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J&J to Stop Selling Surgical Mesh

By JONATHAN D. ROCKOFF And SHIRLEY S. WANG

Johnson & Johnson JNJ -0.21% is stopping sales of its versions of surgical mesh products that aimed to relieve the intense pelvic discomfort of thousands of women, but have resulted in numerous reports of injury and several deaths.

The decision is the latest action by the health-care giant tackling a range of problem products, such as the bottles of children's Tylenol and other popular over-the-counter medicines, as well as some contact lenses and certain hip implants, that the company recalled due to manufacturing problems.

The surgical meshes, sold by J&J's Ethicon unit, are among a class of products made by various companies whose safety and effectiveness the Food and Drug Administration warned about in 2008. J&J's meshes are also subject to hundreds of product-liability lawsuits, according to a May securities filing by the company.

The company is planning to halt sales world-wide of Gynecare TVT Secur, Gynecare Prosima, Gynecare Prolift and Gynecare Prolift+M mesh products, an Ethicon spokesman said. The company has asked the FDA to allow it to keep selling its Gynecare Gynemesh product, but for insertion through the abdomen only, rather than the vagina as is also currently allowed, the spokesman said.

J&J will be stopping sales over the next three to nine months, with the goal of completing the process by the first quarter of 2013, the company spokesman said.

"This is not a product recall and we continue to have confidence in the safety and efficacy of these products. Our decision to discontinue these products is based on their commercial viability in light of changing market dynamics, and is not related to safety or efficacy," the Ethicon spokesman said in a statement.

Ethicon told the FDA of its plan to halt sales on May 10, an agency spokeswoman said. "The FDA is reviewing the information provided by Ethicon and will respond to the company directly," the spokeswoman said.

"This is the first domino to fall," said Adam Slater, the co-lead plaintiffs attorney involved with hundreds of mesh cases. "I think the other manufacturers will follow."

Other leading manufacturers of the devices are Boston Scientific Corp., BSX -0.36% C.R. Bard Inc. BCR +1.00% and Endo Pharmaceuticals Inc. ENDP -0.19%

Both Endo, whose AMS subsidiary makes a mesh product similar to J&J's, and Boston Scientific expressed their commitment to remain in this business said they are working with the FDA to educate physicians about understanding and using the products. Endo is

also doing additional clinical work.

"We believe these are safe and effective treatments," said Blaine Davis, an Endo spokesman. Bard didn't respond to requests for comment.

J&J's Ethicon unit, which had $4.9 billion in sales last year, doesn't break out the sales of the mesh products when reporting financial results.

Doctors began using surgical meshes in the 1970s to treat severe cases of a painful condition in which organs like the bladder, uterus or bowel drop down and protrude into a woman's vagina after childbirth. Initially, doctors inserted the meshes through the abdomen to support the organs. In the 1990s, gynecologists began inserting them through the vagina.

Complications resulted in some cases. The mesh either contracted and tightened, or moved from its placement, and painfully protruded into the vagina.

Between 2008 and 2010, the FDA received some 1,500 reports of adverse events for meshes made by J&J and other companies. In 2008, the FDA warned about complications including erosion, pain and urinary problems. Last year, the agency issued a new warning that transvaginal use of the meshes for prolapse offers no evidence of greater clinical benefit than from insertion through the abdomen.

The meshes have also been cited in criticism of the FDA's expedited process for approving medical devices without a clinical testing because they simply build on products already approved and on sale.

Ethicon didn't seek FDA approval of its Gynecare Prolift mesh kit before bringing it to market because it considered the product to be essentially the same as a previously approved one, Gynemesh.

Later, the FDA asked the New Brunswick, N.J., company to file for approval of Prolift, according to an Ethicon spokesman. J&J made the request in 2008, more than two years after Prolift was put on the market and used by doctors, the company spokesman said last year.

Generally, companies would be asked to submit an application if the FDA determined they had been marketing a product that was in violation of FDA regulations, according to an FDA spokeswoman, interviewed last year.

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