Products Liability Law Daily Wrap Up, SUPREME COURT DOCKET—Recent petitions and cases pending High Court review, (May 30, 2019)

Products Liability Law Daily Wrap Up

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By Susan Lasser, J.D.

New developments in products liability-related cases before the Supreme Court, with a chart following the progress of cases and petitions before the Court in its current term.

The U.S. Supreme Court has denied a petition by the widow of a man who killed himself while taking the generic version of the prescription anti-depressant Paxil®. She had asked for High Court review of a decision by a panel for the U.S. Court of Appeals for the Seventh Circuit vacating a $3-million jury award in her favor. The Seventh Circuit concluded that the state-law negligence claim on which the drug developer's liability had been based was federally preempted because the U.S. Food and Drug Administration (FDA) had rejected the company's repeated attempts to add a warning regarding the risk of suicide in adults taking the drug (*Dolin v. GlaxoSmithKline, LLC*, petition filed December 19, 2018; cert. denied May 28, 2019).

In support of her request for review, the widow cited *Wyeth v. Levine*, 555 U.S. 555 (2009), in which the Supreme Court had opined that although impossibility preemption was a demanding defense, the High Court could not conclude that it was impossible for a drug manufacturer to comply with both federal and state requirements, absent "clear evidence" that the FDA would not have approved a change to a drug's label. The Seventh Circuit found preemption even though an FDA expert had testified that the manufacturer was permitted to add its drug-specific suicide warning to the drug's label and the FDA had advised the manufacturer to submit its drug-specific warning using a procedure that allowed manufacturers to strengthen warnings [see *Products Liability Law Daily*'s August 23, 2018 analysis]. According to the widow, the Seventh Circuit failed to appreciate the heightened evidence required under *Wyeth*, and that in concluding that no reasonable jury could find that the FDA would have approved an adult-suicidality warning, the appellate court failed to review the evidence in a light most favorable to the widow.

However, the widow also argued that the Seventh Circuit's decision was in direct conflict with a similar decision by the U.S. Court of Appeals for the Third Circuit, *Merck Sharp & Dohme Corp. v. Albrecht*, in which the Third Circuit held that the patients who developed atypical femoral fractures, allegedly as a result of their use of the drug Fosamax® to treat osteoporosis, 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 of a label change were less than highly probable, which was enough under *Wyeth* for the patients to defeat the manufacturer's argument that the failure to warn claims were preempted as a matter of law. The widow noted the factual similarities between *Albrecht* and her case and suggested in her petition that the High Court's resolution of *Albrecht* likely would provide needed guidance to the courts below on how to assess a preemption defense in the context of the facts presented. She recommended that her petition be held by the court pending the disposition of *Albrecht* and that, predicting favorable resolution, upon the Court's ruling in *Albrecht*, the Court could then vacate the Seventh Circuit decision and remand for further proceedings.

Unfortunately for the widow, the Supreme Court vacated and remanded the Third Circuit's decision [see *Products Liability Law Daily*'s May 20, 2019 analysis], holding that "'[c]lear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." Also, the High Court held that preemption is a question of law for a judge to decide, rather than a jury, because "[t]he question often involves the use of legal skills to determine whether

agency disapproval fits facts that are not in dispute." The Court said that "judges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency's determination," and can better understand and "interpret agency decisions in light of the governing statutory and regulatory context." Consequently, having ruled unanimously that the Third Circuit's decision should be vacated, the Supreme Court denied the widow's petition to vacate the Seventh Circuit's holding.

For details about petitions and cases pending before the U.S. Supreme Court, please consult this list of selected products liability cases awaiting decision during the 2018 term. The list has been updated to reflect recent filings of party and amicus briefs. Granted and pending petitions are listed separately, along with a brief summary of the questions raised and status.

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