Products Liability Law Daily Wrap Up, PREEMPTION—MEDICAL DEVICES—S.D. Fla.: Toxic hip claims bumped out of court, (Dec. 1, 2015)

By Mary Damitio, J.D.

A patient's claims against the manufacturer of a hip replacement system which allegedly caused him to experience elevated levels of toxic metal ions in his bloodstream were preempted by federal law and were insufficient to state a valid parallel claim, a federal district court in Florida ruled. Although the court dismissed the patient's lawsuit, he was afforded the opportunity to amend it to state specific facts which could support a parallel claim that the manufacturer violated federal regulations (*Mink v. Smith & Nephew, Inc.*, November 18, 2015, Bloom, B.).

Background. The patient underwent hip replacement surgery using the Birmingham Hip Resurfacing System (BHR System) manufactured by Smith & Nephew, Inc. (S&N). Shortly thereafter, he experienced elevated toxic metal ions in his blood. As a result of the large content of metal ions in his bloodstream, the patient experienced deleterious effects, such as eye problems and an enlarged lymph node near the surgery site that required removal.

BHR study. The patient's orthopedic surgeon initially scheduled surgery using a different system, but the patient alleged that an agent from S&N met with him and stated that if he agreed to use the BHR, he would be included in a 10-year post-approval study, during which he would be regularly monitored at no cost.

Study terminated. The patient was unable to continue in the BHR study because he was notified that the study had been terminated at his regional hospital and there was no clinical site to continue the study's activities. Consequently, the patient was required to monitor his blood toxicity at his own expense, and he eventually underwent a second surgery to remove the BHR System.

Lawsuit. The patient filed suit against S&N, alleging that the BHR System was defective and that S&N did not comply with the Food, Drug, and Cosmetic Act (FDC Act) (21 U.S.C. § 301 et seq.) and various federal regulations. The patient also brought claims for strict products liability, breach of express and implied warranties, breach of contract, and negligent misrepresentation. S&N moved to dismiss the complaint based on federal law preemption and failure to state a parallel claim.

Preemption. All of the patient's claims were expressly preempted by federal law, and he failed to state a valid parallel claim under state law. Under the Medical Device Amendments to the FDC Act, any state claim against manufacturers of Class III medical devices are expressly preempted if they impose obligations different from or additional to those required under federal law (21 U.S.C. § 360k(a)). The U.S. Supreme Court has held that any state law claim relating to "the design, testing, inspection, distribution, labeling, marketing and sale" of medical devices that received premarket approval by the Food and Drug Administration (FDA) is preempted. S&N obtained premarket approval for the device from the FDA in 2006. However, the preemption clause does not prevent a state from providing damages for claims based on violations of FDA regulations.

Although the patient alleged that the BHR System was defective in "design or manufacture" and that S&N made negligent misrepresentations regarding the clinical study, he asserted no supporting facts to establish a violation of federal regulations. The patient's remaining state law claims were similarly preempted by federal law. However, he was granted leave to amend his complaint to allege specific facts to support a valid parallel claim.

The case is No. 15-cv-61210-BB.

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Companies: Smith & Nephew, Inc.

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