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FEDERAL DISTRICT COURT EXCLUDES DUBIOUS “SCIENTIFIC” OPINIONS IN MIRENA MDL

by Evan M. Tager and Jonathan S. Klein

Although courts don't always apply *Daubert* with the rigor that is warranted, when they do, it is worth noting. Such is the case with federal district court Judge Paul Engelmayer's thorough and scholarly decision excluding the opinions of all the plaintiffs' general-causation experts in an MDL involving Bayer's Mirena IUD device, *In re Mirena Ius Levonorgestrel-related Products. Liability Litigation (No. II)*.

The Mirena IUD is an intrauterine implant that releases the hormone levonorgestrel (LNG), which acts as a contraceptive. The MDL collects the lawsuits of more than 800 women, who allege that the LNG in Mirena causes idiopathic intracranial hypertension, a disease that produces headaches, nausea, blurred vision, and occasionally blindness. Because the plaintiffs and Bayer agreed that the outcome of the action will depend partly on the plaintiffs' ability to prove general causation—whether Mirena can cause intracranial hypertension generally, not whether Mirena caused an injury to any particular plaintiff—the district court expedited briefing on Bayer's motions to exclude the testimony of the plaintiffs' general-causation experts under *Daubert*.

Judge Englemayer's October 24, 2018 decision excluding the testimony of the plaintiffs' experts emphasizes that most of the experts relied principally on a study later repudiated by its author and that none of the witnesses offered a cogent, evidence-based explanation for concluding that Mirena causes intracranial hypertension.

The decision begins by surveying the academic literature, which shows that intracranial hypertension occurs in about one out of 100,000 people every year. But several risk factors dramatically increase the likelihood of intracranial hypertension: The illness occurs about three times as often in women of child-bearing age than in the general population, about six-and-a-half times as often in overweight women, and about 20 times as often in obese women.

Because an oral contraceptive (“the pill”) is less effective in obese women than in women of an average weight, doctors tend to prescribe Mirena more often to obese women than to others. But the literature on which the plaintiffs' experts relied, a 2015 study by Dr. Mahyar Etminan, failed to account for doctors' tendency to prescribe Mirena to obese women more often than to others. In the first half of the study (the only part that arguably supported the plaintiffs' claims), Dr. Etminan searched the FDA's adverse-event database for complaints about intracranial hypertension and found that the reports disproportionately involved Mirena users.

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Because Dr. Etminan searched the entire FDA database, the data included people (such as men) who faced a lower risk of intracranial hypertension than is naturally faced by Mirena's users, who tended toward being overweight and who were necessarily women. In other words, although obese women of child-bearing age (a) suffer from intracranial hypertension more often than the general population and (b) use Mirena more often than the general population, Dr. Etminan failed to separate the effect of Mirena from the age, weight, and gender risk-factors.

Shortly before Bayer deposed Dr. Etminan in a case that was not part of the MDL, Dr. Etminan recanted his finding and admitted that a methodologically sound study showed no relation between Mirena and intracranial hypertension. Despite Dr. Etminan's repudiation of his study, several of the plaintiffs' experts in the MDL continued to rely on the study. This reliance contributed significantly to Judge Englemayer's decision to exclude the plaintiffs' experts; as Judge Englemayer bluntly explained, an expert's reliance on a report later repudiated by the author "is presumptively unsound."

Although the plaintiffs' experts also relied on a 2017 study, Judge Englemayer concluded that the study failed to support their general-causation opinions. At most, the study showed a "correlation" between Mirena and the illness, and the study itself warned that "[o]ur investigation does not indicate that an LNG" contraceptive such as Mirena can cause intracranial hypertension.

Several other defects (some common to all of the plaintiffs' experts and others particular to one or two experts) contributed to the exclusion of the experts' opinions. Most importantly, the opinions did not satisfy any of the four indicia of reliability identified by *Daubert*. None of the experts tested their conclusions; none of the experts published a peer-reviewed article concluding that Mirena causes intracranial hypertension; none of the experts identified an "error rate" for their methodology; and none of the experts offered a causation theory that is generally accepted by the scientific community.

Judge Englemayer also criticized one expert for failing to acknowledge contrary evidence that consistently showed no association between Mirena and intracranial hypertension. As we discussed in a past *WLF Legal Pulse* post, failing to grapple with conflicting studies is a hallmark of unreliable, result-oriented expert testimony.

Finally, Judge Englemayer observed that several of the plaintiffs' experts failed to explain cogently their conclusion that Mirena causes intracranial hypertension. Scientists and medical experts often consider nine criteria, known as the "Bradford-Hill" factors, to assist in distinguishing "a mere association" from a "causal connection." In evaluating the reliability of an expert causation opinion that applies the Bradford-Hill factors, courts generally require the expert to explain clearly the weight that he or she assigned to each factor.

Absent a clear explanation, a plaintiff's expert can manipulate the Bradford-Hill factors to reach a preordained conclusion, and the expert's causation testimony—scientific-sounding but not scientifically sound—might confuse or deceive a jury. Judge Englemayer suggested that the failure of several of the plaintiffs' experts to explain the weight they afforded to each Bradford-Hill factor was still another reason to doubt the objectivity and reliability of their opinions.

In short, the expert testimony in this case was a paradigm of the sort that *Daubert* was designed to screen out. And Judge Englemayer's decision is the paradigm of a court properly performing its gatekeeping role.