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J&J Marketed Vaginal Mesh Implant Without U.S. Approval

By David Voreacos and Alex Nussbaum - Mar 21, 2012 6:11 PM ET

Johnson & Johnson sold a vaginal mesh implant for three years before U.S. regulators approved the device, now the subject of more than 550 lawsuits by women who claim it injured them.

J&J's Ethicon unit introduced the Gynecare Prolift device in March 2005, touting it in an annual report as an "innovative and effective surgical option" for weakened pelvic muscles. The U.S. Food and Drug Administration said it learned of the Prolift in 2007, when J&J sought approval for a related product. The FDA cleared both devices in May 2008.

Enlarge image

Johnson & Johnson's unauthorized sales might cost it more to resolve lawsuits over the product. Photographer: Daniel Acker/Bloomberg

The company, the world's second-biggest health-care products maker, said it could market the Prolift without approval because it was so similar to an approved device, the Gynecare Gynemesh, Morgan Liscinsky, an FDA spokeswoman, said in a March 16 e-mail. "FDA disagreed with this assertion," concluding distribution began "without appropriate" clearance, she said.

J&J's unauthorized sales might cost it more to resolve lawsuits over the product. J&J already has endured recalls of artificial hip implants and over-the-counter drugs. Three J&J units have pleaded guilty in the past two years to bribery or illegal marketing of drugs. A fourth agreed to plead guilty in a marketing case.

"They were initially able to put the Prolift on the market without even telling the FDA," said attorney Adam Slater, who is suing J&J on behalf of more than 100 women. "Even though Johnson & Johnson (JNJ) supposedly lives by a credo to put the patient first, this is an example of fast-tracking a product to market quickly rather than going to the FDA first."

New Questions

The conduct by Ethicon also raises anew questions about the FDA's approval process, which lets companies introduce products without human testing if the agency decides they're similar to devices already for sale, or so-called predicates.

Congress has been pushing for changes to the system in response to industry complaints about slow reviews and inconsistent standards. The FDA also has faced criticism after high-profile recalls, including J&J's withdrawal in 2010 of 93,000 hip prosthetics with higher-

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than-expected failure rates.

In 2007, the FDA required J&J to submit a so-called 510(k) application to review the Prolift, Liscinsky said. The FDA learned of the Prolift after J&J cited it in July 2007 as a predicate for a follow-on device, the Prolift+M, she said.

J&J introduced the original Prolift in March 2005 after "applying the relevant FDA guidance and based on the safety and effectiveness" of Gynemesh, Matthew Johnson, a spokesman for the New Brunswick, New Jersey-based company, said in an e-mail.

Actions 'Responsible'

"Throughout this process, our actions were responsible, appropriate and consistent with FDA regulations," he said. "Numerous clinical studies suggest that when combined with proper surgical technique, surgical mesh can improve patient outcomes, and Ethicon's devices are among the most studied devices on the market for this condition."

Andrew Sokol, an associate professor of obstetrics/ gynecology and urology at the Georgetown University School of Medicine, said he was "absolutely concerned" after hearing that J&J marketed the Prolift without FDA approval.

"That information would have been important for most surgeons," Sokol said. "Most surgeons probably would have not used a completely new product if there was no oversight."

Surgeons use mesh products to treat incontinence or help women with pelvic organ prolapse, a condition in which weakened muscles fail to support internal organs. Several mesh products, like the Gynemesh and the Prolift, are threaded in place through an incision in the vagina.

Fivefold Jump

An FDA report in July found a fivefold jump in deaths, injuries or malfunctions tied to vaginal mesh for prolapsed organs. In September, an advisory panel urged the FDA to reclassify such mesh as "high-risk" devices needing human testing. In January, the FDA said J&J, Murray Hill, New Jersey- based C.R. Bard Inc. (BCR) and other makers must study organ damage and complications related to the products.

The dispute between the FDA and J&J centers on how the company should have acted in light of differences between the Gynemesh Prolene Soft Mesh, the Prolift and the Prolift+M. The FDA cleared the Gynemesh on Jan. 8, 2002, for the repair of hernias and other defects with connective tissue.

The Gynemesh and Prolift are made of the same nonabsorbable polymer, while the Prolift kit included pre-cut mesh and instruments to help surgeons implant the device.

'Insignificant Change'

J&J applied in 2007 for the Prolift+M, which also included an absorbable type of mesh and cited the Prolift as a predicate, Liscinsky said. That application said the Prolift was an "insignificant change" to the previously approved Gynemesh under the 510(k) process, Liscinsky said.

When an FDA reviewer contacted Ethicon in July 2007 about that conclusion, the company cited the agency's guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device," according to Liscinsky and Johnson.

"The lead reviewer determined that Ethicon should have submitted a separate 510(k) for

Prolift," she said.

The reviewer asked Ethicon for "information to support the safety and effectiveness" of the Prolift, Liscinsky said. The FDA reviewed that data during the Prolift+M application.

Both devices were cleared based on adequate J&J data to support "substantial equivalence in safety and effectiveness to predicate devices," Liscinsky said today in an e-mail.

Companies that market devices without required approval are subject to compliance actions such as warning letters, seizure of illegally marketed devices, and injunctions or financial penalties against companies and managers, she said.

'Good Faith'

"FDA typically would not take these actions against companies that relied in good faith -- albeit mistakenly -- on agency guidance," she said. "But absent this reliance, or in response to repeated mistakes, these actions might follow."

Companies also can decide on their own whether a device modification requires a new 510(k), based on the agency guidance that J&J used, Liscinsky said.

A review of an FDA database of reported malfunctions, deaths or serious injuries shows the agency got 123 complaints about Prolift from 2005 to May 15, 2008, when the device won clearance.

The last came the day of that clearance and involved a patient who was experiencing "discomfort" and "a scalloping and ridging erosion" of a pelvic muscle, according to the database. The entry also noted the patient's "tissue was poor prior to the procedure." A surgeon removed the implant.

2.3 Million Pages

The mesh lawsuits blaming J&J for injuries are pending in state court in Atlantic City, New Jersey. J&J has produced more than 2.3 million pages of documents through the pretrial exchange of evidence known as discovery. Superior Court Judge Carol Higbee is coordinating discovery in those cases.

On Feb. 7, the Judicial Panel on Multidistrict Litigation consolidated more than 150 federal lawsuits against pelvic mesh makers. U.S. District Judge Joseph R. Goodwin in Charleston, West Virginia, will oversee evidence-gathering efforts in cases against J&J, Boston Scientific Corp. (BSX) and the American Medical Systems unit of Endo Pharmaceutical Holdings Inc.

Goodwin is already handling mesh litigation against Bard. Henry G. Garrard III, an attorney in Athens, Georgia, is helping to lead that litigation on behalf of women claiming injuries. He said he has spoken to doctors and patients around the U.S. about mesh litigation and FDA regulation of devices. He said he also has discussed how the Prolift was marketed without agency approval.

"People are absolutely amazed and shocked," said Garrard, of Blasingame, Burch, Garrard & Ashley PC. "People are quite upset with those facts. There are a lot of physicians who are not well educated about these issues."

Company Witnesses

In Atlantic City, patients' lawyers are seeking to interview more than 70 company witnesses, including Gary Pruden and Sheri S. McCoy, the leader of J&J's pharmaceutical and

consumer products unit. Both Pruden and McCoy previously served as company group chairman and worldwide franchise chairman of Ethicon.

McCoy was one of two executives in the running to succeed outgoing Chief Executive Officer William Weldon. J&J announced Feb. 22 that the post will go to Alex Gorsky, who oversees medical devices and the company's supply chain.

Plaintiffs' lawyers should be allowed to ask McCoy about Prolift, given that the device was put on the market in early 2005, "yet 510K clearance was not obtained to legally market the Prolift until May 15, 2008," said Slater, of Mazie Slater Katz & Freeman LLC in Roseland, New Jersey, in a March 8 filing.

"Ms. McCoy's knowledge or lack thereof as to this and other issues is directly relevant to establishing the defendants' liability in this litigation," Slater said.

J&J opposes the request to interview McCoy and Pruden, saying neither possesses "specific or unique knowledge or information that cannot be obtained from less obtrusive and burdensome methods," according to a Feb. 23 court filing.

Pfizer Inc. (PFE), based in New York, is the biggest maker of medical products based on annual sales.

To contact the reporters on this story: David Voreacos in Newark, New Jersey at dvoreacos@bloomberg.net; Alex Nussbaum in New York at Anussbaum1@bloomberg.net

To contact the editors responsible for this story: Michael Hytha at mhytha@bloomberg.net; Reg Gale at rgale5@bloomberg.net

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montag 2 hours ago

Once upon a time, J & J was a well run, ethical company. When did they let the sociopaths take control?

Amy Gezon 4 hours ago

I am certain J and J will find a way to circumvent any consequences. I suggest a new name for Johnson and Johnson Ethicon Division- J&J Ethicless

Neena Malloy 4 hours ago

This is shocking. Did the FDA take any action against Johnson & Johnson when they found

out? Does anybody look out for consumers? Disgusting and frightening.

Jane Akre 7 hours ago

Excellent and complete story!!!