

Boston Scientific Wins First Pelvic Mesh Injury Trial

By **David Siegel**

Law360, New York (July 29, 2014, 11:17 PM ET) -- A Massachusetts jury returned a verdict in favor of Boston Scientific Corp. on Tuesday in the first product liability lawsuit involving the company's pelvic mesh products to go to trial, according to attorneys involved in the case.

The jury reached a verdict after two days of deliberations following a nearly monthlong trial, finding Boston Scientific's Pinnacle Pelvic Floor Repair Kit was not defectively designed and the company adequately warned of the device's risks.

The verdict could have a substantial impact on similar lawsuits consolidated in Middlesex County Superior Court. More than 500 pelvic mesh cases relating to Boston Scientific's products are pending before Justice Diane M. Kottmyer, according to court filings.

Boston Scientific spokeswoman Denise Kaigler told Law360 the company is pleased with the jury's verdict.

"Patient safety is of utmost importance to Boston Scientific and we dedicate significant resources to deliver safe, high-quality products," Kaigler told Law360. "Transvaginal mesh remains an important treatment option for women who suffer from pelvic organ prolapse and stress urinary incontinence."

Fidelma Fitzpatrick, an attorney with Motley Rice LLC who represented the plaintiff, told Law360 she was disappointed by the verdict but didn't think it would have any impact on the viability of other pelvic mesh cases.

According to Fitzpatrick, pre-trial rulings prevented the jury from seeing key evidence related to the warnings and defect issue, a factor Fitzpatrick said distinguished this case from other pelvic mesh trials resulting in verdicts favoring the plaintiffs. Fitzpatrick said the plaintiff's team was looking "very seriously" at an appeal based on those evidentiary issues.

Plaintiff Diane Albright said in her 2012 complaint that Boston Scientific's Pinnacle kit caused severe pain and other physical side effects after she had the device implanted in 2010 to treat a cystocele, also known as bladder prolapse. Albright claims neither she nor her physicians were warned about the Pinnacle kit allegedly being defectively designed before her surgery.

During opening arguments, Albright's attorneys told the jury the Pinnacle device was too large to be safely implanted and is made of a plastic that in addition to being too heavy, makes the device nearly

impossible to remove in the event of complications, according to a transcript of the proceedings.

Boston Scientific is also embroiled in cases involving its pelvic mesh products consolidated into multidistrict litigation before a West Virginia federal court.

On July 18, the company asked U.S. District Judge Joseph Goodwin to throw out testimony from a regulatory expert for the plaintiffs in the MDL, noting that her opinions on the subject have been barred in similar litigation against another company.

The attack on the plaintiffs' expert came as the parties gear up for the first trial in the MDL, which is scheduled to begin in October. The more than 10,000 lawsuits against Boston Scientific allege injuries from its Obtryx Sling System and Pinnacle Pelvic Floor Repair Kits, the same device implanted into Albright.

Pelvic mesh products have recently become subject to greater regulatory scrutiny following the thousands of lawsuits filed against Boston Scientific and other companies including Johnson & Johnson's Ethicon unit, Covidien PLC and C.R. Bard Inc.

In April, the U.S. Food and Drug Administration issued two proposed orders that would reclassify surgical mesh for transvaginal repair of pelvic organ prolapse as a high-risk device and require manufacturers to apply for premarket approval with the agency.

That same month Endo International PLC, another pelvic mesh manufacturer, reached an \$830 million settlement resolving most of the 22,000 vaginal mesh suits against its American Medical Systems Inc. subsidiary.

The plaintiff is represented by Fred Thompson III, Fidelma Fitzpatrick and Jonathan Orent of Motley Rice LLC; Edward A. Wallace of Wexler Wallace LLP; Erin Copeland of Fibich Leebron; and Kimberly Dougherty of Janet Jenner & Suggs LLC.

The defendant is represented by Jon Strongman and Robert T. Adams of Shook Hardy & Bacon LLP and Susan Donnelly Murphy of Murphy & Riley PC.

The case is Diane Albright v. Boston Scientific Corp., case number MICV2012-00909, in the Superior Court of the Commonwealth of Massachusetts, County of Middlesex.

--Editing by Chris Yates.