

WALL STREET JOURNAL: "DePuy's Hip Replacement: The New Big Thing in Product Liability Suits?"

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A story over at Brand X today discusses a troubling loophole that exists in the Food and Drug Administration's regulation of implants.

Unlike new drugs that must go through clinical trials before getting FDA approval, some implants can be sold without the tests if it resembles an implant already in use, the story says.

Enter the Articular Surface Replacement, a hip replacement device made by DePuy Orthopaedics, a unit of Johnson & Johnson.

Many patients who have received the implant claim to have developed curious pain, and surgeons who have replaced the implant say they have found mysterious masses of dead tissue near patients' thighs. Some patients allege that they have high levels of cobalt ions in their blood, prompting them to fear they risk poisoning themselves.

Predictably, the lawsuits are lining up. Recently, the U.S. Judicial Panel on Multidistrict Litigation consolidated the suits and shipped them off to the Northern District of Ohio.

One suit, filed by California attorney Dana Taschner, alleges DePuy should have known its hip replacement devices fail in a high percentage of patients.

"Such failures have been shown to give rise to symptoms such as severe pain, inflammation and death to surrounding tissue and bone, a partial or complete lack of mobility, and the need for revision surgery to remove and replace the device giving rise to even more debilitation, a prolonged recovery time, and an increased risk of complications and death from further surgery," the suit says.

According to the suit, DePuy received notice of several hundred complaints made to the FDA in 2007-08 but didn't issue a recall until late August 2010. The suit says DePuy has offered doctors \$50 for obtaining the patients consent to receive his or her medical records and is asking doctors to send any devices that have been removed.

A DePuy spokeswoman said the company is happy an experienced judge has been selected to

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address the litigation and that it remains committed to "covering reasonable and customary costs of testing and treatment for patients who need services, including revision surgery if it is necessary," tied to the recall.

The next court hearing on the MDL is scheduled for January 20 before U.S. District Judge David A. Katz.