The Legal Intelligencer
THE OLDEST LAW JOURNAL IN THE UNITED STATES 1843-2011
PHILADELPHIA, MONDAY, JANUARY 25, 2015
An ALM Publication

Parties Spar Over Pelvic Mesh Efficacy in Second Trial

Max Mitchell,
Of the Legal staff

The device at the center of the second pelvic-mesh trial in Philadelphia was the "worldwide gold standard" in treating the stress-related incontinence that the plaintiff had suffered, an attorney defending its design told jurors during her opening -statement Monday.

Attorney Laura Hensley Smith, who made the opening statement for Ethicon, the defendant in Carlino v. Ethicon, denied allegations that the pelvic mesh device implanted in Sharon Carlino was defectively designed, and told the jurors the company is proud of the fact that the device was the first mesh "sling" aimed at treating stress-related incontinence.

"It was revolutionary in helping women deal with incontinence," Smith said. "The synthetic mid-urethral slings were used by many surgeons, and considered to be the worldwide gold standard in treating women with incontinence."

But Carlino's attorney, **Shanin Specter of Kline & Specter**, said the device was defective for several reasons, and the company relied on biased research when developing the product.

Specter told jurors during his opening statement that the mesh, which is placed between the vaginal wall and the urethra to support the urinary tract and prevent incontinence, was first developed by a gynecologist who had an incentive to produce favorable testing results so Ethicon would purchase his mesh-development company.

According to Specter, those results were never fully analyzed but were used in additional studies that Ethicon has pointed to in defending the mesh's efficacy and safety.

"They didn't even ask to see [the doctor's study materials]. Instead, they blindly accepted [the doctor's] data," Specter said. "It was never properly analyzed and -verified by anyone."

According to Specter, development of the mesh began in 1996, and the device hit the market in 1998. In 2005, Carlino had the mesh installed to treat her incontinence. During the procedure, she also underwent a hysterectomy.

In 2007, she complained to her doctor about feeling "something sharp" in her vagina, and the doctor found that a portion of the mesh had eroded through her vaginal wall, Specter said.

Carlino underwent a procedure to remove the mesh, and she made a good recovery, according to Specter. However, in 2010, she again reported feeling something sharp in her vagina, and she underwent a second removal surgery.

By late 2012, Carlino again began having discomfort and pain during sex, but according to Specter, the remaining pelvic mesh could not be safely removed.

Specter told jurors the mesh was defective because its pores are too small, and also it should have been cut using a laser, as opposed to a machine, which can make the edges of the device more friable.

According to Specter, large pores in the mesh allow for new tissue to grow around the synthetic mesh material, but smaller pores lead to inflammation and scar tissue, which, he argued, was at the root of Carlino's injuries.

Specter additionally argued Ethicon failed to tell the treating doctor that the mesh could result in permanent injury.

"The defendants knew there could be chronic foreign body response, they knew the mesh could degrade in the human body," Specter said. "They didn't tell" the doctor.

Smith, however, contended that Carlino's treating doctor was well-trained in installing the mesh, and the doctor had agreed it was the best choice for addressing Carlino's incontinence. Smith fur-

ther said the treatment was within the standard of care, and one of Carlino's subsequent treating doctors had recommended she have mesh installed again when some incontinence returned after the second -removal surgery.

The reason the mesh had to be removed, according to Smith, was because Carlino's vaginal wall had thinned.

"The fact that erosion occurred doesn't mean it was defective," Smith told the jury. "Whatever problems she's having currently are not related to the mesh."

Smith also told jurors that they will likely hear testimony about Ethicon, and potential outcomes from having pelvic mesh devices implanted, but she said jurors should stay focused only on what happened with Carlino.

"This case is about one woman," Smith said. "Ask yourself what the testimony has to do with Mrs. Carlino and her case."

Carlino's suit is the second case to be tried out of Philadelphia's pelvic-mesh mass tort program.

The first case, Hammons v. Ethicon, resulted in a $12.5 million verdict for plaintiff Patricia Hammons, which included $5.5 million in compensatory damages and $7 million in punitive damages.

The latest court statistics show there are 180 cases pending in the mass tort program.