Johnson & Johnson knowingly sold faulty hip implants

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Medical products company Johnson & Johnson was aware of an egregious fault in a hip replacement implant it sold, newly released court documents reveal. An internal company analysis conducted in 2011 found the metal device had a failure rate of 40 percent within five years of implantation.

Since 2008, executives at Johnson & Johnson's DePuy Orthopaedics division knew of problems with the implant, called Articular Surface Replacement (ASR). This was a year before the company stopped production, and fully two years before recalling them. At the time of its analysis, the *New York Times* reported Tuesday, Johnson & Johnson was publicly downplaying findings from a British medical implant registry about the ASR's high early failure rate.

"The company's analysis also suggests that the implant is likely to fail prematurely over the next few years in thousands more patients," the *Times* reported, "in addition to those who have already had painful and costly procedures to replace it."

The analysis was included in documents, motions, and pre-trial depositions released January 18 as a result of the first of many lawsuits over the implant failures. The trial is scheduled to begin Friday in California Superior Court in Los Angeles.

Approximately 93,000 patients worldwide received the implants, 37,000 of them in the US. Some 10,100 US patients are expected to sue.

In 2009, DePuy executives decided to phase out the device after the federal Food and Drug Administration sent a letter requesting additional safety data about the implant. In addition to the failure rate, the FDA cited concerns that the device was causing "high concentration of metal ions" in the blood of patients. The FDA has no ability to enforce a recall.

Rather than halt sales of the hip implants, Johnson & Johnson continued to sell off its inventories.

The company attempted to deal with the failures on an individual basis through out-of-court settlements and special charges running into the billions of dollars. DePuy has offered to pay for replacement procedures.

The ASR is no longer recommended in standard hip replacement surgeries because the all-metal implants have been found to grind together and release metallic debris that damage bone and cause tissue death.

A DePuy engineer stated in pretrial testimony released last week that company executives were aware in 2008 of the high levels of metal ions.

DePuy executives have maintained that the company responded in a timely and appropriate way to the ASR defect. When the implant was recalled in 2010, Johnson & Johnson said it was responding to data from the National Joint Registry of England and Wales showing that the ASR was failing prematurely at a higher rate than other implants—but the registry's estimate was lower than DePuy's internal analysis suggested.

When the British registry revised its failure rates upward to one in three, closer to the company's own data, DePuy publicly challenged the estimate. Other medical organizations also projected similarly high failure rates for the ASR.

The revelation is only the latest in a long line of medical scandals in the US. The players are familiar: a billion-dollar company knowingly selling a faulty product; the federal regulatory agencies subordinate to the industry; and the mass of the population who are victimized in the name of profit.

The problem may be far wider than the DePuy products. While all-metal devices now account for only 5 percent of hip implants, an estimated 500,000 patients in the US have received artificial hips that may fail over the next decade.

The FDA has proposed clinical trials for metal hip implants to justify their use, but the impact of such a proposal will have little impact on medical manufacturers, and as the *New York Times* reported January 17, "industry lobbyists may oppose its adoption or seek to modify it." Moreover, agency officials told the *Times*, "it would most likely take a year for the rules to be finalized; after that, producers will have 90 days to submit clinical data to support a device's safety and effectiveness."

The DePuy trial comes on the heels of a nationwide fungal meningitis outbreak that has stricken hundreds with severe infections and killed dozens. The cause of the outbreak was fungus-contaminated steroid medication produced by New England Compounding Center, a Massachusetts compounding pharmacy, which was not under FDA oversight because of its classification as a pharmacy. The company had been cited for violating safety standards since 2006, but was not prevented from continuing to produce tainted drugs. At least 14,000 people were put at risk of developing meningitis.

Many products that have been approved by the FDA have also caused death and suffering. Merck's arthritis drug Rofecoxib, marketed under the brand names Vioxx, Coexx and Ceeoxx, received FDA approval in 1999 and was a top seller around the world for the next five years. More than 80 million patients took the drug, generating sales revenues of $2.5 billion. In 2004, Merck withdrew Rofecoxib after it was revealed that the company knew from the beginning that the drug caused increased risk of heart attack and stroke. As many as 140,000 people developed serious heart disease, and some 60,000 people died as a result of taking the drug.

In October 2012, the FDA announced a recall of a generic high-dosage version of Wellbutrin XL, a widely prescribed anti-depressant, because it did not work and produced unusual side effects. The drug had been sold since the FDA approved it in 2006 without testing it.

In November, drug company Ranbaxy announced a recall of its generic version of the cholesterol-lowering drug Lipitor because the pills contained glass particles, a problem the FDA did not catch when it approved the drug. Lipitor is the most prescribed drug in the US, meaning that thousands of patients were likely prescribed the cheaper generic version of the drug.

The FDA approved 39 new drugs in 2012, the most in 16 years, 10 of them on "fast-track" status.