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WOMEN'S HEALTH

J&J to stop selling troublesome surgical mesh products

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A major manufacturer of the transvaginal mesh implants that we warned about in our recent report on unsafe medical devices is voluntarily halting marketing of four of the products. In a letter to judges overseeing multiple patient lawsuits in West Virginia and New Jersey, Johnson & Johnson said its Ethicon division will "cease commercialization" of the implants within 120 days. The devices are implanted to correct pelvic organ prolapse, a condition affecting women in which the bladder and uterus drop from their normal positions.

A loophole in the law allowed these implants to be marketed without any advance safety testing, based on their similarity to other mesh products marketed previously for completely different uses in different parts of the body. Thousands of women have reported infections, as well as painful, even disabling complications when the mesh shifted, shrank, or in some cases eroded through their vaginal tissues.

Johnson & Johnson's decision is "a victory for consumers because these products that have harmed so many are being removed from active marketing," said Lisa McGiffert, director of the Safe Patient Project of Consumers Union, Consumer Reports' advocacy arm. But she pointed out that a bill making its way through Congress right now, updating the law governing the Food and Drug Administration's regulation of devices, has not closed the offending loophole.

"Some products may get recalled, or in this case, withdrawn, but they they'll be replaced with new ones that may be equally bad, sometimes worse, because there's no change in the law," said Diana Zuckerman, president of the National Research Center for Women and Families.

The affected products, sold under Ethicon's Gynecare brand, are: TVT Secur, Prosima, Prolift, and Prolift +M. However, similar products by other manufacturers remain on the market.

Here's our advice for women contemplating surgery for pelvic organ prolapse:
1. Consider whether you really need the surgery. Pelvic surgeons have told us that this condition is common and not life-threatening and if you don't have bothersome symptoms, need not be treated at all.
2. If you do need surgical repair, ask for it to be done without using mesh, a procedure known as "native tissue" repair. Though this type of surgery has been done for years, not all gynecologic surgeons are trained in the technique. If your surgeon is not, ask for a referral to one who is.

Source
J&J To Halt Sales of Vaginal Mesh Implants [Pharmalot]

—Nancy Metcalf

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