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Tenth Circuit Explains and Applies the Scope of Federal Preemption of Product Liability Suits Based on Medical Device Failures

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The Tenth Circuit waded into the "legal quagmire" facing parties who plead state-law claims for failure of a medical device and attempt to avoid preemption under the Medical Device Amendments to the federal Food, Drug, and Cosmetics Act.

In *Brooks v. Mentor Worldwide*, 985 F.3d 1272 (2021), the U.S. Court of Appeals for the Tenth Circuit waded into the "legal quagmire" facing parties who plead state-law claims for failure of a medical device and attempt to avoid preemption under the Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetics Act (FDCA). Id. at 1276. Holding that plaintiffs failed to thread the needle, the circuit court affirmed the dismissal of their product liability claims.

Background on the MDA

In 1976, Congress passed the MDA, in which it regulated the safety and effectiveness of medical devices. Id. at 1276. The device at issue in *Brooks*, the "MemoryGel" silicone breast implant, was a Class III device. See id. at 1277. Such devices are subject to the strictest requirements, including a premarket approval (PMA) process administered by the FDA that consumes an average of over 1,200 hours and may last years. Id. Among other things, the PMA review includes warning and labeling. Id. The FDA can also impose post-approval reporting requirement on manufactures and can revoke approval based on new or existing data. Id.

Plaintiffs' Allegations and the District Court's Rulings

As alleged by the two plaintiffs, defendant (Mentor) applied for and was granted premarket approval of its MemoryGel implant, subject to Mentor conducting post-approval studies. Id. Plaintiffs claimed that Mentor failed to properly conduct those studies and to report their results and also failed to fulfill reporting obligations not tied to specific post-approval studies. Id. After Mentor completed the PMA process, plaintiffs received the implants and experienced negative effects. After the implants were removed, some

of their symptoms persisted. Id.

Plaintiffs sued Mentor in the U.S. District Court for the District of Kansas and pled claims for failure to warn and manufacturing defects sounding in ordinary negligence, negligence per se, and strict liability. Id. at 1277-78. The district court, applying Missouri law, ruled that federal law preempted all the claims and that, in any event, plaintiffs had failed to state a claim. Id. at 1277. The court also denied their request for leave to amend their complaint. Id. at 1278.

The Tenth Circuit's Federal Preemption Analysis

The Tenth Circuit first addressed preemption. The FDCA and MDA contain two relevant preemption provisions. The first expressly preempts certain state laws by forbidding states from establishing any requirement for a medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." Id. (quoting 21 U.S.C. §360k). Under this provision, "Federal law preempts a tort claim unless the federal requirements impose duties that are at least as broad as those imposed by the state law." Id. at 1279 (citation and quotation marks omitted).

The second preemption provision states that, "Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States … ." Id. (quoting 21 U.S.C. §337). Under this provision, the MDA may be enforced only by the federal government. Id. It thus impliedly preempts state tort claims that exist solely due to a FDCA violation. Id.

Against this backdrop, the circuit court first addressed the failure-to-warn and manufacturing-defect theories based on negligence per se. The court concluded that federal law preempted these claims. Id. The court noted that a plaintiff can sue *for* conduct that violates the MDA but not *because* it violated the MDA. Id. Plaintiffs' negligence-per-se claims looked to the MDA to supply the duty of care and lacked viability under either Kansas or Missouri law (thus obviating the need to choose which state's law applied). Id. at 1279-80.

This left ordinary negligence and strict liability for failure to warn. Plaintiffs alleged that Mentor breached the duty to warn patients, doctors, and the FDA. Id. at 1280. But plaintiffs identified no federal requirement to provide warnings directly to either patients or doctors, so these claims were expressly preempted. Id. As for the FDA, plaintiffs alleged that Mentor didn't properly conduct post-approval, FDA-Mandated testing and reporting. Id. at 1280–81. But they identified no state-law duty for a manufacturer to comply with these FDA requirements, and in any event, only the federal government could enforce these requirements. Id. at 1281. The MDA thus impliedly preempted this claim. Id.

Pleading Deficiencies and Denial of Request To Amend

Applying the *Iqbal/Twombly* standard, the circuit court separately affirmed the dismissal of the manufacturing defect claims for failure to state plausible claims for relief. The court reasoned that plaintiffs had failed to allege any negligence in manufacturing the implants or any defects in the implants. Id. at 1281-82.

Finally, plaintiffs contended that the district court abused its discretion in denying their request for an opportunity to amend their complaint. Id. at 1282. Plaintiffs made this request in a one-sentence statement at the end of their response to the motion to dismiss. Id. The Tenth Circuit found this request to be insufficient and affirmed the district court's denial. Id. at 1283. The circuit court noted that plaintiffs had three available options: (1) amend the complaint as of right within 21 days after Mentor served its Rule 12(b) motion; (2) move for leave to amend after the time to amend as of right had expired; or (3) move to reopen the case after dismissal by filing a motion under Rule 59(e) or 60(b) and then seek leave to amend under Rule 15. Id. at 1282-83. But plaintiffs chose none of those three options, and the court “[did] not recognized plaintiffs' single sentence as a cognizable motion[.]” Id. at 1283.

Stephen Masciocchi and Jessica Smith are attorneys at Holland & Hart specializing in complex commercial litigation. Steve assists clients with federal and state appeals and class actions in high-stakes trial and appellate litigation. Jessica has substantial appellate experience and leads the firm's religious institutions and First Amendment practice.

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