Leads identification numbers begin with 6930, 6931, 6948 or 6949.

HOT TOPICS

How Social Networking Website Content Can (and Will) Damage Your Claim

Many lawyers are embracing social networking websites such as Facebook, Twitter, MySpace and various blogs to investigate information about plaintiffs during the discovery phase of litigation. This is becoming increasingly popular by lawyers involved in all types of legal matters ranging from family law, criminal proceedings, employment law, insurance defense, personal injury, and products liability claims. Information you post about yourself such as interests and hobbies, friends, photographs, and status updates can all be used against you. For example, a person may claim to be permanently disabled and unable to work, but then post profile photos of himself water-skiing. Or, a person convicted of drunk driving who continuously posts photographs of drinking and partying. Many courts are allowing into evidence this type of information even from persons who have set their profiles as "private." It is important that you understand what you write on sites such as Facebook can be discoverable. Most experts agree the practice of seeking evidence from social networking sites will only increase due to the popularity and ease of staying "connected" to friends and family. Finally, you should never post information regarding pending lawsuits, settlement negotiations or confidential settlements.

facebook twitter

myspace.com a place for friends

Recent Settlement News

We hope that you will contact the law firm of **Alley, Clark & Greiwe** for a free consultation if you or a loved one is in need of an attorney. Our entire practice is devoted to personal injury claims involving medical malpractice, defective drugs and medical devices, automobile accidents, and complex products liability claims. The following cases have been recently resolved by our experienced civil trial attorneys:

$400,000.00 Confidential Settlement (Partial) of medical malpractice lawsuit involving a woman discharged from the hospital without orders for anti-coagulant medication (blood thinners) after total knee replacement surgery causing numerous blood clots to form which led to her death. The lawsuit remains ongoing against the remaining defendants.

$318,000.00 Settlement in a product liability case involving a recalled drug.

$650,000.00 Confidential Settlement (Partial) of wrongful death lawsuit involving a construction worker operating a crane that lifts and transports metal beams. The clasp that holds the beam in place malfunctioned causing the beam to slam into the crane killing the man on impact. Another defendant settled for policy limits of $250,000.00 in 2009.

$580,000.00 Settlement in a confidential pharmaceutical litigation case.

Please visit us on the web: www.tampatriallawyers.com