Under the Shadow of the Dalkon Shield: Assessing the Allegations Against the Mirena IUD

Rachel R. Dunlap, MST and Eli Y. Adashi, MD, MS
The Warren Alpert Medical School of Brown University (author 1,2), Fellow of the American Congress of Obstetricians and Gynecologists (author 2)

Background
Over the past several years, there have been hundreds of legal claims made against the makers of Mirena, the most popular intrauterine device (IUD) marketed and sold in the United States. Law firms have advertised to women on television and social media sites, alleging that Bayer Healthcare Pharmaceuticals failed to warn consumers about the risks associated with Mirena and willingly sold a defective product. These legal claims are juxtaposed against a contraceptive landscape in which IUDs, and Mirena in particular, are gaining a significant role in preventing unwanted pregnancies. The Centers for Disease Control and Prevention estimates that 6.4 percent of American women ages 15 to 44 years used an IUD from 2011 to 2013. A historical precedent for legal action against IUDs exists with the class action lawsuit against the injurious Dalkon Shield IUD in the 1970s. This research project aims to describe the tenor of the Mirena lawsuits, review the published literature on IUD perforation rates, explore the adverse events data reported to the Food and Drug Administration (FDA), examine Mirena's warning labels, and discuss the relevant and influential factors regarding the lawsuits.

Methods
The legal claims against Bayer were examined through reading of court documents. A literature review was conducted to investigate the safety profile of Mirena, particularly regarding perforation rates of Mirena and other IUDs that are currently available. Additionally, the adverse events data reported to the FDA were acquired through a Freedom of Information Act request and were subsequently analyzed.

Results
While the lawsuits include a broad list of allegations, ranging from defective design, fraudulent misrepresentation, and failure to warn about potential risks, the cases center around uterine perforation and migration of the IUD. The complaint hinges on the allegation that Bayer failed to adequately warn patients about the risk of the device migrating outside of the uterus during a period of time ranging from weeks to years after the insertion of the IUD. Bayer's labeling warns both patients and physicians of the possibility of perforation during insertion. According to published literature on uterine perforation from IUDs, the overall perforation rate is 1 perforation per 1000 insertions. Recently, researchers in a large European study with over 60,000 patients showed a perforation rate of 1.4% for levonorgestrel IUDs[1]. From 2000 to 2013, the FDA received 1,300 reports of uterine perforation, a smaller figure than expected, given that over 2 million women in the United States use Mirena. Finally, the FDA's Adverse Events data include an extensive list of symptoms, including anxiety, breast cancer, hypertension, headaches, and fatigue. These symptoms are also listed in advertisements recruiting lawsuit plaintiffs, but do not appear in filed court documents.

Conclusion
The lawsuits against Mirena appear to have little to do with a higher than expected rate of perforation, and rather may embody a perceived discrepancy in Bayer's warning labels regarding the timing of perforation. Mirena does not pose a significantly increased risk of perforation compared to other IUDs on the market. Additionally, plaintiff recruitment ads list many detrimental symptoms that are not addressed by the lawsuits, which may lead patients to perceive Mirena as unsafe. We advise physicians to carefully discuss the known benefits and risks of Mirena with patients while addressing their concerns about the lawsuits.

1. Heinemann, K., et al., Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices. Contraception, 2015. 91(4): p. 274-9.