

First Phila. pelvic-mesh trial goes to jury

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What is the value of a lawsuit against the maker of a surgical implant that causes some women such excruciating pain during sexual intercourse they are forced into celibacy?

That is probably the most important question underlying a 21/2-week trial before Philadelphia Common Pleas Court Judge Mark Bernstein. Testimony concluded and on Thursday the jury began deliberations.

The trial involved allegations by Patricia Hammons, 65, a Walmart shelf stocker from Indiana, who underwent surgery in 2009 to correct a sagging bladder, a consequence of childbirth and a common problem in middle-aged women. It causes urinary incontinence and interferes with sex.

Her surgeon implanted a pelvic mesh barrier made by Ethicon, a subsidiary of global health-care products giant Johnson & Johnson, to shore up Hammons' bladder. But a short time later, Hammons complained sex had become so painful she had to cease relations with her boyfriend. In her lawsuit, Hammons

claimed J&J's pelvic mesh implant was inherently unsafe, having a tendency to bunch up inside the pelvis while piercing her bladder. And she said that J&J knew about its safety problems but concealed them from doctors and patients.

Her lawsuit, the first to be tried in Philadelphia, is one of as many as 100,000 nationwide against makers of pelvic mesh implants. The outcome of a handful of cases like hers will decide how this overall legal battle will end. To say the stakes are enormous would be something of an understatement. Nationwide, there have been 16 verdicts in recent years against pelvic mesh manufacturers, including J&J, totaling \$247 million. That includes a verdict in May in which a Wilmington jury awarded \$100 million to a woman who said a pelvic implant made by Boston Scientific caused pain during sex.

Judging from the Hammons trial, it isn't a slam dunk for either side. Over the course of the trial, Hammons' lawyers, **Shanin Specter of Kline & Specter** in Philadelphia and Adam Slater of Roseland, N.J., who was assisting in the trial, elicited testimony from J&J executives that the company rushed to get

the pelvic mesh product to the market in the face of competition from other companies.

Though use of pelvic mesh already had been associated with pain during sex - the medical term is dyspareunia - by the time J&J began selling it in 2005, no mention of this risk was made on the product label.

During the trial, one expert for the plaintiffs testified that removing the mesh completely was exceedingly difficult, if not impossible, and that doing so typically was a surgical "train wreck." Yet, in one particularly troubling bit of testimony, J&J product engineer Scott Ciarrocca said no one at the company had given any thought to how to remove the mesh if it failed.

One fact bolstering Hammons' case: J&J itself seems to have lost confidence in its mesh device named "Prolift." In 2012, the company pulled the product from the market.

J&J focused its defense on studies purporting to show the product was far more effective than earlier therapies, and testimony that the mesh was a safe and effective way to deal with pelvic organ prolapse - the sagging of organs into the vagina.

But J&J's defense wasn't entirely high road. While it argued that studies show the treatment was safe and effective, it also suggested Hammons' smoking habit may have played a role in her malady. And that will shape the extent of J&J's liability in the tens of thousands of cases that remain.

J&J lawyers also suggested the real reason Hammons wasn't having sex was that her boyfriend was impotent. In his concluding argument, Specter treated that assertion with contempt. Of Hammons' boyfriend, he said to the jury, "He was ready."

If I were sitting on the jury, I would likely decide that J&J knew too little about potential adverse outcomes and had brought the product to market prematurely, as one of the plaintiffs experts emphatically testified. The product had obviously failed in some patients and the company knew too little about how it would work in the real world.

But, for all the science bandied about in trials like these, verdicts often come down to judgment calls. The truth is no one can say with absolute certainty what caused Hammons' dyspareunia. Was it the vaginal mesh? Was it a hysterectomy she had undergone after the implant? Was it the natural atrophying of vaginal tissue that sometimes attends the aging process?

Evaluating the science is not an exact science. But juries usually are able to cut through conflicting data and claims and see through to the bottom line. What makes Hammons' lawsuit especially important, apart from her own claim to be compensated for a wrong she says was done to her, is that this case and a handful of others will help to form a legal consensus about J&J's conduct.