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Mirena MDL Shows How A Lack Of Experts Can Doom A Case

By **Emily Field**

Law360, New York (August 1, 2016, 10:25 PM ET) -- The exclusion of four plaintiffs' experts from a sprawling multidistrict litigation against Bayer over claims that its intrauterine device Mirena harmed women set the stage for the dismissal of more than 1,200 suits, attorneys say, underscoring the importance of having reliable expert testimony when dealing with complex medical issues.

U.S. District Judge Cathy Seibel had dismissed four experts on causation in March. But the women suing Bayer AG continued to press forward without expert testimony — a somewhat uncommon move in an MDL, attorneys say.

"It's kind of unusual to have a situation where a plaintiff is trying to proceed in an MDL without any expert on general causation," said Max Kennerly, of counsel at Tor Hoerman Law.

Instead, the women had attempted to rely on statements from Bayer employees, arguing that such admissions could stand in for expert testimony on the issue of general causation. On Thursday, Judge Seibel ruled that the more than 1,200 suits couldn't survive on the company's admissions alone.

Judge Seibel declined to be the first court to hold that such admissions could be an adequate stand-in for expert testimony. Without the benefit of expert witnesses to elucidate complex medical facts, jurors would still be at sea and could only speculate on general causation, she said in her ruling.

Jurors would be left to their own devices to decide complex medical and causation issues, the ruling said, namely, whether Mirena can perforate the uterus subsequent and unrelated to its insertion, an injury called secondary perforation.

"Typically, those statements are lifted out of context by the parties in litigation and don't reflect an analysis of a scientific data set," said David Cohen of Butler Snow LLP. "Lifting statements hither and thither is not a methodology and not good science, so the decision advances the Daubert decision's important principle that the causation be grounded in good science from my perspective."

Shaped like a T and made out of plastic, Mirena is implanted in the uterus to prevent pregnancy by slowly releasing hormones over time. While its label has long warned about the risk that the uterus might be perforated, most often during insertion, it did not warn about post-insertion risks during the 2008 to 2014 time period covered by the women's suits.

Bayer had maintained that, according to the scientific community's consensus, secondary perforation

can’t happen — any injury to the uterus occurs when it's inserted, even if that injury is detected or the IUD moves later.

Judge Seibel, for a number of reasons, had barred the four causation experts — Roger C. Young, John Jarrell, Susan Wray and Richard Strassberg — from testifying about their qualifications and the reliability of their opinions.

Young, for example, had tried to compare the uterus to a pig’s heart — an analogy that failed to win the judge’s approval.

He’d said that a Mirena IUD can exert a force of 390 pounds per square inch — enough to penetrate the uterus — compared to the amount of force necessary to penetrate heart muscle, which is about 290 pounds per square inch. In support of that figure, he’d cited an article about a pig heart study, according to the March order.

Pig hearts were an appropriate equivalent, Young had argued, because he’d felt a lot of uteruses during hysterectomies. They felt, he said, like the pig hearts his grandmother would buy when he was a child.

“Such subjective comparison of muscle of a pig heart to a female uterus creates simply too great an analytical gap between the data and the opinion proffered to pass muster,” the judge said in her order.

Without causation experts, the women were left with regulatory experts to opine on U.S. Food and Drug Administration regulations and labeling standards and one lone epidemiological expert who was also restricted from testifying on certain areas outside her expertise.

It’s unclear why the women didn’t attempt to find new causation experts, attorneys say, especially given the resources of an MDL.

“There are litigations where plaintiffs’ experts have been struck and they’ve come back with new ones, but that’s obviously not what happened here,” Cohen said.

Following the decision to bar their experts, two women voluntarily dropped their cases on the eve of an April trial date, giving scant public explanation. At the time, Bayer said that it was because of the expert testimony ruling.

The dismissal of the Mirena MDL follows a similar decision by a Pennsylvania federal judge in April that ended more than 300 cases claiming Zoloft caused babies’ heart defects, attorneys noted.

“It is interesting that it is the second MDL this year, which has been dismissed for want of sufficient, valid evidence to support conclusions of general causation,” Nathan Schachtman of Schachtman Law said.

--Editing by Rebecca Flanagan and Aaron Pelc.
