# Suits Target Mesh Manufacturers, Surgeons Disagree

Kate Brumback, AP

Soon after her surgery, Susan Harrison had a string of infections that caused intense pain, leaving her weak and unable to pick up and play actively with her young grandchildren. The discomfort and fatigue often kept her from her job as a kindergarten classroom assistant. For years, Harrison thought it was just an unfortunate consequence of the surgery to repair weak muscles in her pelvic region, but she discovered five years after her 2006 procedure that she was one of thousands of women who say their pain was caused by surgical mesh implanted to fix the problem.

"I felt so bad, I felt sad thinking that I had to spend the rest of my life living this way," Harrison said. The mesh is most commonly used after pelvic organ prolapse, or when muscles in the area weaken, causing organs to bulge or slip down into the vagina. It can happen because of age, childbirth or other reasons and can cause pain and bladder leakage. While many women benefit greatly from the mesh surgery, the Food and Drug Administration has warned some can suffer complications, and many women have sued, claiming manufacturers should have warned of potential harm. But some doctors have said the FDA's warning — and the lawsuits against the manufacturers — are misguided. The doctors blame inexperienced surgeons.

Harrison's case is among more than 6,000 federal lawsuits against some of the biggest manufacturers of pelvic mesh products. The cases have been consolidated in a federal court in West Virginia, with some trials to begin this year. 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 FDA.

The lawsuits seek unspecified compensation for pain and suffering, reimbursement of medical costs and punitive damages. Harrison had most of the mesh removed in October 2011. She said she still feels weak and has bladder leakage that requires her to take extra precautions when she leaves the house, but she feels better than she has in years.

Lynn Waits, a former police officer-turned-nurse from Covington, Georgia, had incontinence and pelvic collapse after having two children. She said she experienced bleeding and severe pain immediately following her mesh surgery in 2008. The incision next to her vagina never fully healed and she could feel the mesh if she touched that spot, she said. She continued to have bleeding for two years until she finally went to another doctor and had the mesh removed in 2010,

she said.

She still has shooting pains, a constant achiness and can't take a long car ride without discomfort, which she blames on the mesh. The experience has also changed her marriage. "Since I had surgery, sex is out. I'm celibate," she said. "Now it's a very platonic relationship. You get used to it."

Kathy Barton's doctor suggested the mesh when she mentioned that she had bladder leakage when she laughed or coughed. Shortly after the surgery, it felt like razors were slicing her organs and a sharp edge of the mesh cut her boyfriend during sex, she said. Even though she eventually had it removed, the 55-year-old west Georgia woman still has pain she believes is caused by the mesh. The women interviewed for this article who had problems with the mesh were made available by their lawyers.

When pelvic mesh products were introduced, they were seen as a high-tech improvement over traditional surgery using stitches and a woman's own body tissue, which also can have complications. Since similar mesh was already used in other types of surgery, including for repairing hernias as far back as the 1950s, the products received fast-track approval from the FDA without the tests that the agency requires for first-of-a-kind devices. The FDA cleared the mesh 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.

Dr. Cheryl Iglesia, a surgeon in Washington who was on the FDA panel, said things have come a long way over the last year. A national registry to track pelvic prolapse surgeries should help identify problems more quickly — whether they're caused by patient complications, surgeons with inadequate experience or the mesh itself, she said. Some doctors have also been reconsidering when to use the implantation, and the mesh products have become smaller and lighter, she said. She uses the newer, smaller mesh products on some of her patients. "To some degree, the marketing of the mesh may have been ahead of the science," she said.

Dr. Vincent Lucente, a Pennsylvania doctor who specializes in female reconstructive pelvic surgery, is among a group of doctors who have spoken out against the FDA's warnings. The main problems with the mesh products are caused by surgeons who don't have enough training, he said. Publicity from the lawsuits scares women into refusing treatment with the mesh even though they could benefit from it, he said. "It is a tragic moment in our field where there's public sentiment and perception

being developed by lawyers and not by physicians," he said. "The innovation — and the skill sets to use the innovation — is outpacing the skill sets that the surgeons have, and no one is trying to close that gap." Lucente believes there should be a credentialing process to ensure expertise, as there is for other surgical procedures.

Pamela Danek, a 52-year-old teacher from Vestal, New York, had surgery in July 2007 to repair a prolapsed uterus and cervix. The doctor didn't use mesh, and within three weeks the problem returned, she said. After a second surgery to remove her cervix, she was in a lot of pain. She went to Lucente in August 2008 and he implanted the mesh. After that surgery, she was able to exercise again and her life returned to normal, she said.

"I do understand that there are people who have suffered from the mesh, but in my case it's been very positive and life-changing," she said. "I'd hate to see the whole product go away. ... It's amazing when it's done correctly. What a positive impact it can have on a woman's life." One of the lead attorneys representing women suing the mesh manufacturers, Henry Garrard, said problems may arise because some surgeons don't know much about mesh, but he said it's the manufacturers' responsibility to educate doctors about their products. For the most part, his clients have not sued individual doctors, he said, because he claims the problems are caused by the mesh products themselves.

The cases have been consolidated in West Virginia because that's where a lot of them were initially filed, Garrard said. Several thousand other lawsuits have been filed in state courts, he said. In what is believed to be the first lawsuit of this type to go to trial, a California jury in July awarded a California woman $5.5 million in her case against C.R. Bard. A trial for five bellwether federal cases against Bard is set for June and trials for American Medical Systems, Boston Scientific and Johnson & Johnson subsidiary Ethicon are staggered over the next year.

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