

Lawsuit Filed Against Mentor Worldwide Over Mentor MemoryGel Silicone Breast Implants

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A Seattle woman, Sara Ebrahimi, has filed suit against Mentor Worldwide LLC and its parent company, Johnson & Johnson Services, Inc., alleging the defective manufacturing of **Mentor MemoryGel™ Silicone Breast Implants**. The lawsuit alleges that Mentor and its parent company, Johnson & Johnson, repeatedly failed to follow the requirements imposed by the Food and Drug Administration (“FDA”) in connection with the approval of Mentor’s premarket approval application. It is further alleged that the companies failed to warn the FDA and women receiving the implants of the devices’ known dangerous propensities. The lawsuit -- *Ebrahimi v. Mentor Worldwide LLC, et al.* (case no. 2:16-cv-07316-DMG) -- was filed in the Central District of California in Los Angeles, where Mentor is headquartered.

Mentor develops, manufactures, and markets products for surgical and non-surgical procedures, including **Mentor MemoryGel™ Silicone Breast Implants**. The lawsuit alleges that chemicals Mentor used in the manufacturing process bled through the implants, and into Ms. Ebrahimi’s body, causing her to suffer serious medical problems. It is alleged that Mentor and Johnson & Johnson knew that their devices were defective, yet allowed them to be surgically implanted in Ms. Ebrahimi and other unsuspecting women. It is further alleged that Mentor and Johnson & Johnson failed to warn the FDA of these risks by not providing adequate follow-through studies.

Mentor MemoryGel™ Silicone Breast Implants are regulated medical devices under the Food, Drug and Cosmetic Act that require FDA approval. As a condition of approval, the FDA required that Mentor conduct six post-approval studies to demonstrate, over time, that its silicone implants were safe and effective. The lawsuit alleges that Mentor failed to design effective studies and, as a result, failed to

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provide the FDA with the longitudinal studies that were required as a condition to the devices' approval. It is alleged that:

It was Mentor's obligation to design and execute a study where women were able to access internet forms that are easily understood and provide a working forum to report their experience with implants. Mentor intentionally and systematically failed to make this happen which is a violation of the FDA's conditions for approval. Data collection was sparse and potential serious side effects and harmful complications were downplayed and under-reported due to inadequate sample size.

Ms. Ebrahini is represented by the law firm of Cotchett, Pitre & McCarthy, LLP, which has decades of experience litigating complex cases involving defective products that harm consumers.