# Searcy Denney Attorneys Tackle Manufacturers of Life-Threatening Pharmaceuticals and Medical Devices That Cause Harm to Many

Cases of widespread death, injury, damage, or loss that stem from negligence often fall into the category of the legal term mass torts. Mass tort claims arise when unscrupulous individuals or corporations disregard public health or safety and the consequences affect large groups of innocent victims.

A case in point is when big manufacturers in the health care industry put their profits before safety, and hundreds of people - sometimes thousands - fall prey to dangerous drugs and medical devices.

Mass tort cases are sometimes confused with class actions, since both kinds of claims are brought on behalf of groups of people who have suffered similar harm. In mass tort cases, however, each victim or family has its own distinct claim, while benefitting from the time and cost savings of individual claims that have been grouped together by the courts.

Attorneys at Searcy Denney Scarola Barnhart & Shipley have been representing individual victims of defectively-designed medical devices and dangerous drugs that have injured or killed Americans for many years and have recently expanded this area of their practice. Some of these products have been recalled, while others continue to be used in surgical procedures or prescribed to unsuspecting consumers.

These are some of the current projects being handled by Searcy Denney shareholders Cal Warriner, Brenda Fulmer, and David Sales, all members of the firm's mass tort unit:

# **Medtronic Sprint Fidelis Leads**

Model Nos. 6930, 6931, 6948, 6949

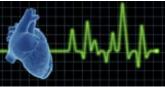
These leads are thin wires that connect an implanted defibrillator to the heart. When leads are defective, they may crack or fracture, sometimes without warning. Unwarranted shocks caused by a defective lead, as well as the failure to pace the heart as intended, can result in heart attack or death. The fractured leads can also puncture the heart, causing a patient's death. Surgery to remove and replace the defective leads is complicated and very risky.

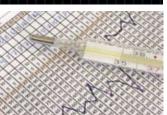
# Digitek (Digoxin)

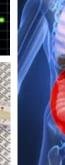
Manufactured and distributed by Actavis Totowa, Bertek/Mylan, and UDL Laboratories Digitek is the generic version of digoxin, a medication in pill form used to treat abnormal heart rhythm and heart failure. Some lots of Digitek were manufactured at twice the intended physical size, thus delivering an overdose. Symptoms of digitalis toxicity or an overdose include nausea, vomiting, low blood pressure, and cardiac instability, which can result in heart attack, stroke, or death.

Digitek has been recalled from the market, and most users were notified by their pharmacies to stop taking the drug. Heart patients who were switched to Digitek from digoxin or some other form of digitalis should be alert to symptoms of toxicity and follow up with their physicians to obtain blood tests to monitor the levels of the drug in their bodies.













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# **Kugel Hernia Mesh**

Composix brand and dual mesh technology designs, manufactured by Davol/Bard This product is a synthetic mesh patch that is used during hernia surgery to close the hernia and help the tissue heal. It includes what is called a "memory recoil ring," a small plastic ring embedded in the patch that permits it to be folded over and then deployed once inside the abdomen. Certain sizes of the Kugel Hernia Mesh were recalled by the FDA in 2007 because the products have a tendency to break, causing bowel perforations, abdominal wall punctures and tears, and adhesions. Further, the mesh patch itself has shown a tendency to migrate within the body and sometimes grow into vital organs due to the dual mesh design.

Symptoms of a defective Kugel Mesh Hernia Patch include persistent or unexplained abdominal pain, fever, and tenderness at the surgical incision site. The complications and resulting damage may require additional surgery for repairs and/or removal of the patch.

### **Ortho-Evra Birth Control Patch**

Manufactured by Ortho-McNeil Pharmaceuticals, a division of Johnson & Johnson The critical difference between the Ortho-McNeil birth control patch and oral contraceptives is indirect versus direct delivery of the hormones. Birth control pills are first processed by the body's digestive system, while similar drugs in a skin patch go directly into the blood stream. The high-dosage concentration delivered by the Ortho-Evra patch can cause blood clots which, in turn, can cause strokes and other life-threatening complications and death.

In January 2008, after thousands of complaints had been logged, the FDA strengthened its warning about the risk of serious blood clots among Ortho-Evra patch users. This product has not been recalled, however, and continues to be marketed as a "safe" option for birth control with the marketing being directed at the very youngest patients.

# **Vaginal Slings and OB Tape**

### Manufactured by Mentor Corporation

This device was produced by Mentor in 2003 for use in certain kinds of surgical procedures to treat stress incontinence, which is common among women. A vaginal sling reinforces muscles weakened by childbirth and other causes, and helps patients control urinary functions. Almost immediately after its introduction, design and manufacturing defects in the Mentor Ob Tape vaginal sling brand were causing severe complications such as breakdown of vaginal tissue, chronic discharge, serious infections, and other injuries that may be permanent.

When the *Journal of Urology* in 2006 documented widespread injuries caused by the Mentor Ob Tape vaginal sling, the device was pulled from the market. By that time, however, an estimated 35,000 women had been fitted with the sling.

## **Pain Pumps**

### Manufactured by Stryker Corporation, I-Flow Inc., DJO Inc., and BREG Inc.

External automatic pain pumps are used frequently in shoulder and other joint surgeries to deliver pain medication directly into the joint. Recently, this direct delivery method has been found to cause serious cartilage destruction – a condition called postarthroscopic glenohumeral chondrolysis (PAGCL), medical terminology for death of cartilage. PAGCL can result in permanent disability and require total joint replacement surgery.

Victims of PAGCL suffer from narrowing or destruction of joint space, which can be diagnosed by x-ray. Patients should seek medical advice if they experience symptoms such as joint weakness, stiffness, pain, decreased motion, or clicking, popping, or grinding when the joint is put in motion.