Products Liability Law Daily Wrap Up, TOP STORY—SUPREME COURT—U.S.: High Court agrees to hear Fosamax® MDL preemption arguments, (Jun. 28, 2018)

Products Liability Law Daily Wrap Up

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By Susan Lasser, J.D.

Today, the U.S. Supreme Court granted review of a petition by the manufacturer of the drug Fosamax®, a bisphosphonate prescribed for the treatment of osteoporosis in postmenopausal women, asking that the Court consider a decision by the U.S. Court of Appeals for the Third Circuit which held that the drug maker failed to carry its burden of proving that failure-to-warn claims by Fosamax users who developed atypical femoral fractures were preempted as a matter of law in the multidistrict litigation that consolidated such claims. The appellate decision had reversed the federal district court in New Jersey presiding over the MDL after the trial court granted summary judgment on preemption grounds [see *Products Liability Law Daily*'s March 23, 2017 analysis] (*Merck Sharp & Dohme Corp. v. Albrecht*, petition for cert. filed August 22, 2017; cert. granted June 28, 2018).

The lower court's decision was based on the High Court's opinion in *Wyeth v. Levine*, 555 U.S. 555 (2009), which held that state-law failure-to-warn claims were preempted when there was "clear evidence" that the Food and Drug Administration (FDA) would not have approved the warning that a plaintiff claimed was necessary. The Third Circuit noted that the "*Wyeth* 'clear evidence' standard is demanding and fact-sensitive," requiring a factfinder "to predict a highly probable outcome in a counterfactual world." The appellate court found that the patients in the MDL provided sufficient evidence for a reasonable jury to conclude that the FDA would have approved a properly-worded warning about the risk of thigh fractures, or, at minimum, to conclude that the odds of FDA rejection were less than highly probable, which was enough under *Wyeth* for the patients to defeat summary judgment and proceed to trial.

The drug manufacturer, Merck Sharp & Dohme Corporation, however, argues that while the Supreme Court held in *Wyeth* that the FDA's approval of a drug label does not by itself insulate a manufacturer from failure-to-warn liability under state tort law, the Court also recognized that if "the FDA would not have approved" the label demanded by state law, then the manufacturer could invoke an "impossibility" preemption defense. In the current case, the drug maker maintains that it was "undisputed" that (1) "the FDA was aware of the possible link" between the manufacturer's drug and the risk at issue; (2) the manufacturer "submitted a comprehensive safety update to the FDA reporting … numerous studies" finding "such an association"; (3) the FDA rejected the drug maker's proposed warning language; (4) the FDA stated that the "conflicting nature of the literature d[id] not provide a clear path forward" and that it needed more time to consider "the issue of a precaution"; and (5) only later, after a report from a task force, did the FDA become "confident" that an association "potentially" existed. Nevertheless, the drug manufacturer asserts, the Third Circuit held that a jury could find that the manufacturer had not shown by clear and convincing evidence that the FDA would have rejected a warning label of the type that the patient claimed state law required.

With that in mind, the manufacturer presented the following question to the High Court: Is a state-law failure-to-warn claim preempted when the FDA rejected the drug manufacturer's proposal to warn about the risk (at issue) after being provided with the relevant scientific data; or must such a case go to a jury for conjecture as to *why* the FDA rejected the proposed warning? Merck contends that if a drug manufacturer "candidly brings a risk to the FDA's attention and proposes an on-point warning" about the risk, then the FDA's rejection should be sufficient as a matter of law to preempt claims alleging failure to warn of the risk. Demanding more "effectively eliminate[s] impossibility preemption in this context," according to the petitioner.

Merck had argued that its petition should be granted because the lower courts have made it impossible for brand-name drug manufacturers to establish preemption because states are permitted to impose liability for failure to warn only if the FDA would have allowed a label change warning of a particular risk. The Supreme Court, on the last day of the 2018 term, agreed and granted certiorari, noting that Justice Alito took no part in the consideration or decision of the petition.

The case is Docket No. 17-290.

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Companies: Merck Sharp & Dohme Corp.

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