Products Liability Law Daily Wrap Up, TOP STORY—MEDICAL DEVICES—S.D. Fla.: Second time no charm for toxic implant claims, (Mar. 15, 2016)

Products Liability Law Daily Wrap Up

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By Susan Lasser, J.D.

An action by a patient who alleged that a manufacturer's hip implant system raised the level of toxic metal ions in his blood which caused other injuries was dismissed with prejudice by a federal district court in Florida after it found that his state-law claims were preempted by federal law. After ruling in a prior decision that the patient's claims were insufficient to state a valid parallel claim, and permitting the patient an opportunity to amend his complaint to state specific facts which could support a parallel claim that the manufacturer violated federal regulations, the court determined that the patient failed to present claims that were both valid under Florida law and not preempted by federal law (*Mink v. Smith & Nephew, Inc.*, March 11, 2016 (docketed March 14, 2016), Bloom, B.).

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 and, as a result, developed deleterious effects, including 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 hip replacement system, but another orthopedic surgeon, an S&N representative/agent, met with the patient and told him that if he agreed to use the BHR System, he would be included in a 10-year post-approval study, during which he would be regularly monitored at no cost. The patient agreed and had the surgery with the BHR System, but he was later notified that the BHR study had been terminated at his regional hospital and there was no clinical site to continue the study's activities. Consequently, he was unable to continue in the study and was required to monitor his blood toxicity at his own expense. He eventually underwent a second surgery to remove the BHR System.

Lawsuit and dismissal without prejudice. His initial lawsuit against S&N alleged that the BHR System was defective and that S&N did not comply with the Food, Drug, and Cosmetic Act (FDC Act) 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. The court ruled that all of the patient's claims were expressly preempted by federal law, and that he failed to state a valid parallel claim under state law (see *Products Liability Law Daily*, December 1, 2016 analysis).

Federal law framework. The BHR System underwent a rigorous premarket approval (PMA) process pursuant to the Medical Device Amendments (MDA) to the FDC Act and received conditional approval by the Food and Drug Administration (FDA) as a Class III device. The classification permitted S&N to distribute the system in accordance with certain conditions imposed by the FDA, including agency approval of supplemental changes affecting the safety or effectiveness of the device, post-approval reporting requirements, and adverse reaction and device-defect reporting. Under the MDA, any state claim against manufacturers of Class III medical devices are expressly preempted if they impose obligations "different from, or in addition to" those required under federal law. 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 FDA is preempted. However, pursuant to the U.S. Supreme Court's opinion in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the MDA preemption clause does not prevent a state from providing damages for parallel claims based on violations of FDA regulations.

The patient's common-law negligence claim was based on S&N's purported breach of its duty to comply with and not deviate from the PMA requirements contained in the BHR System's FDA approval (as well as other applicable federal requirements). Specifically, the patient alleged a list of many violations of federal regulations. His strict products liability claim similarly relied on S&N's purported violation of federal regulations by deviating from the manufacture specifications approved by the FDA in its PMA Approval Letter. As such, the patient concluded that the hip implant system was defective and unreasonably dangerous when it left S&N's possession.

Eleventh Circuit case and pleading requirements. In order to withstand the express preemption provision, case law for the U.S. Court of Appeals for the Eleventh Circuit required that the patient plead that S&N breached federal requirements applicable to BHR and that the breach was parallel to a claim under Florida state law (*Wolicki–Gables v. Arrow International, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011)).

Negligence. The court held that the patient's negligence claim was preempted by federal law. The first requirement of the two-pronged inquiry to determine whether a state-law claim is expressly preempted was met because requirements specifically applicable to the device were imposed by the FDA's PMA. Thus, only the patient's claims which properly pleaded parallel claims survived express preemption. The court noted that suits by private litigants for noncompliance with medical device provisions are impliedly preempted by the FDCA, and that *Riegel* and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), created only a narrow gap through which a plaintiff's state-law claim must fit in order to survive express or implied preemption. For a proper parallel claim, the complaint had to allege facts "pointing to specific PMA requirements that have been violated."

The patient's negligence claim was predicated upon S&N's purported violations of a number of federal regulations, and he had increased the specificity of his allegations in his second amended complaint, setting forth the specific PMA requirements violated and how they were violated. However, he failed to meet the second prong of the preemption test requiring that his common-law claims be based on state law requirements. His negligence claim sought enforcement of the PMA requirements against S&N. This was not an assertion of a state-law claim, particularly because Florida did not permit a private action to enforce violations of FDA requirements. The court stated that the patient could not "recast" his claim for violation of the FDCA as a state-law negligence claim merely by pleading it as such. Although his allegations noted with specificity the provisions violated and how they were violated, the patient's claims alleged that the device maker violated the FDCA and its implementing regulations through various failures. His preface that the allegations were "parallel to and not different from or in addition to the requirements of federal law" did not negate the fact that the allegations were an attempt to circumvent preemption.

Strict products liability. Similar to his negligence claim, the patient's strict liability claim also was predicated on a violation of federal regulations, including 21 C.F.R. § 814.80. His theory was that S&N manufactured the BHR System differently from the manufacturing specifications in the PMA. Thus, his strict liability claim based on a manufacturing defect was impliedly preempted for the same reasons as his negligence claim. The patient's claim for products liability alleged that S&N failed to comply with the requirements of the PMA—specifically, the regulation providing that "[a] device may not be *manufactured*, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." Because the FDC Act impliedly preempts suits by private litigants for not complying with the medical device provisions, the patient could not maintain a cause of action in which the exclusive foundation for the action was noncompliance with the medical device provisions.

The case is No. 15-CIV-61210-BLOOM/VALLE.

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