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J&J Vaginal Surgical Mesh Faces FDA Panel as Number of Lawsuits Increase

By Alex Nussbaum and David Voreacos - Sep 8, 2011

Johnson & Johnson (JNJ) and rival makers of transvaginal meshes told Food and Drug Administration advisers they agreed on the need for more safety studies of the implants as well as labeling changes to warn of potential risks.

Manufacturers including J&J and Endo Pharmaceuticals Holdings Inc. (ENDP) proposed that new versions of the devices require clinical trials before they can be sold and existing implants be tracked for safety. That stopped short of a recommendation from FDA staff last month that the mesh be reclassified as high risk and face even more regulatory controls.

Transvaginal mesh is "not the optimal solution for everyone but it will be for some," Piet Hinoul, a director of medical affairs for J&J's Ethicon unit, told the FDA panel at a hearing in Gaithersburg, Maryland, today.

More than 75,000 women received vaginally implanted meshes last year to buttress weak pelvic muscles that fail to support internal organs. Patients claiming the meshes led to internal injuries have filed almost 500 lawsuits against two of the manufacturers, New Brunswick, New Jersey-based J&J and C.R. Bard Inc. of Murray Hill, New Jersey.

The panel of outside advisers is meeting today and tomorrow on whether mesh devices are safe and effective. If not, companies may be required to provide more data to keep their products on the market. Most were approved under an abbreviated FDA process known as 510(k) that required manufacturers to show only that they were similar to already cleared devices.

'Moderate-Risk'

The FDA can continue approving meshes as "moderate-risk" devices while requiring additional safety studies or labeling changes, said Ginger Glaser, a senior director for Endo Pharmaceuticals, based in Chadds Ford, Pennsylvania. Reclassifying them as high-risk would put even greater burdens on companies, including approvals of manufacturing procedures, plant inspections and longer review times, she said in an interview at the hearing.

While acknowledging the need for studies, manufacturers think existing studies have already shown the devices safe and effective, said J&J's Hinoul.

"Serious adverse events that are mesh-specific are very low," he said.

While the advisory panel won't take formal votes this week, the FDA will poll the panel of researchers and physicians on whether to reclassify the devices and gather thoughts on how to conduct clinical studies, said Karen Riley, an agency spokeswoman, in a telephone interview yesterday. It's unclear when the FDA will make a final decision on the devices, she said.

J&J fell 48 cents to $64.95 at 4 p.m. in New York Stock Exchange composite trading. Bard declined 64 cents to $93.57 and Endo Pharmaceuticals fell 53 cents to $30.75.

FDA Control

Reclassifying would give the FDA control over clinical trials the companies must conduct, Julia Corrado, a clinical reviewer for the agency, told the panel. Keeping the devices in the 510(k) system "would mean a new device only needs to be as good as a device currently on the market and we are concerned that is not good enough," she said.

More clinical trials are needed to establish whether the benefits of the meshes outweigh their risks, said Denise Elser, a Chicago-area physician speaking for the American Congress of Obstetricians and Gynecologists. The Washington, D.C.-based group, with 56,000 members, would also like to see a registry to follow patients already with implants, she said at the hearing.

National surgeons' groups told the panel the devices should be used in limited numbers and only by well-trained physicians on carefully chosen patients.

Appropriate Training Needed

"At this time, the use of transvaginal mesh to repair" weakened pelvic muscles "should not be widespread," said Edward Varner, president of the Society of Gynecologic Surgeons. "It should only be performed by surgeons with appropriate training."

He also said that credentialing the surgeons would be "a huge political issue," and that there weren't "enough well- trained pelvic surgeons to take care of the problem."

The FDA is weighing a U.S. Institute of Medicine report in July urging it to scrap the 510(k) process for moderate-risk devices. The current system allows devices like the mesh implant to enter the market if manufacturers show they are "substantially equivalent" to others already for sale. The IOM said a new process should be devised that provides reasonable assurance of the

safety and effectiveness of moderate-risk devices.

Effectiveness 'Not Demonstrated'

"The clinical effectiveness of surgical mesh for transvaginal repair of pelvic organ prolapse has not been demonstrated," said William Maisel, deputy director of the FDA Center for Devices and Radiological Health, in a telephone interview. "We believe proper studies would need to be done."

While the mesh has been used for more than three decades, mainly for hernias, its use "has evolved over the past few years" as manufacturers expanded into other conditions, Herbert Lerner, an acting director in the FDA's device-approval center, told the panel today. "As industry modified surgical mesh for these indications, none of the mesh has been evaluated for clinical data."

Adam Slater, the New Jersey attorney who represents about 100 women who have sued J&J or Bard in New Jersey state court, said the agency is "at an important crossroads" over how to protect patients.

"The 510(k) process utterly failed to protect the thousands of women who were implanted," Slater wrote to the advisers. "Now the FDA now has the opportunity to at least protect women on a going-forward basis."

Recall 'Too Extreme'

A recall of the devices would be too extreme, said another pelvic surgeon, Andrew Sokol, an associate professor at Georgetown University School of Medicine in Washington. He helped conduct a clinical trial of transvaginal mesh that found a 15.6 percent erosion rate after three months. Still, he said that the devices have their benefits for some women.

"We do these surgeries all the time without risk," said Sokol. "Thousands and thousands of these surgeries are done without complications. The data is still emerging. It's easy to react but what needs to be done are good studies."

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