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Ethicon Safety Commitment Questioned In Pa. Mesh Trial

By **Matt Fair**

Law360, Philadelphia (December 4, 2015, 7:44 PM ET) -- The research and development head for a Johnson & Johnson subsidiary faced questioning Friday before a Pennsylvania jury, over whether the company had adequately warned surgeons about the risk of complications in patients implanted with a pelvic mesh product blamed for injuring an Indiana woman.

Plaintiff Patricia Hammons' attorney, Adam Slater of Mazie Slater Katz & Freeman LLC, suggested that Ethicon Inc. R&D director Scott Ciarrocca and other key decision makers had ignored a request for a stronger warning in the Prolift pelvic mesh's instructions prior to the product's March 2005 market debut. The case is the first in Philadelphia County to be tried over injuries from the mesh.

While Slater pointed to an email from an Ethicon official in France who asked that the warning be included in instructions for use, or IFUs, for the product, he said that Ciarrocca and others had ultimately opted not to include the language because the document had already been printed.

"If you print an IFU and it's missing an important warning, shouldn't you throw that away so you can include the warning?" Slater asked.

The question was one of a string Slater raised Friday over whether Ethicon had taken proper steps to ensure patient safety as they worked to pursue what company documents pegged as a \$300 million market opportunity for the product.

Hammons had filed suit in Philadelphia in May 2013, alleging that shards of the Prolift mesh, which was implanted between her bladder and vagina in 2009 in an effort to correct sagging of her internal organs, had become implanted in her bladder.

Attorneys for Hammons contend that her injuries have caused urinary dysfunction and all but prevented her from having sex.

Trial in the case **got underway Tuesday** and is expected to last about two weeks.

Ciarrocca said Friday that Ethicon put a premium on patient safety and suggested all important warnings would have been placed in the product instructions.

"We would certainly want to include warnings for all the things we thought were critical," Ciarrocca said.

Slater also questioned whether the clinical study designed by Ethicon prior to the product's hitting the market had shown the mesh failing in an excessive number of patients.

Ciarrocca testified that the study's parameters had set a 20 percent failure rate as the threshold for the company to reconsider whether to move forward with the project.

Slater, however, pointed to a 2006 statistical analysis of results from 87 patients that extrapolated a maximum failure rate of 20.1 percent.

"Based on the documents we have, the results of the study, the documents in your files say, 'Don't sell Prolift,'" Slater said.

But Ciarrocca countered that the 20.1 percent figure was the upper limit of a confidence interval that dipped as low as 7.3 percent. The actual failure rate for the 87-patient group stood at 12.6 percent, according to documents shown in court.

He added that a prior analysis of the first 40 patients in the study to receive the implant must have been lower than 20 percent, or else the product would not have been greenlighted by Ethicon.

Anything lower, Ciarrocca said, "would've been a stop."

"We certainly would not want a dangerous product to slip through and get to the market," Ciarrocca said. "If we thought a product was dangerous, we would not have sold it."

Ciarrocca's testimony is expected to continue Monday.

According to Slater, the jury heard testimony Thursday from an executive with the electronic discovery consultancy Epiq Systems Inc. that Ethicon had destroyed tens-of-thousands of documents in violation of litigation holds put in place as early as 2003.

Briefing from J&J in the case, however, characterized the documents as being "inadvertently lost" and noted that a significant portion of the lost material was recovered and produced from other sources in the company.

The Hammons case is one of over 180 pending in a mass tort in the Philadelphia County Court of Common Pleas. Four others have been listed for trial. According to plaintiffs counsel in May, there are some 26,000 claims pending against Ethicon in a federal multidistrict litigation program in West Virginia and nearly 8,000 in consolidated litigation in New Jersey.

The case was presented for the plaintiffs by Adam Slater of Mazie Slater Katz & Freeman LLC.

The defendants are represented by Susan Robinson of Thomas Combs & Spann PLLC, Matthew Moriarty of Tucker Ellis LLP, Molly Flynn of Drinker Biddle Reath LLP, and Tarek Ismail of Goldman Ismail Tomaselli Brennan & Baum LLP.

The case is Hammons v. Ethicon Inc. et al., case number 130503913, in the Court of Common Pleas of the State of Pennsylvania, County of Philadelphia.

--Additional reporting by Dan Packel. Editing by Edrienne Su.

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