Wyeth v. Levine: U.S. Supreme Court Finds That State-Law Failure-to-Warn Claims Are Not Federally Preempted

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On March 4, 2009, the U.S. Supreme Court handed down its much-anticipated decision in*Wyeth v. Levine* and held that plaintiff Diana Levine's state-law-based failure-to-warn claims are not preempted. In response to the question of whether the U.S. Food and Drug Administration's ("FDA") judgments in the field of drug labeling "preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use," the Supreme Court concluded that the FDA's approval of the label for Wyeth's drug, Phenergan, did not afford a complete defense to Levine's claims.

Levine filed suit against Wyeth seeking damages for her pain and suffering and lost income resulting from the amputation of her forearm and her inability to continue her career as a professional musician. Levine's injuries developed from the administration of Wyeth's Phenergan via the IV-push method, rather than the IV-drip method. Although Phenergan's label warned that gangrene and amputation could result from an inadvertent intra-arterial injection of the drug, Levine successfully argued to a Vermont state court jury that Wyeth's failure to include an explicit warning against the administration of Phenergan by the IV-push method, as opposed to the IV-drip method, rendered the drug unsafe. The jury awarded Levine $7.4 million and found that Phenergan's labeling was defective insofar as it did not contain an adequate warning involving the IV-push method of the drug's administration.

Wyeth argued to the Supreme Court that it would have been impossible to comply with both a state-law imposed duty to change Phenergan's labeling and the warnings specifically approved by the FDA. According to Wyeth, the conflict between state-law labeling requirements imposed by a jury and federal law requirements imposed by the FDA's regulations under which the label was approved, required the dismissal of Levine's claims. In addition, Wyeth argued that the trial court's verdict was an obstacle to achieving the full purpose and objective of Congress. Thus, Wyeth asserted that Levine's state law claims should be dismissed on the basis of both conflict and obstacle preemption.

As a foundation to the Supreme Court's opinion, the majority gave credence to "two cornerstones" of preemption jurisprudence. First, the majority emphasized that "'the purpose of Congress is the ultimate touchstone in every pre-emption case.'" After reviewing the legislative history of the federal regulation of pharmaceuticals, the Court concluded that there is not and has never been any congressional intent to preempt state law in this area. In support of its conclusion, the Court noted that despite ample opportunities to do so, Congress has not enacted an express preemption provision in the context of prescription drugs, in contrast to the regulation of medical devices. In addition, the Court relied upon the presumption against preemption in instances in which Congress has legislated in a field that states have traditionally occupied, here, the health and safety of their citizens.

In rejecting Wyeth's contention that state-law-based claims are federally preempted on the basis of conflict preemption, the Court found that the FDA's "changes being effected" ("CBE") regulations provided Wyeth with the ability to comply with both federal and state laws. To that end, the majority held that through the CBE process Wyeth could have unilaterally strengthened Phenergan's warnings with reference to the IV-push administration method, subject to subsequent FDA approval, and that Phenergan would not have been misbranded if Wyeth had done so. The Court also emphasized that drug manufacturers have the primary responsibility for drug labeling, as opposed to the FDA, and that drug manufacturers maintain a duty to ensure drug warnings are adequate as long as the drug is on the market. The Court, however, noted that the ultimate authority remains with the FDA to reject any labeling changes made by a drug manufacturer under the CBE regulations. Vital to the Court's decision was its recognition that there was a lack of evidence that the FDA would not have approved strengthened warnings regarding the IV-push method had Wyeth proposed them.

The Court also rejected Wyeth's argument that Levine's claims should be dismissed under the theory of obstacle preemption. Wyeth maintained that the purposes and objectives of federal drug-labeling regulations would be obstructed if it had to comply with a state court jury's imposition of additional warnings beyond those imposed by the FDA. Turning aside this contention, the Court reiterated that Congress has not enacted an express preemption provision during the many decades in which the federal government has regulated the approval and use of prescription drugs. In so holding, the Court said that Congress "did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."

Although Wyeth relied on a 2006 preamble to an FDA labeling regulation as evidencing the agency's policy in favor of the preemption of state court lawsuits challenging FDA-approved drug labels, the Supreme Court did not ascribe any weight or deference to the FDA's 2006 preamble. The failure to provide states or interested parties with any notice or an opportunity to comment on the FDA's preamble, the Court found, made such pronouncements devoid of the weight or deference that Wyeth sought to ascribe to this expression of FDA intent. Moreover, the majority stressed that the FDA's 2006 preamble contradicted the FDA's long-standing position that state law was not preempted in this area, a position that it had held at the time of Levine's injury.

While each of Wyeth's preemption arguments was rejected in this decision, the Court has not completely foreclosed future preemption challenges to state-law-based failure-to-warn claims. Preemption claims remain viable in cases in which a factual record evidences the FDA's *actual* rejection of a proposed labeling change that a state court jury is asked to find necessary for a drug's labeling to be sufficient. A federal preemption defense may also be viable in situations in which the FDA rejects a labeling amendment made by a drug manufacturer pursuant to the CBE process.

Additionally, plaintiffs' state-law-based claims against generic drug manufacturers continue to be at risk for dismissal on the grounds of federal preemption. In regulations proposed in January 2008 and approved in August 2008, after a notice and comment period, the FDA stated that generic drug manufacturers may not utilize the CBE regulations to effect changes to a generic drug's labeling, which must remain identical to the brand drug's labeling. Thus, an implied preemption defense may continue to be available to generic drug makers even after *Wyeth v. Levine*.

For Further Information

If you have questions about this Alert or would like more information, please contactAlan Klein, Sharon L. Caffrey, Karen Shichman Crawford, any other member of theProducts Liability and Toxic Torts Practice Group or the attorney in the firm with whom you are regularly in contact.