Ohio Judge Rules Preemption May Still Be Valid Defense, Even After U.S. Supreme Court's *Levine* Decision

The U.S. Supreme Court held that federal law does not preempt certain state law "failure to warn" lawsuits against drug manufacturers.

In a recent United States Supreme Court case, *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172 (March 4, 2009), the Court held that federal law does not preempt certain state law "failure to warn" lawsuits against drug manufacturers.

Levine originated in Vermont state court, after Diana Levine, a professional musician, received a dose of the prescription drug Phenergan as treatment for migraine-induced nausea. Ms. Levine received Phenergan through an "intravenous-push," which injects the medication directly into the bloodstream. Ms. Levine subsequently contracted gangrene from the drug's administration, which required amputation of her hand and forearm. Wyeth, the drug's manufacturer, included a warning on the Phenergan label cautioning that if Phenergan was injected directly into an artery, gangrene was likely to occur, but failed to include a specific warning discouraging administration through the intravenous-push method. Ms. Levine brought a suit in Vermont state court alleging that Wyeth failed to provide adequate warnings against the risks associated with the intravenous-push administration of the drug. A jury found for Ms. Levine and the Vermont Supreme Court affirmed.

The United States Supreme Court granted *certiorari* and addressed the question, "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." In a 6-3 decision, the Supreme Court rejected two preemption arguments: (1) it would have been impossible to comply with a state law duty to modify the warning label without violating federal law, and (2) recognizing such a state-tort action creates an obstacle to Congress' ability to accomplish its objectives.

In addressing the first argument, the Supreme Court held that Wyeth could comply with both state and federal law by modifying the drug's warning label. The Court explained that while the FDA requires approval of drug labels, and a manufacturer must obtain further approval to change the label, the FDA provides an exception to its approval rule when the change adds or strengthens a drug label warning. Levine's state claim was not preempted because Wyeth could have added an additional warning about the risks associated with intravenous administration

without FDA pre-approval. Wyeth could have complied with both state and federal law if it made the label changes.

The Supreme Court similarly dismissed the second preemption argument, that a state failure to warn claim creates an obstacle to Congress' ability to accomplish its objectives. Wyeth relied on the language of a preamble to a 2006 FDA regulation, in which the FDA declared that its labeling requirements preempted conflicting or contrary state law. The Supreme Court held that the preamble did not merit deference as this particular preamble was the only expression of preemption in the entire history of Federal Drug and Cosmetic Act. The Court held that Congress has not authorized the FDA to preempt state law, and accordingly, the failure to warn claims did not frustrate the federal drug labeling regulations.

Shortly after the ruling in *Levine*, the United States District Court for the Northern District of Ohio examined the ruling in its opinion in *Longs v. Wyeth*, No. 1:03 CV 2042, 2009 WL 754524 (N.D. Ohio March 20, 2009). The plaintiff in *Longs* alleged that fen-phen, the diet drug at issue, was so dangerous that there was no adequate warning that could make it safe enough for state tort law. The District Court initially dismissed the suit, holding that all claims relating to pre-FDA approval are preempted by the FDA and, in addition, to the extent that a plaintiff alleges defendants concealed or misrepresented information to the FDA, these claims are preempted as well.

On reconsideration, the Court upheld its original decision, reasoning that *Levine* applies only to *post*-FDA approval claims. The Court held that *Levine's* ruling does not apply to the pre-FDA approval claims raised in *Longs*. According to the Court, though *Levine* may stand for the proposition that post-FDA approval claims are not preempted, pre-FDA approval state claims will most likely be preempted by federal law.

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