

# SDSBS Attorneys Pursue Justice for Victims of Defective Drugs and Medical Devices

*These are some of the current projects being handled by SDSBS 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 attacks 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.

## Fentanyl Pain Patches

Manufactured by Johnson & Johnson, Janssen Pharmaceutica, Sandoz, Actavis, Corium, Abrika, Alza Corp., Cephalon, and Watson Pharmaceuticals

Fentanyl pain patches are widely used to provide narcotic pain relief. The drug is 60 to 80 times more powerful than morphine. The patches utilize a reservoir design to contain powerful painkillers with the intention that the patches slowly deliver the drugs through a patient's skin over a 72-hour time period. Manufacturing and design defects in the patches, however, have resulted in leakage of the pain medication. Patients who receive an overdose of fentanyl experience respiratory distress, loss of consciousness, confusion, and death. A patient wearing a leaking fentanyl patch can also transfer the drug to others who come into close contact.

## Pain Pumps

Manufactured by Stryker Corp., 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), which is a medical term 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. Consequently, 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.



## Yaz, Yasmin, and Ocella Birth Control Pills

Manufactured by Bayer

The top-selling oral contraceptives Yaz, Yasmin, and Ocella (which combine ethinyl estradiol and drospirenone) have been the subject of much controversy since their launch several years ago. Yaz, Yasmin, and Ocella are approved for treatment of the very significant psychiatric condition of Premenstrual Dysphoric Disorder (PMDD), but improper marketing has falsely suggested that the drugs are approved by the FDA for the treatment of common PMS symptoms. Yaz, Yasmin, and Ocella have been linked to a number of serious and potentially life-threatening conditions: blood clots, strokes, heart attacks, deep vein thrombosis (DVT), pulmonary emboli, and gallbladder disease, and recent studies have shown that they are more dangerous than other birth control pills that have been on the market for years.

## Reglan (metoclopramide)

Manufactured by A.H. Robbins, ESI Lederle Generics, Wyeth, Teva, IVAX, Rugby, Pliva, URL, Qualitest, and Invamed

Reglan (also known as metoclopramide) is a drug routinely prescribed for post-operative nausea and vomiting and gastroparesis. The FDA approval of the drug was solely for short-term use (less than 12 weeks) due to the significant incidence of tardive dyskinesia (a devastating condition which is essentially untreatable and incurable) and other neurological and neuromuscular movement disorders associated with long-term use of the drugs. Despite the manufacturers' knowledge of the substantial percentage of patients who will develop tardive dyskinesia, the drug companies aggressively marketed Reglan and metoclopramide for long-term use for treatment of chronic conditions such as gastroesophageal reflux without proper warnings to physicians and patients.

## Gadolinium MRI Contrast Material

Manufactured by General Electric, Bayer, Tyco, Mallinckrodt, Berlex, and Bracco Diagnostics

Gadolinium-based contrast materials were widely used over the past several years in connection with MRI and CT scans. The enhanced image quality achieved when using a Gadolinium-based contrast material, however, is far outweighed by the devastating toxic effects suffered by a number of patients with pre-existing renal impairment whose bodies were unable to quickly excrete the injected contrast material. Gadolinium-induced Nephrogenic Systemic Fibrosis (NSF) is a newly-discovered disease that is caused solely by exposure to Gadolinium in susceptible patients with impaired renal function. When patients with kidney disease are unable to quickly clear Gadolinium from their system, the toxin becomes unstable and is distributed throughout the body where it causes fibrosis of the skin and vital organs, which ultimately leads to contractures, disability and death.

## Kugel Hernia Mesh

Manufactured by Davol/Bard

Composix brand and dual mesh technology designs

These products are synthetic mesh patches that are used during hernia surgeries to close the hernia and help the tissue heal. Many of the patches include 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 2005, 2006, and 2007 because the products have a tendency to break, causing bowel perforations, abdominal wall punctures and tears, and adhesions. What's more, 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.

### CONSUMER PRODUCTS

AMO Contact Lens Solution  
Goodyear Dunlop D402 Tires  
Yamaha Rhino ATV  
Suzuki GSX-R1000 Motorcycles

### PRESCRIPTION & OVER-THE-COUNTER DRUGS

Accutane  
Avandia  
Bisphosphonates (Fosamax, Boniva, Actonel, Zometa, Aredia, Didronel, Bonefos, Skelid, Reclast)  
Chantix  
Digitek and Digoxin  
Duragesic or Fentanyl Pain Patches  
Hydroxycut  
Gadolinium-Based MRI Contrast Agents  
Ketek  
Levaquin  
Ortho-Evra Contraceptive Patch  
Raptiva  
Reglan  
Seroquel and Zyprexa  
Tequin  
Trasylol (Aprotinin)  
Visicol, OsmoPrep, and C.B. Fleet Phospho-Soda Bowel Prep Solutions  
Yaz, Yasmin and Ocella  
Zicam

### MEDICAL EQUIPMENT & IMPLANTED DEVICES

Bard Composix Kugel Hernia Mesh  
Medtronic Paradigm Quick-set Insulin Pumps  
Medtronic Sprint Fidelis Leads  
Medtronic Synchromed Intrathecal Permanent Pain Pumps  
Mentor OB Tape Vaginal Sling  
NuvaRing Contraceptive Device  
Post-Operative Disposable Pain Pumps  
Zimmer Durom Cup Hip Implants

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