First Trial Regarding Safety Of Surgical Mesh Begins

The first of thousands of federal surgical mesh lawsuits filed nationwide has gone to trial in West Virginia.

The case is one of four bellwether cases that U.S. District Judge Joseph Goodwin will hear in Charleston to determine the next step in litigation for the remaining lawsuits.

The Judicial Panel on Multidistrict Litigation assigned the cases to Goodwin. Its latest report in May shows more than 18,000 cases are pending before Goodwin.

Lawsuits also have been filed in state courts.

The lawsuits accuse the companies of inadequate testing, failing to disclose potential risks and fraudulently promoting the mesh as a safe medical device. The manufacturers deny those allegations in court documents. Some companies have said in statements their testing was rigorous, that their products are safe and effective and that they're working with the Food and Drug Administration.

The FDA cleared the mesh — often a soft, lightweight porous plastic — for pelvic organ prolapse in 2002, and the agency said in a 2008 public notice that problems were "rare." In July 2011, however, the agency said it erred in its initial assessment and estimated the most common problems occur in 10 percent of women within a year of surgery.

The mesh can be inserted through the vagina or through an incision in the abdomen, though the latter is less common and has significantly fewer complications, the FDA said. The problems involve shifting and erosion of the mesh, as well as infections.

A year ago, the FDA ordered several dozen manufacturers to conduct rigorous studies to track the complication rates with their surgical mesh products over time. Some companies have undertaken those studies, while others chose to stop producing certain products.

Opening arguments were scheduled Tuesday in the first trial, which involves a lawsuit filed by Donna Cisson of Georgia against C.R. Bard Inc., the Charleston Gazette (http://bit.ly/15a7vFg) reported.

In June, Goodwin granted summary judgment to C.R. Bard dismissing several of the lawsuit's claims, including a manufacturer's defect. He also said a jury may award punitive damages, if appropriate, in a separate trial.

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