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Bayer Beats 1,200 Suits Over Mirena IUD Injuries

By **Jeff Overley**

Law360, New York (July 28, 2016, 8:39 PM ET) -- A New York federal judge on Thursday wiped out more than 1,200 suits alleging harm from Bayer Healthcare's intrauterine device Mirena, concluding that the absence of expert testimony makes it impossible to prove that Mirena can cause injuries after insertion.

The grant of summary judgment from U.S. District Judge Cathy Seibel ends multidistrict litigation alleging that Bayer failed to warn women that Mirena could perforate the uterus subsequent and unrelated to insertion. Judge Seibel in March barred the women from introducing expert testimony after concluding that the experts were unqualified or unreliable, and Thursday's order rejected various attempts to salvage the cases in the absence of such testimony.

"The court reaches this conclusion reluctantly, knowing that it will doom hundreds of cases, but in the court's view it is compelled by the law," Judge Seibel wrote on Thursday.

Mirena is a T-shaped, hormone-releasing insert used to prevent pregnancy. Its label has long warned about the risk of perforation of the uterus, "most often during insertion," but said nothing about post-insertion risks during 2008-2014 period covered by the roughly 1,200 lawsuits. Bayer denies that perforation after and unrelated to insertion is possible, according to Thursday's ruling.

As one backup argument, the women argued that expert testimony isn't needed to show that Mirena could have caused their injuries. But Judge Seibel balked at leaving the disputed medical questions entirely in the hands of a jury, saying that average citizens could not be expected to resolve such intricate matters on their own.

"There is no basis on which to conclude that it is within the ordinary experience and understanding of lay people that an IUD could spontaneously travel through or become embedded in an intact uterine wall," the judge wrote.

Judge Seibel was also unmoved by suggestions that statements from Bayer employees could be used to prove Mirena's risks. She concluded that jurors would still be left in an untenable position and that it would discourage drug and device makers from conducting candid assessments of product safety.

"Such a ruling would disregard the purpose of the requirement for expert testimony, leaving jurors to speculate, and would chill free and frank discussion by manufacturers of drugs or devices," according to Thursday's opinion.

Even if such employee statements could constitute admissions of Mirena's purported dangers, they would have to be unmistakably clear, and none of the statements by Bayer employees meet that standard, Judge Seibel added.

"Assuming there could ever be admissions that would suffice to allow a jury to find general causation without speculating, the admissions to which plaintiffs point here do not fit the bill," she wrote. "They are not sufficiently clear, concrete or detailed."

In a brief statement on Thursday, Bayer called Judge Seibel's decision "a significant ruling that dismisses all 1,225 cases pending in the MDL."

Attorneys for the women couldn't immediately be reached for comment.

The plaintiffs are represented by Diogenes Kekatos of Seeger Weiss LLP, Matthew McCauley of Parker Waichman LLP, James Ronca of Anapol Weiss, Fred Thompson III of Motley Rice LLC and Michael Johnson, Kenneth Pearson and Rolf Fiebiger of Johnson Becker PLLC.

Bayer is represented by Shayna Cook, Brian O'Donoghue and Christopher Cook of Goldman Ismail Tomaselli Brennan & Baum LLP, Paul Schmidt, Phyllis Jones and Michael Imbroscio of Covington & Burling LLP, E. James Shepherd of Shook Hardy & Bacon LLP and William Harrington of Bleakley Platt & Schmidt LLP.

The case is In re: Mirena IUD Products Liability Litigation, case number 7:13-md-02434, in the U.S. District Court for the Southern District of New York.

--Editing by Christine Chun.