THE WALL STREET JOURNAL.
WSJ.com

HEALTH INDUSTRY | SEPTEMBER 8, 2011

FDA Panel Takes Second Look

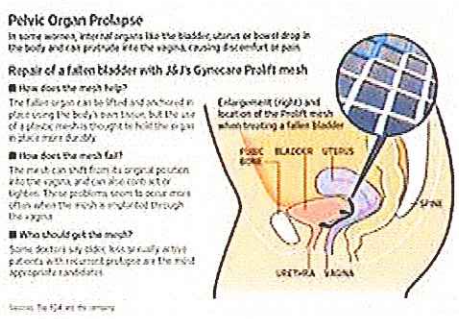
Expedited Approval of a Less Invasive Prolapse Treatment May Be Rescinded Following Injury Reports

By SHIRLEY S. WANG

Several years ago, a new, less invasive treatment for pelvic organ prolapse—a painful condition affecting thousands of women—hit the market via an expedited regulatory process.

Despite a lack of clinical data about surgical mesh when it is inserted through the vagina in the procedure, physicians and patients swiftly embraced the approach.

Perhaps too swiftly, regulators and critics say now.



On Thursday, after numerous reports of injury and seven deaths, an advisory panel convened by the Food and Drug Administration will discuss whether the mesh kits should be more closely regulated. Makers of the devices, which include Johnson & Johnson and Boston Scientific Corp., also face lawsuits from women contending they were injured when the procedure failed.

Product makers could face a tough road if the panel votes this week to recommend upgrading the product to the Class III high-risk category, as the FDA proposed doing last week. Class III rules would require additional clinical testing for products on the market, and new mesh couldn't be approved under the expedited process, known as 510(k), that was used for existing devices.

"The use of surgical mesh has an established track record and the 510(k) process has really enabled good learning and medical advances in this field," said Matthew Johnson, a spokesman for J&J's Ethicon subsidiary. "We do think it can be managed in the Class II designation."

A spokeswoman for Boston Scientific agreed. "Boston Scientific's first priority continues to be patient safety," said Denise Kaigler. "We believe in the strength of the 510(k) process."

But the debate over use of the mesh has renewed criticism from watchdog groups and doctors about the 510(k) process, through which a device can be introduced, marketed by industry and taken up by the medical community without much data on its safety and efficacy.

The 510(k) review allows manufacturers to begin selling certain new devices without conducting clinical trials if a product is "substantially equivalent" to an existing device. "The 510(k) process is designed so that, in many cases, companies don't have to keep reinventing the wheel, which can help get innovative products to patients faster," said Karen Riley, an FDA spokeswoman.

Increasingly, though, the risks and benefits of some 510(k)-approved products have been questioned. In July, the Institute of Medicine, an independent group that advises the government on health policy, issued a report recommending an overhaul of the FDA's medical-device process to require more oversight.

"If companies were required by the FDA to do things, they would," said Christopher Maher, a urogynecologist in Brisbane, Australia, who published a reviewed of the existing data on the treatment of pelvic organ prolapse. "The higher you put the hurdle in the beginning, the more clear the benefit to the consumer ends up being."

In the case of the transvaginal mesh, proponents say it's safe when used properly because it is based on similar plastic mesh used to treat hernias and incontinence. It potentially offers a more durable repair than surgery without mesh, they say, and inserting it via the vagina cuts down on recovery time.

"For those who are really good at this, who have the education and credentials, this is a really useful alternative," said Kevin Wiggins, a spokesman for Endo Pharmaceuticals, which owns American Medical Systems, the marketer of Elevate mesh kits.

But critics say that because of the complexity of pelvic surgery, data on using mesh transvaginally for prolapse should have been collected. Among other differences, more mesh is required to repair prolapse than incontinence, according to J. Eric Jelovsek, a surgery professor at the Cleveland Clinic and a member of the National Institutes of Health network on prolapse surgery and urinary incontinence.

"Clinical trials should have been done," said Adam Slater, a plaintiffs attorney who is involved in nearly 300 mesh cases. "Instead, they used real patients as guinea pigs."

Some degree of pelvic organ prolapse, in which such internal organs as the bladder, uterus or bowel drop down and protrude into the vagina, is estimated to affect about half of women who have born children. In severe cases it can cause significant discomfort and pain and require surgical intervention.

Traditional surgery uses a woman's own tissue to support the organs. In the 1970s, surgical mesh, which was being used to repair abdominal hernias, started to be inserted through the abdomen to treat prolapse and incontinence.

In the 1990s, gynecologists began inserting the mesh through the vagina, and in the past decade, products designed specifically for transvaginal procedures hit the market, according to FDA website documents.

Once the new mesh kits were introduced and companies began marketing them as a "revolutionary" new treatment for prolapse, the procedures were used more frequently, and often by doctors who hadn't had much experience in pelvic surgery.

About 75,000 transvaginal mesh surgeries for prolapse were conducted in the U.S. last year, according to the FDA. The kits cost about $500 apiece.

Many doctors were eager to learn a cutting-edge procedure to improve their outcomes—traditional surgery has a recurrence rate of 30% to 40%—and to potentially expand their patient base. Some manufacturers assured doctors that even those without much prior prolapse-repair experience could do it. In recent years, there have been three times as many procedures for prolapse as for urinary incontinence, according to experts in the field.

But in some cases of transvaginal use, the mesh contracts and tightens, or shifts from its placement, causing prickly parts of the mesh to protrude into the vagina. Some sufferers say the erosion and shrinkage prevents them from having sex or even standing or sitting for long periods. The mesh can be trimmed, doctors say, but not removed from the body completely.

But "I think the dilemma becomes, once the train starts going, it's very hard to stop it," said Ingrid Nygaard, a professor of obstetrics and gynecology at the University of Utah, who argued the mesh should be taken off the market until more research is conducted.

The FDA issued a safety notice in 2008 about possible complications, including erosion, pain, infection and urinary problems. It updated the alert in July to warn that use of the mesh transvaginally for prolapse offers "no evidence of greater clinical benefit." Between 2008 and 2010, the agency received some 1,500 reports of adverse events.

Still, many physicians say the products are useful for appropriate patients and the decision about whether to perform the procedure should be between a patient and her doctor.

"I think there are some instances where transvaginal mesh might be the only option for someone," said Deborah Myers, American Urogynecologic Society president. "I would hate to see that not exist, but I do feel strongly we need more data."

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