

# Defective Drugs

## **Accutane**

Accutane (also known as isotretinoin) is an acne medication manufactured by Roche Pharmaceuticals. Accutane has come under scrutiny by the Food and Drug Administration due to psychiatric side effects, including birth defects, lupus, inflammatory bowel disease and suicide.

## **Acetaminophen and Liver Failure (e.g. Tylenol)**

The drug found in Tylenol and many other over the counter and prescription drugs, is the number one cause of drug induced liver failure in the U.S. The potential for liver failure is greatly increased when this drug is combined with alcohol or during periods of fasting (due to illness, anorexia or malnutrition).

## **Actiq**

Actiq is a narcotic painkiller that looks and tastes like a lollipop and was designed to speed relief to cancer patients. The Food and Drug Administration approved Actiq for cancer patients who suffer from intense pain. Recent studies show that more than 80% of patients who use the drug are using it for reasons other than treating cancer pain. Instead, doctors are prescribing it "off label" for pain related to migraines or back pain. Actiq use has been linked to overdose, addiction and death.

## **Actos**

Actos is prescribed to treat type 2 diabetes. It has recently been linked to increased likelihood of bladder cancer. Sale of Actos has been suspended in some European countries.

## **Actonel**

Actonel is used to treat osteoporosis (os-te-o-pur-o-sis). Although used to strengthen bones, some patients develop a serious disease called osteonecrosis (os-teo-ne-crosis) which is the deterioration of the jaw bone. Symptoms include loosening of the teeth, severe infections and swelling.

## **Advair**

Advair, a drug used for the long term treatment of Asthma may be associated with an increased risk of respiratory deaths and other life-threatening Asthma episodes, according to information collected by the FDA.

## **Alli (Orlistat)**

The over-the-counter weight loss drug Alli has been linked to liver, kidney and pancreas damage.

## **Avandia (Rosiglitazone Maleate)**

Avandia is prescribed to treat type 2 diabetes. It has recently been linked to increased likelihood of heart attack, stroke and sudden death.

## **Aredia**

Aredia is used to treat osteoporosis. Although used to strengthen bones, some patients develop a serious disease called osteonecrosis (os-teo-ne-crosis) which is the deterioration of the jaw bone. Symptoms include loosening of the teeth, severe infections and swelling.

## **Baycol**

Baycol® (also called cerivastatin) was pulled from the market after it was linked to at least 40 deaths. Eventually, the number of deaths associated with the use of Baycol® rose to more than 100. Baycol®, a cholesterol-lowering drug which is suppose to reduce a patients' risk of heart attack, was taken by nearly 700,000 Americans. Food and Drug Administration physicians have linked the drug to a rare muscle side effect which destroys muscle tissue and then releases it into the bloodstream. Most commonly, patients suffer severe muscle pain concentrated in the lower back and calf muscles. In the severe cases, it leads to kidney failure and death.

### **Bextra**

Bextra is a nonsteroidal anti-inflammatory drug (NSAID) known as a COX-2 inhibitor used to relieve the symptoms of arthritis and pain related to menstrual cramping and migraine headaches. On April 7, 2005, Bextra was taken off the market. Bextra was prescribed to millions of patients over the years, and despite the potential risks of deadly SJS, heart attack and strokes, it is still available for purchase.

### **Byetta**

Byetta, a drug used to treat diabetes, has been linked to acute pancreatitis, a sometimes fatal inflammation of the pancreas. Symptoms of acute pancreatitis include severe abdominal pain. Byetta has also been linked to kidney failure.

### **Chantix**

Chantix is a prescription drug used to help people stop smoking. Chantix side effects may include suicidal thoughts, depression, violent behavior, heart trouble, seizures and diabetes.

### **Clomid (Birth Defects)**

Children born to women who use the prescription fertility drug Clomid have a higher incidence of severe types of birth defects such as cleft palate or spina bifida.

### **Crestor**

According to data published by the Food and Drug Administration (FDA), the anti-cholesterol drug Crestor® may be linked to kidney damage and a painful muscle condition called rhabdomyolysis. A recent study published in the Journal of The American Heart Association revealed that patients taking Crestor® are more likely to develop serious side effects than patients taking Lipitor® (atorvastatin), Zocor® (simvastatin), or Pravachol® (pravastatin). During clinical trials, patients taking Crestor® experienced proteinuria (elevated levels of protein in the urine) as well as hematuria (blood in the urine). The presence of blood and elevated levels of protein in urine could be signs of serious liver toxicity.

### **Celebrex**

Celebrex is a NSAID (Non-Steroidal Anti-Inflammatory Drug) prescribed for the relief of osteoarthritis, management of acute pain in adults and relief of rheumatoid arthritis symptoms. Recent study shows that patients taking Celebrex are two times more likely to suffer from a heart attack or stroke. There are other reports showing that patients who take Celebrex are at an increased risk of developing ulcers.

### **Darvon, Darvocet (propoxyphene)**

Pain relievers sold under the name Darvon, Darvocet and other generic names containing the active ingredient propoxyphene (pro pox e fene) were pulled from the market by the FDA after a study revealed that the drugs may cause potentially fatal irregular heart rhythms.

### **Denture Creams**

Zinc found in denture creams such as Super Poligrip, Fixodent and others, can be ingested through the gums or stomach and cause zinc poisoning, paralysis and other serious neurological disorders.

### **Depakote (Birth Injury)**

Depakote, a drug prescribed for bipolar disorder and other conditions has been linked to serious birth defects.

### **Effexor (Birth Defects)**

Some babies born to mothers who took Effexor during pregnancy may have increased rates of heart defects or other birth defects.

### **Ephedra (also known as Ephedrine, Ma Huang and Epitonin)**

Ephedra is an ingredient used as a dietary supplement, energy booster or to aid with respiratory illness. In some cases it has been reported that people have experienced strokes and heart attacks after using products containing ephedra. Effective March of 2004, the FDA banned retail sales of dietary supplements containing ephedra.

### **Fen Phen, Pondimin & Redux (Pulmonary Hypertension)**

**Ephedra is an ingredient used as a dietary supplement, energy booster or to aid with respiratory illness. In some cases it has been reported that people have experienced strokes and heart attacks after using products containing ephedra.** Effective March of 2004, the FDA banned retail sales of dietary supplements containing ephedra.

### **Fosamax (Also: Zometa or Aredia)**

Fosamax (generic name - Alendronate) is a type of drug known as bisphosphonates used to treat osteoporosis in post menopausal women. Although Fosamax and other bisphosphonates are designed to strengthen bone, for reasons not yet understood, they can have the reverse effect and weaken bones instead. This condition is a serious bone disease called osteonecrosis of the jaw (ONJ) or "dead Jaw". This can also cause femur bone fractures. The Food and Drug Administration and Novartis, the manufacturer of bisphosphonates used in cancer chemotherapy, issued a warning letter to health care professionals on September 24, 2004.

### **Gadolinium with MRI or MRA Scan (NSF or NFD)**

An injectable dye used with some MRI or MRA scans is linked to a serious disorder called Nephrogenic Systemic Fibrosis (NSF) or Nephrogenic Fibrosing Dermopathy (NFD), which can be fatal. Symptoms of NSF/NFD include thickening or tightness of skin, difficulty walking, joint pain and skin sores.

### **Hormone Replacement Therapy (HRT)**

The National Heart, Lung and Blood Institute conducted a clinical study on women taking Hormone Replacement Therapy such as PREMPRO, PROVERA or PREMARIN. Their research showed an increased risk of breast cancer and

several other serious side effects such as heart attacks, strokes and blood clots.

### **Hydroxycut**

Hydroxycut recalled 14 of its products after the FDA discovered that their use could potentially result in serious side effects including liver damage, seizures, muscle damage, kidney failure and other problems.

### **Impotence (Viagra, Levitra, Cialis)**

A growing number of documented cases show that use of Viagra, Levitra or Cialis may be linked to temporary or permanent vision loss in one or both eyes.

### **Infuse Bone Graft (Spinal Fusion Surgery)**

The Medtronic InFuse bone graft system used a liquid bone protein which encouraged bone growth in spinal fusion surgery. Its use in non-FDA approved types of fusion surgery may have led to serious adverse affects.

### **Ketek**

Ketek was approved in 2004 for the treatment of acute bacterial infections from chronic bronchitis, sinusitis and pneumonia. Recent reports indicate a link between this drug and liver damage and liver failure.

### **Levaquin (Tendon Injuries)**

Levaquin is one of a group of antibiotics that have been linked to tendon injuries, including tendon rupture.

### **Lexapro & Celexa**

Antidepressants such as Lexapro and Celexa may be linked to suicidal behavior. The FDA has asked drug companies to strengthen warnings for these antidepressants to include an increased risk of suicide in some people.

### **Liptor**

Lipitor was prescribed to help lower Cholesterol. Its ability to produce cholesterol, thus preventing or reducing the harmful build-up of plaque in artery walls has contributes to heart disease, stroke and other maladies. Symptoms associated with this drug are muscle pain and kidney problems or dark urine related health problems.

### **Meridia**

Meridia is a prescription weight loss pill that was taken off the market because studies linked it to an increased risk of heart attack and stroke.

### **Neurontin**

Neurontin was approved for sale in the mid-1900s as a treatment for epileptic seizures. However, it was believed that approximately 80 percent of all Neurontin prescription were filled for unapproved medical conditions. Neurontin is believed to be linked to suicidal behavior.

### **Oral Sodium Phosphates (Fleet)**

Patients often take oral sodium phosphates, such as Fleet Phospho-soda to clean their intestines before a colonoscopy. However, taken at higher doses, these products can cause severe problems such as kidney damage.

### **Ortho Evra (Birth Control Patch)**

Ortho Evra birth control patch may be three times more likely to cause a stroke or a blood clot than leading birth control pills. According to the Associated Press, in 2004 about a dozen women, primarily in their late teen's and early 20's,

died from blood clots and a dozen more survived strokes and other blood clot-related problems including deep vein thrombosis, pulmonary embolisms and heart attacks.

### **Oxycodone, Codeine or Hydrocodone (Birth Defects-Painkillers)**

Children born to women who use painkillers such as Codeine, Oxycodone and Hydrocodone while pregnant have a higher incidence of birth defects such as cleft palate or spina bifida.

### **Pain Patch**

On July 15, 2005 the FDA issued a Public Health Advisory concerning the use of Pain Patches (Fentanyl transdermal) in response to reports of deaths in patients using the patch.

The Pain Patch is indicated for the management of severe, chronic pain (such as cancer pain) that cannot be managed with less powerful drugs. If the medication leaks out of the patch, exposure to the medication can result in inadvertent ingestion or increased transdermal absorption of the active opiate component fentanyl, leading to potentially life-threatening complications.

### **Pain Pump (Shoulder Surgery)**

A new study has revealed that a pain pump used to deliver pain medicine following shoulder surgery may cause the destruction of shoulder cartilage.

### **Paxil, Lexapro, Zoloft, Prozac, Celexa & Effexor (Birth Defects)**

Recent studies of pregnant women who took SSRI antidepressants during their pregnancy show increased rates of heart defects among their newborns.

### **Permax (Paroxetine HCl)**

The Mayo Clinic research has discovered what may be a link between Pergolide Mesylate (per-go-lyed mess-a-late), sold as Permax, and serious heart valve disease. Three women who were taking Pergolide for Parkinson's disease developed serious heart valve damage in spite of having no history of heart disease. Two of the three women required surgery as a result.

### **Plavix**

Results of a recent study show that taking the anti-clotting drug Plavix (generic name: Clopidogrel) along with aspirin to prevent heart attacks may actually increase the risks of strokes, heart attacks and death. No benefit of combining the two drugs has been found; in fact, combining these drugs may cause more harm than good in people who are at high risk.

### **Pradaxa**

The blood thinner Pradaxa may increase the risk of serious bleeding problems as well as death.

**Propecia** Propecia is sold by Merck to treat hair loss but recent studies have shown that its use can lead to sexual dysfunction.

### **Raptiva**

The Psoriasis prescription drug Raptiva has been linked to a deadly brain infection, Lymphoma and other serious infections.

### **Reglan**

Reglan (Generic: Metoclopramide) is a drug prescribed for acid reflux disease. Long term use can cause a serious neurological disorder called Tardive

Dyskinesia. Reglan has also been linked to other illnesses such as Neuroleptic Malignant Syndrome (NMS) which can be fatal.

### **Propulsid**

Propulsid has been prescribed to aid in the relief of migraine and cluster headaches. In some cases it has been reported that people have experienced heart attacks, strokes, hypertension, and some have died. Usually an incident will occur shortly after taken, or within a few days of taking Propulsid.

### **Rezulin**

This is the information that has been reported. Rezulin was prescribed to treat type 2 diabetes. As of March 21st, 2000, Rezulin was taken off the market because of reports concerning liver damage and liver failure.

### **Risperdal**

Risperdal (Ris-per-doll) was approved by the FDA in December 1993. It has recently been reported that serious side effects can result from taking Risperdal including a condition called Tardive Dyskinesia (Tar-dive Disk-en-easy-ah). This is a movement disorder which can cause a loss of muscle control and is often referred to as False Parkinson's.

### **Serzone**

Serzone is used to treat depression. On January 2002, new warning regarding the association of Serzone with liver-failure was placed on the drug labeling. From April 1, 2002 through May 12, 2003, FDA adverse event data recorded a total of 20 reports of death due to liver failure in people using Serzone.

### **Serevent**

Serevent, a drug used for the long term treatment of Asthma may be associated with an increased risk of respiratory deaths and other life-threatening Asthma episodes, according to information collected by the FDA.

### **Seroquel**

Seroquel (quetiapine) is a popular antipsychotic drug administered for treatment of schizophrenia and bipolar disorder. A number of studies have linked Seroquel to an increased risk of diabetes. The FDA has also issued a public health advisory concerning increased mortality rate among elderly patients treated for dementia.

### **Topamax (Birth Defects)**

Topamax is a prescription drug approved to treat epilepsy and migraine headaches. Children born to women who use Topamax while pregnant have a higher incidence of birth defects such as cleft palate.

### **Tequin**

Tequin (generic name - Gatifloxacin) is an antibiotic used to treat sinus, lung and urinary tract infections as well as certain venereal diseases. Bristol-Myers Squibb has quietly pulled the drug from the market after studies revealed concerns about serious blood sugar-related side effects.

### **Transvaginal Mesh**

Women who have had surgery to repair Pelvic Organ Prolapse (POP) or Stress Urinary Incontinence (SUI) using a surgical mesh device have reported complications such as infections, pain and scarring.

## **Vioxx**

Vioxx was most often prescribed to aid in the relief of arthritic pain. On September 30, 2004, Merck, the manufacturer of Vioxx, recalled Vioxx worldwide after a study showed that Vioxx increased the incidence of heart attacks and strokes.

## **Zicam (Cold-Eeze)**

These over the counter cold remedies contain zinc gluconate (ZINK GLUE koe nate) which has been shown to cause a loss of smell. The manufacturer of Zicam, Matrix Initiatives, did not do any studies on its product concerning loss of smell prior to putting Zicam on the market.

## **Zocor**

Zocor (also known as Simvastatin) is used to reduce LDL (bad) cholesterol and increase HDL (good) cholesterol in your blood. These actions may reduce the risk of hardening of the arteries, which can lead to heart attacks, stroke, and peripheral vascular disease.

## **Zometa**

Zometa is used to treat osteoporosis. Although used to strengthen bones, some patients develop a serious disease called osteonecrosis which is the deterioration of the jaw bone.

## **Zyprexa (Olanzapine)**

A study examining 8 years of data collected by FDA identified 289 cases of diabetes in patients taking Zyprexa. Of these 289 cases, 225 were newly diagnosed cases, 100 of which developed ketosis (a serious complication of diabetes). In addition, 22 people developed pancreatitis.

# **Medical Devices**

## **Aneurysm (Stent) Surgery**

Guidant Corporation subsidiary Endovascular Technologies recently pled guilty to 10 felonies and agreed to pay \$92.4 million in penalties related to the Ancure "stent-graft" device, which was used during operations to treat abdominal aortic aneurysms (bulges in the wall of the main artery leaving the heart). Charges include shipping misbranded products and lying to the government; the company was charged with failing to report as many as 2,600 malfunctions since September, 1999.

According to the Food and Drug Administration, complications occurred during the insertion or removal of the device when it would get stuck or lodged in the patient's body, which often led to internal bleeding, damaged arteries and/or surgery to remove the device. In the most severe cases, open heart surgery was necessary.

### **Blood Clot Filter (Bard Vena Cava Filters)**

Vena Cava filters are placed in a large vein to trap blood clots before they travel to the lungs. Severe injuries may occur when pieces of the device break off and move in the body.

### **Defibrillator Lead Wire (Medtronic & St Jude)**

Medtronic & St Jude have pulled their Sprint Fidelis defibrillation lead wires from the market after fractures in the leads were linked to five patient deaths. Patients with these lead wires may have received a warning letter from the manufacturer.

### **DePuy ASR Total Hip Replacement**

DePuy Orthopaedics pulled the ASR hip implant from the market after reports of the device failing shortly after implant surgery.

A large number of patients reported crippling pain following surgery, often requiring additional surgery to have this device replaced.

### **Gastric Bypass Staplers**

The FDA has received reports of numerous deaths and other injuries resulting from defective staplers used in gastric bypass surgery.

### **Guidant Medtronic Cardiac Defibrillators**

Guidant recalled 50,000 of its implantable cardiac defibrillators because of defects. Guidant reported there had been 45 device malfunctions, and seven patients with the recalled devices died.

Guidant Cardiac Defibrillators are programmed to deliver a potentially life-saving electrical shock when the heart rhythms go awry. Due to a faulty switch that could prevent delivery of the shock, patients who currently have one of the defective models implanted may be at risk.

### **Guidant / Medtronic Pacemakers**

Guidant Corporation has warned doctors that about 28,000 of its earlier generation pacemakers may malfunction and need to be replaced in some patient. The problem involves a bad seal which allows moisture into the pacemaker causing it to gradually degrade.

For patients that depends on the pacemakers to maintain a normal heart rate, failure of the device can cause sudden faintness or loss of consciousness, and can result in death.

### **Knee Replacement Surgery**

News reports revealed problems with 2 models of Smith & Nephew cementless artificial knees that led to a recall in September, 2003. The two models, the Oxinium Genesis 2 and the Profix 2 were used in implant operations between June of 2002 and March, 2003. These models failed to bond properly and became loose. As a result, many patients required additional corrective surgery, suffered infections and experienced further joint and muscle damage, often leading to painful rehabilitation.

### **Kugel Hernia Patch**

The Bard® Composix® Kugel® Mesh Patch is used to repair hernias caused by thinning or stretching of scar tissue that forms after surgery. The patch is placed behind the hernia through a small incision. The patch is then held open by a "memory recoil ring" that first allows it to be folded for insertion, and then causes

it to spring open and lay flat once it is in place. The recoil ring that opens the patch can break, leading to bowel perforations and to abnormal passageways between the intestines and other organs. Symptoms associated with ring breakage include abdominal pain, fever and tenderness at the implant site.

### **Stent**

The FDA has been receiving reports of complications related to stent devices used most often in angioplasty and abdominal aneurysm surgeries. Common problems include clot formation, leakage around the device, respiratory alterations and blood pressure changes.

Follow-up surgeries for removal or replacement may be required to repair these problems. In the worst cases, these complications may lead to rupture of the device or death.

## **Toxic Substances/Toxic Torts**

### **Asbestos (Mesothelioma)**

Mesothelioma is a form of cancer that develops in the tissues of cells that line the lungs, heart and stomach. These tissues are called mesothelial cells and they become infected by inhaling particles of dust from asbestos fibers.

It is estimated that about 3,000 to 4,000 cases of mesothelioma are diagnosed each year in the US.

Symptoms of mesothelioma may not appear until 20 to 50 years after exposure to asbestos. Shortness of breath, cough, and pain in the chest due to an accumulation of fluid in the pleural space are often symptoms of pleural mesothelioma.

### **Benzene**

Benzene is known carcinogen linked to leukemia and various other forms of cancer. Although Benzene was banned as a solvent in the U.S. more than 22 years ago, it's estimated that more than 3 million workers are exposed every year. People working with petroleum solvents are at the greatest risk of exposure, both from inhalation and absorption through skin contact.

### **Bone/Tissue Implant Surgery**

The FDA has issued a warning that some bone and skin tissue taken from cadavers and later used in surgery may not have been properly screened for infectious disease. As a result, individual who have had a bone, skin or tissue transplant or a spinal fusion since 1998 may be at risk for contracting infectious diseases such as HIV and hepatitis.

### **Diacetyl-Lung Disease (Popcorn Lung)**

According to the National Institute for Occupational Safety and Health (NIOSH), from 1992 to 2000 eight former workers of a popcorn factory in Jasper, Missouri developed a rare lung disease called bronchiolitis obliterans. The chemical Diacetyl, a common ingredient in artificial butter flavoring, is believed to have caused the lung disease. In the worst cases, the factory workers may eventually need a lung transplant. Diacetyl is also found in dairy products, oils, vegetables,

coffee, vinegar and beer.

### **Oil Spill**

BP's oil spill has resulted in significant damage to the fishery ecosystem and the coast of Florida, Alabama and Louisiana.

### **Welding Rods**

Exposure to welding fumes may be linked to the early onset of Parkinson's Disease, as well as increased risk for certain types of cancer. Long term health hazards associated with welding can be serious, and sometimes fatal.

Exposure to toxic substances released in welding smoke, such as cadmium and arsenic, can put workers at an increased risk for several cancers, including lung cancers and cancer of the larynx.

## **Product Liability Cases**

### **ATV Rollover Accidents**

All terrain vehicles (ATVs) have greatly increased the number of serious injuries associated with their use. Hundreds of people, many under the age of 16, die each year from ATV rollovers.

### **Chinese Drywall**

Between 2003 and 2007 defective drywall imported from China was used in homes built in the U.S. This drywall contains sulfur which often is detected by a strong rotten egg smell. In addition to the smell, moisture, often from an air conditioning system, can cause major corrosion in air conditioning systems, copper fixtures, copper electrical wire and other metals.

### **Contact Lens Eye Infection**

There is a possible link between the AMO Complete® MoisturePlus™ Multi-Purpose Solution and 138 confirmed cases of Acanthamoeba Keratitis, a rare form of Keratitis, which is described as a painful eye infection that can lead to permanent vision loss or blindness. As a result of this link, there was a nationwide recall of this contact lens solution.

There is also a possible link between corneal eye infections (keratitis) and other multi-purpose contact lens solutions including but not limited to ReNu with MoistureLoc & ReNu MultiPlus (Bausch & Lomb), Opti-Free (Alcon), SOLOcare (Ciba Vision), and Complete® MoisturePlus™ Multi-Purpose Solution (Advanced Medical Options).

## **Malpractice**

### **Birth Injury (Cerebral Palsy)**

Cerebral Palsy is a term that describes a group of disorders that affect movement

control. There is not one specific cause of cerebral palsy, however, it can be caused by lack of oxygen to the brain or trauma to the head during labor and delivery.

### **Bypass Surgery (Heart Bypass)**

The FDA has been receiving reports of complications related to a new aortic connection device used in coronary bypass surgeries performed since spring of 2001. Common problems include blood clots, postoperative hemorrhage (leakage around the device) and failure to attach properly. Followup surgeries may be required to repair these problems. In the worst cases, these complications may lead to a heart attack or death.

### **Lasik Surgery**

Lasik eye surgery procedures are meant to correct faulty or myopic vision, sometimes this procedure has tragic results. To lose your vision as a result of the negligence of a medical professional is a very serious situation.

### **Medical Malpractice (Personal Injury)**

Medical malpractice involves negligence by doctors or their staff at hospitals, doctor's offices and nursing homes, and can lead to tragic injuries. According to an article published in the Journal of the American Medical Association (JAMA), more than 225,000 people die each year due to the actions of health professionals. This has become the third leading cause of death in the United States, after deaths from heart disease and cancer.

## **Additional Topics**

### **Disability / Insurance Claim Denial**

Insurance companies often unreasonably either limit or deny claims. Tactics employed by insurance companies include delays in paying claims, failing to actually research claims, reducing eligibility over time, and adding exceptions to the contestability clause.

### **Investment Recovery**

Smith Barney, Merrill Lynch and 9 major brokerage firms have agreed to pay \$1.4 billions in fines for conflict of interest and giving misleading advice to individual investors.

One firm has set aside \$1.5 billion to repay investors who lost their money! Other brokerage firms have agreed to pay \$675 millions for penalties.

### **Nursing Home Abuse**

Every day, vulnerable people in nursing homes, assisted living centers and people receiving home health care are abused and neglected by the very caregivers we entrust with their well-being.

### **Vehicle Accidents**

Millions of Americans are injured in car accidents every year. In 2005, more than 43,000 people died on American roads.