Johnson & Johnson Recalls Hip Implants

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More than two years after the Food and Drug Administration began receiving complaints about the failure of a hip replacement implant made by the DePuy Orthopaedics unit of Johnson & Johnson, the company said Thursday that it was recalling two kinds of hip implants.

DePuy said that it had made the decision to withdraw the products because many patients required a second hip replacement after the company's implants had failed.

The news compounded problems for Johnson & Johnson, which has recalled a succession of some of its best-selling and best-known products, including liquid children's Tylenol in the United States and, just this week, Acuvue contact lenses in Japan and other countries in Asia and Europe. The Tylenol recall led to the temporary closing of a plant owned by the McNeil Consumer Health Care unit, which is the subject of a federal inquiry over its handling of recent recalls of over-the-counter products.

In addition to DePuy's recall, the F.D.A. this week criticized the company in a warning letter, contending that it had illegally marketed an unapproved knee device and had also sold a hip implant for an unapproved use. (A spokeswoman for DePuy said that the company was examining the F.D.A.'s concerns.)

"All this makes it seem like it's pile-on time for J.& J.," said William Trombetta, a professor of pharmaceutical marketing at Saint Joseph's University in Philadelphia. "This is a company that was purer than Caesar's wife, this was the gold standard, and all of a sudden it just seems like things are breaking down."

In the latest Johnson & Johnson case, DePuy said in a statement that it was recalling two products: the ASR XL Acetabular System, a hip socket used in traditional hip replacement, and the ASR Hip Resurfacing System, a partial hip replacement that involves placing a metal cap on the ball of the femur, a method intended to preserve more bone. The traditional implant has been available worldwide, and the resurfacing implant was approved for use in countries outside the United States.

About 93,000 of these devices have been implanted worldwide, said Lorie Gawreluk, a DePuy spokeswoman. The New York Times reported in March that for more than two years, the F.D.A. had been receiving complaints that the devices failed early in some patients, requiring expensive and painful operations to put in new hip replacements. Since the start of 2008, the F.D.A. has received about 400 complaints involving patients in the United States who received the devices, an agency spokeswoman said Thursday.

DePuy said that the majority of hip replacements using the ASR devices had been successful. But the company advised patients who had had hip replacements with the recalled products to visit their surgeons for an evaluation and annual monitoring. The company said it would pay reasonable and customary medical costs associated with the recalled products, including new hip replacement operations.

DePuy had sales last year of about $5.4 billion, according to a Johnson & Johnson earnings report.

The high early failure rate of the ASR implants was reported this year in severalarticles in The New York Times. These devices have come under scrutiny over the last few years because they are part of a category of implants called metal-on-metal bearings, which can generate debris from wear, causing inflammation and tissue damage in certain patients.

In March, the British agency that regulates medical devices issued an advisory on metal debris generated by hip implants. A spokeswoman for the F.D.A. said the agency was planning to meet soon with professional medical groups to discuss the British advisory.

Late last year, DePuy said it was phasing out the implants because of slowing sales. In March, the company warned doctors that the implants might have a high failure rate in some patients.

In one New York Times article, some orthopedic experts expressed dismay that DePuy had not halted sales of the devices earlier. About 12 to 13 percent of patients needed a second hip replacement within five years of receiving an ASR implant, the statement from DePuy said, citing new unpublished data from a national registry in Britain. Previously reported follow-up data, including internal company information and clinical trials, had reported lower rates of second hip replacement comparable to similar devices by other companies, the statement said.

But many medical centers in the United States that specialize in joint replacement surgery had already noticed a higher failure rate with the DePuy hip implants, said Dr. Joshua J. Jacobs, the chairman of orthopedic surgery at Rush University Medical Center in Chicago.

“Most major medical centers have seen issues with this device,” Dr. Jacobs said. “This does not come as a surprise.”
Dr. Jacobs added that the DePuy recall pointed to the importance of having a national registry for joint implants that can serve as an early warning system for product problems. Britain, Australia and some other countries have such national registries, he said, but the reporting system currently used by the F.D.A. does not necessarily capture every device failure.

David Floyd, president of DePuy, said in a statement that the recall would be a concern for patients and their family members and for surgeons.

“We are committed to assisting patients and health care providers by providing information through multiple channels and paying for the costs of doctor visits, tests and procedures associated with the recall,” he said.

Johnson & Johnson comprises more than 250 different operating companies in 60 countries. But the recent recalls and F.D.A. warning letters to several units at Johnson & Johnson raise questions about whether there may be companywide problems, industry analysts said.

“No. 1, is there a systemic issue at J.& J.?” said Rick Wise, an analyst at Leerink Swann, a health care investment bank. “No. 2, is this” hip implant recall “reflective of that systemic issue? And, No. 3, is there more to come?”

Mr. Wise added that F.D.A. warnings and J.& J. recalls had come at a time of increased vigilance about product safety by the agency and health care companies. He said that he believed the various problems at J&J were separate and not part of a systemic issue.

Dr. Trombetta, the pharmaceutical marketing professor, compared Johnson & Johnson to Toyota, another multinational firm whose reputation has suffered this year during a series of recalls. The recalls may be tarnishing Johnson & Johnson’s apple-pie image, Dr. Trombetta said, but he predicted that the company would eventually recover public trust as Toyota largely had.

Shares of Johnson & Johnson closed at $57.80 on Thursday, down 18 cents.