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## **HEART SICK**

### **Hazardous Heart Devices and the Importance of Litigation**

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### **EXECUTIVE SUMMARY**

Heart disease is the number one killer in the United States. Medical device companies have invested billions of dollars developing devices to repair and protect the heart. While saving many lives, heart implants are also among the most dangerous and recalled medical implants ever made.

Because of medical risks, heart implants are not always removable even if the device fails or is later recalled. Sometimes devices are recalled long after manufactures were aware of problems and tens of thousands of devices are implanted in patients, forcing them to live with ticking time bombs in their chests.

Time and again, medical device companies have shirked their responsibilities to ensure the safety of heart devices. Some heart devices have been placed on the market without adequate clinical testing. This has been with the acquiescence of the FDA, a troubled agency that has repeatedly been unable to properly oversee this hazardous industry.

Only through litigation were many of these patients or their families compensated, did the public learn how dangerous some of these devices were, and ultimately, was the public protected. This report tells the story of some of these devices.

#### **HEART VALVES**

##### **Björk-Shiley Convexo-Concave Artificial Heart Valve**

- Only on the market for seven years, Shiley (later bought by Pfizer) marketed the Björk-Shiley Convexo-Concave Heart Valve with a shoddy design and manufacturing defects, which caused the device to fracture. When finally withdrawn from the market in 1986, it had caused hundreds of deaths and the valve continued to kill and injure patients while creating sheer terror for patients living with this implant.

- A congressional committee found that Shiley intentionally tried to obstruct government knowledge and oversight of design and production defects and misled the medical community, causing even more deaths. It also found serious questions about the FDA's willingness and ability to protect the public.
- Although the company initially insisted on confidentiality upon settling lawsuits, ensuring that future victims never learned of these defects, many victims did receive compensation. The company also paid the government \$10.75 million to settle civil claims. As a result of lawsuits, critically important information eventually came to light about this tragic episode.

### **Heart Valve Problems Have Continued**

St. Jude Medical's Silzone valve, which went on sale in 1998, was recalled in 2000, because the valve's silver coating caused it to leak, resulting in many injuries and death.

### **ENDOVASCULAR GRAFT STENTS**

- This stent is a treatment for abdomen aortic aneurysms (rupture of the main artery taking blood from the heart). While there are safe treatments for this condition, the endovascular graft stents manufactured by Medtronic and Guidant were not safe and caused many injuries and deaths.
- In 2003, a Guidant unit, Endovascular Technologies, plead guilty to 10 felonies and paid a large fine for failing to notify the FDA about device malfunctions and patient deaths.

### **ARTIFICIAL PACEMAKER AND DEFIBRILLATORS**

- Pacemakers are a two-part heart implant (generator and leads) that keep the heart in regular rhythm. Pacemakers have been subject to hundreds of recalls over many years. Defibrillators, which also regulate the heartbeat, can also deliver electric shocks to accomplish this.
- Pacemaker failures have included: fracturing of the leads (wires) causing problems like perforating the aorta or shocking the patient; battery failures; and moisture buildup, which has caused the device to fail.
- In 2005, at the encouragement of two well-respected cardiologists, the *New York Times* broke the story about a Guidant defibrillator that was short-circuiting at a rate of about once a month. Three years earlier the company had changed its manufacturing process to correct the problem but never told doctors and continued to sell its defective inventory. Patients died and the FDA kept this information from the public for many months.
- Both victims and taxpayers (via state Attorneys General suits) have received compensation from litigation, and lawsuits uncovered important information about this episode.

In the 2008 case *Riegel v. Medtronic*, the U.S. Supreme Court immunized from liability companies that manufacture defective heart devices. This decision leaves heart patients with no legal recourse should they be injured, and removes the most significant and effective financial consequence to a company for choosing to keep a dangerous heart device on the market. Legislation to remedy this situation is currently before Congress.