Injured Women Sue Johnson & Johnson Over Vaginal Mesh Product

By COURTNEY HUTCHISON, ABC News Medical Unit

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What was supposed to be a simple surgery to relieve bloating and constipation turned into a living nightmare for Linda Gross, 46, of Watertown, S.D.

Gross experienced pelvic organ prolapse, a condition in which the organs of the pelvis begin to shift because of a weakened pelvic wall. Her doctor implanted Gynecare Prolift, a relatively new type of surgical mesh, into her pelvic wall through incisions made in her vagina.

Ever since that implantation in 2006, Gross says she has had urinary complications, constant pain and swelling as her body continues to reject the mesh. She says she can't sit for more than 20 minutes, she can't have sex with her husband, she can't be active for more than a few minutes at a time. Twelve surgeries have failed to remove all the mesh or relieve her pain and swelling.

"It's horrible. There are unknown amounts of the mesh still in me. I have extreme pain. It feels like the inside of my vaginal wall is on fire," Gross told ABCNews.com. "I wouldn't wish this on anyone."

Gross' story may not be as unusual as doctors once believed. Between 2008 and 2010, the FDA received 1,503 reports of injury, malfunction or death associated with the surgery. These reports represented a five-fold increase compared to a few years -- a spike that led the agency to issue warnings about these products last July.

Now the FDA is considering pulling the product from the market, pending further safety data, and convened a two-day meeting of the Obstetrics and Gynecology Devices Panel Thursday to review the safety of using transvaginal mesh to treat pelvic organ prolapse.

In the meantime, Gross and more than 100 other women are taking the situation into their own hands. Asserting claims of negligence and defective product design they are suing the makers of the device, Johnson & Johnson's Ethicon, for compensatory and punitive damages. Several calls to Ethicon seeking comment on the lawsuit were not immediately returned, but in court filings the company has denied the allegations.

"My experience, I can't change that, but I want other women to understand the dangers of the mesh product," Gross says.

Although Gross says her doctor told her that implanting the Prolift device was a safe, low-risk procedure, the mesh had not actually gone through the rigorous safety testing the FDA usually undertakes for surgical devices. Instead, the device was approved using an abbreviated approval process, known as 510(k), which allows devices to go to market taking a short cut through the regulatory procedures as long as they are proved to be "substantially equivalent" to something already on the market. In this case, the Prolift was compared to Gynemesh, a similar mesh product sold Johnson & Johnson has sold since 2002.

"The whole concept of the 510(k) process should be scrapped," says Adam Slater, the New Jersey attorney representing Gross and the other women who are suing Johnson & Johnson.

"The doctor who created the product has even said that they need more studies to determine if this mesh

has long-term safety and effectiveness. If you didn't have the 510(k) process, J & J would have had to do those studies before they could sell it on the market," he says. According to the FDA's 510(k) databaser, J & J didn't even have the 510(k) approval until 2008, which means the device implanted Gross and many others may have been sold without FDA clearance to do so.

Transvaginal Mesh for POP – Safety Questionable?

In the past, pelvic organ prolapse was often treated by hysterectomy -- removing the uterus -- and putting in sutures to add support and prevent further prolapse.

Surgical mesh treatments were developed over the past decade in part to avoid having to perform a hysterectomy on women with pelvic organ prolapse. Some studies had also suggested that the suture procedure had a high failure rate.

While surgical mesh has been used safely to treat hernias or urinary incontinence for decades, the use of a mesh device, such as Prolift, which has several "arms" that spread out and attach at several places in the pelvis, is only a few years old.

According to the FDA, about 75,000 patients were treated for pelvic organ prolapse using transvaginal surgical mesh. The most common problem with the mesh is that it can begin to erode within months of being implanted and pieces of the mesh may dip down into the vaginal canal.

In a review issued by FDA staff reviewers before Thursday's meeting, reviewers found that erosion occurred in 35 percent of all adverse events associated with mesh used in treating pelvic organ prolapse. Pain was reported 31 percent of the time; infection, 16 percent; and bleeding, 8 percent.

But while erosion is a commonly reported problem, the high rate of adverse effects seen with the Prolift and similar products may have to do with the "arms" of the device, not the mesh itself, Dr. Emanuel Trabuco, a Mayo Clinic surgeon who has removed a number of the devices from patients experiencing adverse effects, told ABCnews.com.

"The arms pass through several structures in the pelvis. They can be put in overly taut and pull on the groin muscles, causing pain," he says. Other complications may be attributed to the several incisions that are made in the vagina to insert the mesh and its several arms.

The preliminary review presented at the hearing this week urged that surgical mesh devices for pelvic organ prolapse be reclassified and put through the standard safety regulations, but Trabuco said an all-out ban on these products should be avoided.

Echoing the comments made by the American Urogynecological Society, he said that more stringent use of the products and more safety data is necessary, but not an all-out ban.

"Though the adverse reactions can be severe in some cases, we have no idea if these strong reactions r epresent one percent or just a fraction of a percent, or more than that, of all the users. We need more data," he said.