FDA: pelvic mesh for women riskier than thought

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A product commonly used in surgery to treat incontinence and other women's health problems causes far more complications than previously thought and is likely exposing patients to unnecessary risks, according to U.S. health officials.

The Food and Drug Administration said Wednesday that women who have a surgical mesh implanted to support their reproductive organs are at greater risk of pain, bleeding and infection than women who have traditional surgery with stitches.

"The added benefit of using the mesh is not evident, but there certainly appears to be an added risk," said Dr. William Maisel, FDA's chief scientist and deputy director of the center for devices.

More than a half-million women undergo surgery for pelvic organ collapse, known as prolapse, or incontinence each year, though not all procedures involve mesh. About 75,000 women had prolapse surgery with mesh last year, and more than 200,000 women had the procedure for incontinence.

Between 2008 and 2010 the agency received more than 1,500 reports of complications from women undergoing prolapse surgery with mesh, up 500 percent from the prior three years. There were fewer complications among incontinence patients.

Wednesday's warning applies only to mesh for prolapse. The agency is also reviewing the use for incontinence, though side effects have not been as frequent. Doctors who perform the procedures say incontinence surgery uses less mesh, possibly resulting in fewer complications.

In a rare mea culpa, FDA scientists said a 2008 public notice from the agency that called the problems "rare," was mistaken. After reviewing the medical literature over the last 15 years, the FDA now estimates the most common problems occur in 10 percent of women within a year of surgery. These patients often undergo multiple surgeries to remove the mesh.

Manufactured by a half-dozen companies, the plastic mesh is used to strengthen the pelvic wall in cases of stress urinary incontinence and pelvic organ prolapse, in which the bladder or other reproductive organs slip down into the vagina. The mesh is often inserted through the vagina, using a small surgical incision.

Despite the high rate of injury, FDA's top device scientist said the government would not withdraw approval for the product because certain patients may still benefit.

"Rather than remove mesh from the market and not have an important product available to these patients, what we'd like to do is make sure it's used in the proper patients," said Maisel, in an interview with The Associated Press.

But patients who have suffered through mesh-related complications say the device should be banned in all but the most dire cases.

"It's not about finding a better patient, it's about not using this product unless there is no human tissue available," said Lana Keeton, a Miami resident who has undergone 17 surgeries to remove mesh that was implanted in 2001. Keeton's group, Truth in Medicine, has lobbied the FDA on the risks of mesh in recent years.

The FDA will hold a two-day meeting in September to discuss studies that would identify which patients benefit most from mesh implants. Such studies usually take years and millions of dollars to conduct.

For now, Maisel said surgeons should first consider traditional prolapse surgery, in which the pelvic floor is repositioned and tightened using stitches.

While safe, surgeons say the procedure has a failure rate ranging from 20 to 45 percent, which first led doctors to begin using mesh to try and reinforce the pelvic wall.

The most common side effects occur when the mesh does not bond properly and works its way through the vaginal wall, which can cause infection, urinary difficulties and pain during sex.

Follow-up surgeries can involve two or three hospitalizations.

"It's not necessarily a straightforward procedure and sometimes the entire mesh cannot be removed," said Dr. Jill Brown, a medical officer in FDA's device review division.

Dr. Charles Rardin, an associate professor at Brown University's medical school, said he will continue using mesh, but mostly in cases where patients have failed traditional surgery.

The reassessment of surgical mesh comes as FDA reviews its fast-track system for clearing medical devices, which has been largely unchanged since the 1970s.

Like 90 percent of medical devices sold in the U.S., pelvic mesh was cleared under the FDA's fast-track system, which grants market approval in 90 days to devices that are considered low-risk.

Medical device manufacturers have spent the last year lobbying the FDA and Congress to speed up device approvals as the government reviews the process. They point out that European regulators approve many devices faster than the FDA, leading some companies to launch their products overseas first.

Safety advocates say the agency has been overusing the system and clearing high-risk devices that should be subject to more testing.

Dr. Diana Zuckerman said the agency should have required the studies it is now contemplating before mesh products were approved.

"If they had been required to go through the more rigorous approval process, similar to that for prescription drugs, it would have been obvious years ago that surgical mesh has more risks than benefits in many types of surgery," said Zuckerman, who directs the National Research Center for Women & Families.

The FDA will ask panelists at September's meeting whether pelvic surgical mesh should be reclassified as a high-risk device.

Surgeons began using mesh to repair hernias in the 1950s, and over the next 40 years they adapted the technique for women's health conditions. FDA cleared the first mesh for prolapse in 2002, but since it was similar to devices that had been used for decades it did not have to undergo human testing.

Manufacturers of pelvic mesh include Boston Scientific Corp., Johnson & Johnson, Covidien plc, CR Bard Inc. and American Medical Systems.