

[Products Liability Law Daily Wrap Up, TOP STORY—PREEMPTION—10th Cir.: Patients' tort claims against breast implant manufacturer did not pass 'legal quagmire' to survive dismissal, \(Jan. 27, 2021\)](#)

Products Liability Law Daily Wrap Up

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By Leah S. Poniatowski, J.D.

Preemptive force of federal statutes, lack of parallel state law, and unsubstantiated allegations supported the lower court's ruling in favor of the manufacturer.

Two patients who suffered negative health issues after being implanted with silicone breast implants failed to overcome the manufacturer's motion to dismiss because the crux of their tort claims was expressly preempted by federal law, the U.S. Court of Appeals for the Tenth Circuit ruled, affirming the lower court. The appellate court also determined that the manufacturing defect claim was unsupported with adequate facts and that the patients did not successfully preserve leave to amend their claims ([Brooks v. Mentor Worldwide LLC](#), January 26, 2021, Carson, J.).

Two patients who were implanted with the "MemoryGel" silicone breast implants filed a multi-count products liability lawsuit in federal court against the manufacturer, Mentor Worldwide LLC. They experienced several negative health effects after the implanted devices leaked, and some issues remained even after the devices were removed. Concluding that federal law preempted the lawsuits, the federal district court dismissed them with prejudice. The patients filed the present appeal.

Federal statutes. The manufacture and sale of medical devices is governed by two federal statutes—the federal Food, Drug, and Cosmetic Act (FDCA) and the Medical Device Amendments (MDA) thereto. Under the MDA, medical devices subject to the strictest controls, Class III devices, must pass the pre-market approval process, which is administered by the Food and Drug Administration (FDA). The process is broad in scope, rigorous, and extensive, including review of the warnings and labels accompanying the device. Both statutes preempt certain state laws, with the FDCA provision expressly preempting state tort laws that impose a requirement that relates to the safety or effectiveness of the implant and differs from or adds to the federal requirements. The MDA provision is easier to interpret and apply than the first, the appellate court explained, characterizing the challenge of successfully pleading a tort claim for the failure of a medical device as a "legal quagmire."

The appellate court summarized that in order for the patients' claims to survive preemption, they must plead conduct that (1) violates the FDCA (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA. Falling short of that, the court should dismiss the claim.

Negligence per se. The appellate court held that the failure-to-warn and defective manufacturing claims based on negligence per se were preempted by federal law. The patients' theory relied upon the federal requirement to supply the duty of care and asserted that a violation of the federal requirement was the breach of that duty, effectively seeking to enforce the requirement instead of a parallel duty under state law. Because only the federal government can enforce the requirements of the MDA, these claims were preempted. Moreover, the appellate court determined that state law did not support the negligence per se claims and, thus, the lower court's dismissal of the claims was not in error.

Failure to warn. The appellate court also concluded that the patients' claim that the manufacturer breached its duty to warn patients, physicians, and the FDA about the health risks associated with the implants was preempted. The pleading did not demonstrate that there was a federal requirement that the manufacturer provide a direct warning to patients, and federal law expressly preempted the addition of a state-law duty to

do so. Similarly, the patients did not identify a federal requirement that the manufacturer warn physicians. The final prong of their assertion, that the manufacturer did not properly conduct the post-approval FDA-mandated testing and report negative results, which would have indirectly warned physicians of the device's dangers, failed because the patients did not assert a state-law duty that the manufacturer comply with federal requirements and the federal government is the only body that can enforce those requirements. Therefore, the lower court properly dismissed the failure-to-warn claims.

Manufacturing defect. The appellate court explained that the patients needed to present plausible claims supported by facts in order for their manufacturing defect claim to survive the manufacturer's motion to dismiss. However, the patients only presented conclusory assertions that the breast implants had manufacturing defects. The appellate court noted that the patients focused on a story identifying regulatory noncompliance, whistleblower complaints, misrepresented data, and other "horrors," but did not provide any facts to support the claim that the implants were the product of a defective manufacturing process or identify a specific flaw in the at-issue devices. Accordingly, the manufacturing defect claim was properly dismissed by the lower court.

Leave to amend. The appellate court also was not satisfied that the patients' "one-sentence request at the end of their response to [the manufacturer's] motion to dismiss" was sufficient for the lower court to grant leave to amend. Additionally, the appellate court pointed out the available procedural steps the patients could have taken to amend the complaint but chose not to. Therefore, the lower court did not abuse its discretion when it denied the request, and its ruling was affirmed.

The case is No. [19-3240](#).

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Companies: Mentor Worldwide LLC

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