Products Liability Law Daily Wrap Up, PREEMPTION—MEDICAL DEVICES—E.D. Pa.: Preemption, poor pleading prevent hip implant claims from sticking, (Apr. 6, 2015)

Products Liability Law Daily Wrap Up

Click to open document in a browser

By Susan Lasser, J.D

In an action for damages stemming from injuries sustained by a patient after undergoing hip replacement surgery with artificial hip components designed and manufactured by Smith & Nephew, Inc. (S&N), the patient's claims against the manufacturer were either preempted by the Federal Food Drug and Cosmetic Act (FDC Act), as amended by the Medical Device Amendments of 1976 (MDA), or inadequately pleaded, a federal district court in Pennsylvania held. The court granted the manufacturer's motion for summary judgment and/or dismissal, dismissing the patient's complaint in its entirety, but allowing leave to amend insofar as he wanted to pursue parallel claims based on the manufacturer's off-label promotion of the hip component products (*Shuker v. Smith & Nephew, Inc.*, March 31, 2015. Sanchez, J.).

Background. On April 29, 2009, Walter Shuker (Shuker or patient) underwent right total hip replacement surgery in which his surgeon, Dr. Kevin Terefenko, implanted components manufactured by Smith & Nephew, Inc.: (1) a modular femoral head made of cobalt-chrome, (2) a modular head sleeve made of cobalt-chrome, (3) a femoral stem component, (4) an R3 no-hole hemispherical acetabular shell, and (5) an R3 acetabular liner made of cobalt-chrome, *i.e.*, an R3 metal liner. The first four components were cleared by the Food and Drug Administration (FDA) under the agency's §510(k) review process (a limited review of a new device allowing it to be marketed without further regulatory analysis if "substantially equivalent" to a preexisting device). However, the R3 metal liner component did not receive §510(k) clearance as part of the R3 System. Instead, the metal liner was part of the R3 metal on metal cup which received premarket approval (PMA) (approval is granted only if the FDA is reasonably assured of the device's 'safety and effectiveness') as part of another system manufactured by S&N, the Birmingham Hip Resurfacing (BHR) System. The FDA did not approve the R3 metal liner for use with the R3 System in a total hip replacement procedure. Therefore, Dr. Terefenko's use of the metal liner component in Shuker's surgery was an "off-label" use—meaning that it was used for a purpose other than its FDA-approved use.

About 21 months after his surgery, the patient began to develop increased pain and discomfort. He subsequently underwent an aspiration procedure. From the results, his doctor determined that his pain was caused by metal sensitivity due to the degeneration of the metal-on-metal articulation of his artificial hip and that replacement of the metal-on-metal device was necessary to relieve the pain. In that surgery, the existing metal-on-metal articulation was replaced with an Oxinium head and a polyethylene liner. Shuker still experienced extreme pain after the surgery. Another aspiration procedure revealed an infection at the surgery site. The patient underwent two further surgeries (December 2012 and January 2013) to remove and replace the R3 System.

Withdrawal of metal liner component. In June 2012, almost a year after Shuker's surgery to replace the metal-on-metal articulation, S&N decided to "withdraw" the optional metal liner component within the R3 Acetabular System as a "precautionary measure" based on certain data. The same month, the Medicines and Healthcare Products Regulatory Agency (MHRA), the United Kingdom's equivalent of the FDA, advised surgeons to stop using the R3 metal liner because of the higher revision rates associated with it than with nonmetal liners. At the time of the withdrawal, a majority of the R3 metal liners in use globally had been used in hip replacement, rather than resurfacing, procedures.

Products liability action. In 2013, Shuker, and his wife, Vivian, brought a products liability action against S&N, asserting claims for negligence/negligence per se, negligence based on violations of various FDA regulations,

strict products liability, breach of express warranty, breach of implied warranties of merchantability, fraud, and loss of consortium. S&N moved to dismiss the complaint, arguing the Shukers' claims were expressly preempted by the MDA's preemption provision (21 U.S.C. §360k) and were inadequately pleaded in that they asserted a non-preempted negligence claim premised on violations of FDA regulations. S&N's preemption argument was based on the R3 metal liner at issue having received premarket approval. Because S&N's supporting documents, standing alone, were insufficient to establish the regulatory status of the metal liner used in Shuker's surgery, further discovery was allowed, the preemption argument renewed on summary judgment, and the Shukers were permitted to amend their claims. The court based its rulings on their second amended complaint.

Preemption argument. S&N argued that most of the patient's claims were preempted by the MDA's express preemption provision. In *Riegel v. Medtronic, Inc.* (552 U.S. 312 (2008)), the U.S. Supreme Court established a two-step analysis for determining whether state tort claims relating to a medical device are preempted under §360k(a). A court must first determine "whether the Federal Government has established requirements applicable to [the device]." If it has, the court must then determine whether the plaintiff's state-law claims "are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." The court explained that as to the first step in the preemption analysis, the Supreme Court held that premarket approval imposed "requirements" under the MDA, but that Section 510(k) clearance did not—the distinction being that §510(k) approval is "focused on *equivalence*, not safety." Premarket approval is device-specific; and once granted, the FDA requires the device "to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." Section 360k(a) thus protects a manufacturer of a PMA-approved medical device from civil liability "to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law."

The court said that it was undisputed, following discovery, that the R3 metal liner used in Shuker's surgery received premarket approval as part of the BHR System, while the rest of the components were cleared pursuant to the §510(k) process. Moreover, the FDA never approved the particular combination of components implanted in Shuker for use together as a single device. The court found that insofar as the Shukers' claims challenged the safety and effectiveness of the R3 metal liner, the claims were preempted under §360k(a). Upon the FDA's approval of S&N's PMA application for the multi-component BHR System and PMA supplement for the R3 metal on metal cup, S&N was required to produce and market the device, including all of its constituent components, in accordance with the specifications approved by the FDA. Therefore, under *Riegel*, the FDA's approval of the PMA supplement for the R3 metal on metal cup imposed federal requirements on the cup—and on the R3 metal liner, a component of the cup—for purposes of §360k(a).

The patient argued that the fact that the R3 metal liner received premarket approval for use with the BHR System was irrelevant because Dr. Terefenko used it as part of a different hip system, which was not PMA-approved. The patient contended that the court had to look at the hip system implanted in him as a whole in applying the preemption analysis. The court found, however, that because the R3 System that the FDA cleared via the §510(k) process did not include the R3 metal liner, there was no basis to characterize the hip system implanted in Shuker as §510(k)-cleared. According to the court, by granting premarket approval, the FDA requires the manufacturer of an approved device to place the device on the market in the agency-approved form—and accompanied by the agency-approved warnings and indications for use—but does not prevent physicians from using the device in a different manner. The court, citing *Riegel*, though, noted that a physician's decision to use a PMA-approved device off-label does not change the manufacturer's obligation to produce and market the device "with almost no deviations from the specifications in its approval application." Thus, the court found that "the mere fact a device is used off-label does not render §360k(a) inapplicable."

Requirements "different from, or in addition to" federal requirements. After determining that the FDA's approval of the PMA supplement for the R3 metal on metal cup imposed federal requirements on the R3 metal liner for purposes of §360k(a), the court then determined that the patient's state-law claims imposed

requirements "with respect to" the liner that were "different from, or in addition to" the federal requirements. The court found the patient's claims in the second amended complaint to be "broad-ranging and extremely general," and held that all of the claims unquestionably related to the safety of the R3 System and the R3 metal liner when used together. Thus, as the claims were directed to the PMA-approved liner, they were expressly preempted by § 360k(a), the court ruled. Although the Shukers' claims also purported to challenge the safety of the §510(k)-cleared R3 System, the body of their second amended complaint indicated that the liner was central to each of their claims. The complaint identified the metal-on-metal articulation of the R3 metal liner and the femoral head components of the R3 System as the source of Shuker's injuries, and alleged that this articulation was "prone to wearing down and releasing metal debris into the body of the user[,] causing adverse health effects." Also alleged was that Shuker's physician determined that the patient's pain "was caused by metal sensitivity due to the degeneration of the metal on metal articulation"; and that the metal liner was the source of the problem.

Because the undisputed facts showed that the Shukers' negligence, strict liability, and breach of implied warranty claims were preempted, the court entered judgment for S&N as to those claims. This also included their claim as to the adequacy of warnings accompanying the R3 System. The court determined that a warning against using the R3 metal liner with the R3 System in a hip replacement procedure was undoubtedly a warning that "relates to the safety or effectiveness" of the liner, regardless of whether the warning accompanied the liner or another component. Further, the court said that allowing the patient to pursue a claim that the components of the R3 System should have included such a warning would effectively impose a state-law requirement "with respect to" the liner that was "different from, or in addition to," the warnings the FDA required. Therefore, for preemption purposes, this claim was no different than a claim challenging the warnings accompanying the liner itself.

Express preemption, fraud, and other claims. The court held that because the Shukers failed to plead facts supporting a plausible inference that an express warranty was created, their claim for breach of express warranty would be dismissed with prejudice. As to the Shukers' remaining claims—their claim for negligence based on violations of FDA regulations and FDCA provisions and their fraud claim—the court said that these were premised on S&N's alleged violations of federal law, and that the statute did not prevent a state from "providing a damages remedy for claims premised on a violation of FDA regulations," as "the state duties in such a case 'parallel,' rather than add to, federal requirements." The claim must be grounded in a violation of state-law duty, the court said, finding that this was the case with their negligence claim in which the Shukers alleged that the manufacturer was negligent in breaching its duty to comply with the FDC Act and its associated regulations.

Promotion of the R3 metal liner for use off-label with the R3 System. The court found that the Shukers failed to plead facts supporting a plausible inference that S&N engaged in off-label promotion of the R3 metal liner that influenced the selection of the liner for use in the patient's surgery. Although it was alleged that the manufacturer promoted and advertised the liner as "optional" for use with the R3 System, the only instance of that promotion was a February 2009 press release in which S&N announced the introduction of "an optional 'metal liner' for the R3 Acetabular System." The court said it was not clear whether the press release amounts to off-label promotion. Even if it were the case, the court found that the complaint did not allege facts to suggest that the patient's doctor or the patient were aware of the press release or that its representations led the doctor to use the metal liner in the patient's surgery. Therefore, the court dismissed the patient's fraud claim, as well as his negligence claim, insofar as it was based on off-label promotion. The court gave the patient leave to amend these claims, however.

Failure to report adverse events. The Shukers sought to pursue a parallel claim based on the manufacturer's failure to report adverse events associated with use of the R3 metal liner in hip replacement procedures to the FDA, in violation of 21 U.S.C. §360i, 21 C.F.R. §803.50, and other FDA regulations.

The court agreed with the manufacturer, however, that they failed to plead sufficient facts to render the claim plausible. Even if they did not need to "specify" the particular adverse events that the manufacturer allegedly failed to report, the court said that there had to be "some factual basis from which it can plausibly be inferred that such events occurred" and that the manufacturer failed to report them during the applicable six-month window. Thus, the court dismissed with prejudice the Shukers' parallel claim based on S&N's failure to report adverse events to the FDA.

The case is No. 13-6158.

Attorneys: Eric G. Zajac (Zajac Arias & Trichon PC) for Walter Shuker. Charles E. Leasure, III (Pepper Hamilton LLP), David W. O'Quinn (Irwin Fritchie Urquhart & Moore LLC), and Michael T. Scott (Reed Smith LLP) for Smith & Nephew, Inc.

Companies: Smith & Nephew, Inc.

Cases: CourtDecisions DesignManufacturingNews WarningsNews PreemptionNews MedicalDevicesNews PennsylvaniaNews