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Attorney Slams Pelvic Mesh Maker As 'Beyond Reckless' in Closing

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The attorney representing the plaintiff in the ongoing pelvic-mesh trial in Philadelphia hammered the device makers during his closing argument for their alleged failure to tell doctors and patients about the erosion rates of the device and the risk of permanent harm.

During closing arguments Tuesday, **Kline & Specter attorney Shanin Specter** told the jury in Carlino v. Ethicon that the company's conduct was "beyond reckless."

According to Specter, leaders at Ethicon had been aware that the pelvic mesh device had high failure rates, but they did not put the information in the medical literature, and they placed concerns about sales over patient safety.

"It is conclusive evidence of reckless disregard. Reckless, reckless, reckless. You know these things, and you don't act. You don't fix the product. You don't decline to sell it. You don't tell doctors about the risk, and you don't tell patients about the risks," Specter told the jury of eight women and four men. "It's the epitome of recklessness. It's why they built this courthouse, and this courtroom, and why you got a court summons. You've got to straighten it out. It's as simple as that."

The closings came after more than two weeks of trial in Philadelphia Court of Common Pleas Judge Kenneth Powell's courtroom focusing on the claims of plaintiff Sharon Carlino, who had an Ethicon-manufactured pelvic mesh device implanted in her in 2005 to combat her urinary incontinence. Carlino has alleged that the device failed because it was negligently designed, and that its failure led her to suffer permanent pain during sex.

Specter told the jury the mesh was defective because its pores were too small, it had a tendency to degrade, it was overly friable because it was cut by a machine and not a laser, and the mesh can erode through the patient's tissue.

According to Specter, the small pores of the mesh often caused a reaction where, instead of growing regular tissue around the mesh, hardened scar tissue developed, which caused the mesh to bunch. Specter said heads of Ethicon, which is a Johnson & Johnson subsidiary, had known of the bunching problem when the product was launched, and they had also received numerous reports of the mesh breaking apart in patients' bodies, but they did not change the labeling materials to warn doctors.

"What do they care about? They care about marketing. They care about sales. They weren't caring about safety," Specter said.

Specter contended that safer alternatives to the mesh had been used at the time—including mesh with thinner pores and a procedure, known as the Burch procedure—that involved placing two sutures to address the incontinence.

Specter said the jury had been told the Burch procedure had "stood the test of time."

"They were insistent on fixing something that wasn't broken. Why? To make money," Specter said. "Let's come up with a solution that is worse than the current situation."

However, counsel for Ethicon, Butler Snow attorney William Gage, argued many of the facts of Carlino's case did not add up.

Gage focused on Carlino's medical records to attack the claim that the mesh caused the claimed injuries. Gage noted that Carlino's complaints were primarily on the right side; however, he said the mesh had been removed from her right side in 2010, and only remained on Carlino's left side. Gage further noted that she had prior medical reports of pain and muscle spasms in her right leg and back, and that a doctor had diagnosed her with vaginal atrophy and pelvic floor muscle spasms.

"If the mesh is causing her pain on the right side, why isn't it causing pain on the left side where all the mesh remains?" Gage asked. "How can it be a substantial factor if it's nowhere near the place where it needs to be?"

Gage also noted that Carlino did not begin making complaints of pain

during sex until 2015, after she met with an attorney.

"When you look at these records, the closer we got to trial, the worse the plaintiff's complaints get," Gage said.

Gage also touted long-term studies that he said showed very high success and satisfaction rates, and told the jury the plaintiffs did not meet the high burden required to award punitive damages. He also contended that Carlino could take a cream to alleviate some of her injuries.

Regarding the design defect claim, Specter had said that the plaintiff had not needed to prove a safer alternative design, but Gage contended that Carlino needed to prove a safer product existed and that the plaintiff failed to prove that such a product was on the market.

Gage said Carlino's expert had said the mesh with the smaller pores had a higher rate of erosion, and there had not been any testing on that product as of 2005. Gage also noted that no expert for Carlino was able to point to a mesh from any other company that was more safe than Ethicon's device.

"That is the end of their design defect claim," Gage said. "On design defect, that's not even a close call."

Gage also rhetorically asked the jury why Carlino did not produce any MRI or ultrasound tests to show the mesh had contracted. He also said Carlino's treating doctor testified she did not experience any complications he did not know were a possibility when the device was installed.

"There are a lot of facts that kind of whizzed past us in the courtroom that I'm going to ask you to reconsider them," Gage said.