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CLIENT NEWSLETTER

Alley ◆ Clark ◆ Greiwe

SUMMER 2017

IN BRIEF

Best Lawyers® BEST LAW FIRMS U.S.News & WORLD REPORT 2017

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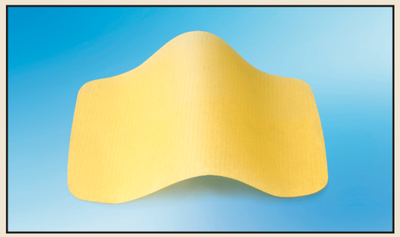
HERNIA MESH COMPLICATIONS

An estimated one million patients undergo surgical hernia repair each year. There are many types of hernias, but the most common are **inguinal** (inner groin), **incisional** (resulting from an incision), **femoral** (upper thigh/outer groin), **umbilical** (belly button), and **hiatal** (upper stomach). Hernia repair surgery can either be performed laparoscopically or through an open incision (commonly referred to as "open repair"). Currently, the vast majority of hernias are repaired using surgical mesh devices (either synthetic material or animal tissue) since the utilization of mesh decreases both the operative time and patient recovery time.

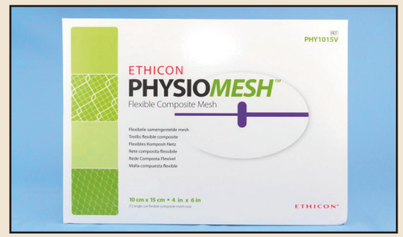
Unfortunately, many serious adverse events have been reported to the FDA on different synthetic hernia mesh products. Some complaints have been associated with recalled mesh products that are no longer on the market, but other complaints concern products that are still widely available. The most common adverse events involving hernia mesh include:

- **Pain**
- **Infection**
- **Hernia recurrence**
- **Adhesion formation**
- **Bowel obstruction**
- **Mesh migration**
- **Mesh shrinkage**
- **Perforation injuries to surrounding organs**

If you have suffered a serious complication following hernia repair surgery or you need (or have had) revision surgery, please contact **Alley, Clark & Greiwe** for a free consultation about your legal rights.



C-Qur™ (Atrium Medical) is a polypropylene hernia mesh with an impermeable Omega 3 coating. This coating is not used on any other hernia mesh products sold in the U.S. This mesh has been associated with widespread complications, but remains on the market.



Ethicon issued a voluntary recall in 2016 over its Physiomesh™ Flexible Composite Mesh due to higher than average failure rates in laparoscopic hernia repair as compared to other mesh products. The product was not returned to the market.

FLORIDA MOTORCYCLISTS TAKE NOTE: OUR ROADS ARE THE MOST DANGEROUS

A recent report from the National Highway Traffic Safety Administration (NHTSA) should make Florida motorcyclists a bit more uneasy on the road. According to the NHTSA, Florida leads the country in motorcycle fatalities. The latest report shows a 30% increase in crash fatalities from 2014 to 2015. Within our state, the top five most dangerous counties for motorcyclists are: Pinellas, Hillsborough, Miami-Dade, Broward, and Palm Beach. Even with the most cautious driving, accidents can and will happen. Our team has decades of experience handling automobile, truck, and motorcycle accident claims. If you or a loved one are injured in an accident, please do not hesitate to contact **Alley, Clark & Greiwe** for a free consultation about your legal rights.

INSURANCE COMPANIES CAN (AND WILL) USE PRIOR ACCIDENTS AGAINST YOU

If you've never been in a car accident, consider yourself lucky. The average driver is estimated to have 3-4 accidents during a lifetime. If you've already had one accident and get involved in another, suffer injuries and want to sue the other driver, can the prior accident be used against you? The answer is yes. The other driver's insurance company will obtain your driving history, discover previous accidents or personal injury claims, and find out what injuries you suffered in those claims. These facts will either be in public records or will be disclosed during the discovery phase of your lawsuit. There are many ways the defendant's insurance company will use this information to defend their case and undermine yours.

- ✓ Insurers may try to assert your injuries were the result of a prior accident or event (and therefore not the defendant's fault or responsibility).
- ✓ Insurers will get access to your entire medical history including any treatment or diagnoses that followed an earlier accident or event.
- ✓ Insurers may take the deposition(s) of your treating doctor(s) and hire their own expert witnesses) to evaluate your injuries.
- ✓ If you filed a lawsuit after a previous accident, or you have filed multiple personal injury lawsuits, claims for disability benefits, or workers' compensation claims, the insurance company attorney may try to paint you as a serial litigant who sees every accident or mishap as an opportunity to make money.

This may seem unfair when you know that one accident has nothing to do with the other, says nothing about your fault or character, and doesn't change the fact that you suffered injuries that were the result of the other driver's negligence. It is very important to hire an experienced personal injury attorney if you've been hurt or lost a loved one in a car accident. Please do not hesitate to contact an experienced trial attorney at **Alley, Clark & Greiwe** for a free consultation about your legal rights.

NEARLY ONE-THIRD OF FDA-APPROVED DRUGS HAD SAFETY PROBLEMS AFTER APPROVAL

There are no prescription drugs without potential side effects or safety risks. Just because a drug is prescribed by a physician or available at your local pharmacy does not mean that the drug has proven to be safe or effective. In recent years, there has been increasing pressure on the FDA to accelerate its regulatory review process to get new drugs on the market faster. More recently, the Trump Administration has vowed to slash restraints on drug development and has promised to speed up the FDA's drug approval process.

According to a new study published in the *Journal of the American Medical Association*, nearly 1 in 3 drugs approved by the FDA between 2001-2010 were later flagged for safety issues. These risks included serious skin reactions, liver damage, cancer, and even death. Drugs brought to market through accelerated approval were slightly more likely to have safety issues identified later than those approved through conventional channels. Clearly, some drugs placed on an expedited approval track provide promising, life-saving benefits to certain patients with serious illnesses who have no other treatment options.

However, other drugs on the fast-track approval trend are drugs not considered "first in class drugs" and are not necessarily innovative, meaning there are alternative drugs in the same therapeutic class already meeting health needs of patients. One has to wonder whether expedited drug approval programs should be strictly limited to drugs providing noticeable clinical advances. The new *JAMA* study is a good argument for continuous monitoring of the safety of drugs throughout their life cycle to ensure patient safety.

Alley, Clark & Greiwe trial attorneys have an average of over 30 years of experience in litigating complex personal injury, products liability, mass torts, and medical malpractice claims. Currently, our attorneys are actively involved in litigation on a number of prescription drugs. If you or someone you love has been harmed by a prescription drug product, please contact us for a free consultation regarding your legal rights.

JAMA STUDY HIGHLIGHTS (MAY 2017)

- From 2001-2010, the FDA approved 222 new drug therapies. The majority of these drugs were trialed in 1,000 or fewer patients to get FDA approval.
- 3 drugs were later withdrawn from the market due to serious safety issues and/or deaths
- 61 drugs later had "black box" warnings added for serious, life-threatening safety risks
- 59 drugs had safety communications issued due to product safety concerns.