J&J recalls 2 hip replacement systems for problems

By LINDA A .JOHNSON (AP) - 4 days ago

TRENTON, N.J. - Johnson & Johnson's artificial joint business is recalling two hip replacement products, just two days after getting hit with a government warning that it is illegally marketing two other products. It is the 11th J&J recall since September.

DePuy Orthopaedics Inc. said Thursday it is recalling two hip replacement products because new data, about to be released, show higher-than-expected rates of patients needing a second hip replacement procedure.

Within five years, one in eight patients needed a revision surgery. That's required when an artificial joint doesn't fit perfectly, causing pain and difficulty walking. The products are the ASR Hip Resurfacing System and the ASR XL Acetabular System.

"We are committed to assisting patients and healthcare providers by providing information through multiple channels and paying for the cost of doctor visits, tests and procedures associated with the recall," David Floyd, president of DePuy Orthopaedics in Warsaw, Ind., said in a statement

That includes monitoring of how well a patient's hip is working and paying for any corrective surgery. Products still on hospitals shelves will be removed, said DePuy spokeswoman Lorie Gawreluk.

Each of the metal systems is used to replace a worn or weakened part of the hip, which consists of a socket at the outer edge of the pelvis and a rounded bone atop the thigh bone that fits into that socket like a ball. Total hip replacement involves replacing both parts at once.

The ASR Hip Resurfacing System replaces the ball portion of the hip and has a metal stem that fits into the top of the hip bone, or femur. The ASR XL Acetabular System is a concave metal piece used to provide a smooth lining for the acetabulum, the bowl-shaped socket in the pelvis.

DePuy, part of Johnson & Johnson of New Brunswick, N.J., said data it received from the National Joint Registry of England and Wales shows that within five years, about 12 percent of people getting the hip resurfacing system and about 13 percent of those getting the Acetabular system needed corrective surgery. Women were more likely to need a second surgery than men.

DePuy said previous data "had shown lower revision rates and that the ASR hip was performing in line with other devices in its class."

Gawreluk said she did not have the actual numbers of patients with problems.

The Acetabular system, launched in 2004, has been sold worldwide. The resurfacing system, introduced in 2003, is only sold outside the U.S.

DePuy decided last fall to discontinue both, Gawreluk said. The company is working on developing a new generation of both products.

On Tuesday, the Food and Drug Administration told DePuy to stop selling its Corail Hip System for two unapproved uses. It also ordered the company to provide information needed to review another product the agency said DePuy has been selling even though it was never approved. It's called the TruMatch Personalized Solution System, and uses software and high-tech CT scanning technology to create a 3-D view of a patient's knee to help a surgeon position a knee implant.

On Monday, Johnson & Johnson recalled millions of 1 Day Acuvue TruEye contact lenses sold in Asia and Europe because some users complained of stinging or pain when they inserted the lenses.

Johnson & Johnson remains under scrutiny by the FDA, Congress and federal prosecutors over eight previous U.S. recalls of nonprescription medicines since last September. Those included millions of bottles of Tylenol, other pain relievers and cold medicines for children and adults, for problems including bacterial contamination and tiny metal savings found in some bottles.

In midday trading, J&J shares rose 2 cents to $58.