

IN BRIEF



In This Edition

FDA Issues Warning On Popular Blood Pressure Medication

Health Care Liens—What You Need To Know

Social Media Privacy

Zofran Claims



Like Us on Facebook
Alley.Clark.Greiwe

FDA ISSUES WARNING ON POPULAR BLOOD PRESSURE MEDICATION

Benicar was approved for sale in the U.S. in 2002 to control hypertension (high blood pressure). In July of 2013 the FDA issued a Drug Safety Communication warning the public that ingestion of Benicar could cause intestinal problems known as sprue-like enteropathy. Symptoms of this condition include severe, chronic diarrhea with substantial weight loss. The enteropathy may develop months to years after starting Benicar, and sometimes requires hospitalization. The connection between sprue-like enteropathy and Benicar was first reported by Mayo



Clinic researchers in June 2012. In the Mayo research, all of the patients had used Benicar for at least a year before developing symptoms.

Alley, Clark & Greiwe continues to litigate a number of pharmaceutical drugs cases. Each personal injury attorney at our law firm has extensive experience representing clients seriously injured due to defective medical devices and drug products. If you or someone you know has developed serious GI problems after taking Benicar, please contact **Alley, Clark & Greiwe** for a free consultation regarding your legal rights.

HEALTH CARE LIENS — WHAT YOU NEED TO KNOW

If you sustain personal injuries as a result of a third party and you later file a lawsuit, your health insurer must be reimbursed for medical expenses it paid for injuries that form the basis of your lawsuit. These are commonly referred to as health care “liens.” Whether you are insured by a private health care plan (i.e. Blue Cross, Cigna, Aetna, etc.), an employee benefit plan, or a

government health program (i.e. Medicare, Medicaid, Tricare) your health insurer has a legal right to reimbursement from your settlement proceeds. The resolution of these health insurance liens can be a long, frustrating process. In most cases, health care liens can be negotiated and/or reduced unless the insurance policy language specifically requires 100% reimbursement.

Important Information About Your Health Insurance Reimbursement Obligations

- | | |
|---|---|
| • Nearly all personal health care policies contain reimbursement language. | • Attorneys are bound by state and federal law to notify insurers of a pending lawsuit. |
| • Paying premiums and co-pays does NOT negate or have any effect on reimbursing an insurer. | • Failure to reimburse an insurer can result in fines, penalties, and loss of coverage for the insured. |

Alley ♦ Clark ♦ Greiwe Attorneys At Law

Representing Plaintiffs Exclusively in the Following Cases:

- | | |
|------------------------|-----------------------------|
| • Medical Malpractice | • Products Liability |
| • Unsafe Drugs | • Defective Medical Devices |
| • Automobile Accidents | • Wrongful Death |

(800) 840-0977

HOT TOPICS

EVERYTHING YOU POST ON THE INTERNET IS PUBLIC

These days almost everyone is on social networking websites liked LinkedIn, Instagram, or Facebook. Despite passwords and privacy settings, you should expect that your pictures, posts, or status updates will be discoverable should you file a personal injury lawsuit. This is confirmed by case law throughout the State of Florida and more recently in the case of *Nucci v. Target Corp.*, 2015 WL 71726 (Fla. 4th Dist. App. Jan. 7, 2015). In this case, the Plaintiff slipped and fell in a Florida Target store and later sued the retail giant and its cleaning company for back, neck, and shoulder injuries. The Plaintiff was ordered to produce “screen shots” and photos she posted on Facebook for the two year period before her accident. The Plaintiff argued that her Facebook account had a privacy setting. The Court, however, noted that in

Florida the scope of discovery in civil cases is broad and that her photos were highly relevant to her personal injury claim. Essentially, the Court felt the Plaintiff’s Facebook page would demonstrate her activities both before and after her slip and fall accident.

Postings on social media websites are likely to become akin to surveillance videos, and this issue will continue to impact personal injury and medical malpractice cases alike.



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

ZOFRAN CLAIMS

OFF-LABEL USE OF ZOFRAN DURING PREGNANCY

Zofran is a medication approved to treat nausea and vomiting during chemotherapy or following major surgery. This powerful anti-nausea drug has been prescribed extensively “off-label” by physicians to women to treat nausea during pregnancy. However, Zofran is not approved to treat pregnant women and there are studies which suggest a link between the drug and serious birth defects. The manufacturer has never conducted a large scale study regarding the safety of Zofran when prescribed to expectant mothers. While drug manufacturers and their sales representatives are not legally allowed to promote off-label uses for prescribed medications, there is no law or regulation preventing doctors from this practice.

GlaxoSmithKline, the manufacturer of Zofran, was sued in 2011 by the U.S. Department of Justice for off-label drug promotion for several prescription

drugs *including* Zofran. The civil lawsuit alleged GSK illugally promoted certain prescription drugs, it failed to report certain safety data, it paid kickbacks to medical providers to promote and prescribe certain drugs, and it alleged false price reporting practices. Simultaneous criminal charges were also filed by the DOJ against GSK relating to the drugs Paxil, Wellbutrin, and Avandia. In 2012, GSK pled guilty to the criminal charges and also agreed to pay the U.S. Government a total penalty of \$3 billion to resolve the civil and criminal liability. This is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

If you or someone you know was prescribed Zofran during pregnancy and later delivered a child with serious birth defects, please contact **Alley, Clark & Greiwe** for a free consultation regarding your legal rights.

Timeline of Zofran Birth Defects Research To Date

2004	Motherisk in Canada published an observational study of 200 mothers which found no link between Zofran and birth defects. They study was supported by an unrestricted grant from GlaxoSmithKline (manufacturer of Zofran).
2012	A study published by the Center for Birth Defects Research & Prevention and conducted by Slone Epidemiology (Boston) and the Centers for Disease Control and Prevention (Atlanta) examined select anti-nausea drugs and birth defect rates, finding that first trimester exposure to Zofran resulted in an increased rate of cleft palate.
Feb. 2013	The <i>New England Journal of Medicine</i> published a study based on select Danish birth records dating from 2004-2011. This study did not detect a link between Zofran and birth defects. Critics of this study state the sample size was too small and included many women who did not start taking Zofran until after Week 10 of their pregnancy, when a fetus is no longer at risk for developing major birth defects.
Aug. 2013	Another group of researchers published a study on Zofran birth defects based on the same Danish birth records data, expanding their scope to examine records ranging from 1997-2010. This study, which is by far the most comprehensive study on Zofran birth defects, found the drug doubles the risk of congenital heart defects and increases the risk of birth defects overall by 30%. The sample group included 1,248 women who took Zofran during their first trimester of pregnancy.