

U.S. Supreme Court Ruling in *Wyeth v. Levine* Rejects Preemption of Failure-to-Warn Claim

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In a highly anticipated decision, the U.S. Supreme Court has rejected a pharmaceutical manufacturer's argument that federal approval preempts state law failure-to-warn claims relating to FDA-approved prescription drugs.

By a vote of 6-3, on March 4, 2009 the Court affirmed the Vermont Supreme Court's decision that the plaintiff could pursue claims that Wyeth failed to provide adequate warnings, even though the FDA deemed those same warnings sufficient when the FDA approved the drug and its labeling. The decision marks a notable contrast with the Court's holding last year in *Riegel v. Medtronic, Inc.*, in which the Court held that federal law expressly preempts state tort claims that challenge the labeling, design, or manufacturing processes of a medical device that received premarket approval by the FDA.

In *Levine*, the plaintiff was injured by an intravenous injection of Phenergan, an antinausea drug, despite the fact that the FDA-approved label expressly disclosed the risks of this mode of administration. Justice Stevens (joined by Justices Ginsburg, Kennedy, and Souter, with Justices Breyer and Thomas filing separate concurrences) held that (1) the FDA's labeling judgments did not make it "impossible" to comply with the state jury's finding that the FDA-approved Phenergan warnings were inadequate, and (2) the federal drug regulation scheme was not "obstructed" in its purposes by that state law finding. Justice Alito (joined by Justices Roberts and Scalia) dissented.

First, the Court held that the FDA's "changes being effected" (CBE) regulation would have allowed the manufacturer—upon submission, but before approval, of a supplemental application to the FDA—to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." Rejecting other arguments based on the regulatory scheme, the Court noted that "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept."

Second, the Court held that Congress did not intend that FDA labeling judgments would provide both a "ceiling" and "floor," and contemplated that state law remedies would remain available. In support of this, the Court cited (1) Congress's failure to provide a federal remedy for consumers, which suggested that "it determined that widely available state rights of action provided appropriate relief"; (2) Congress's failure to enact an express preemption provision for drugs, as it had for medical

devices; and (3) Congress’s silence in the face of “the prevalence of state tort litigation.” The majority also reaffirmed a “presumption against preemption” in cases involving implied preemption.

The Court concluded that FDA oversight is not the exclusive means of ensuring drug safety and effectiveness; rather, state law tort claims serve as a complementary form of drug regulation: “The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. . . . Failure-to-warn actions, in particular, lend force to the FDCA’s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.”

The Court refused to defer to what it characterized as the FDA’s “newfound opinion,” expressed in the preamble to a 2006 FDA regulation, that FDA approval of a drug’s labeling preempts state law. Specifically, the Court stated that the “preamble is at odds with what evidence we have of Congress’ purposes, and it reverses the FDA’s own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA’s regulation of drug labeling during decades of coexistence.”

Although it remains to be seen how lower courts will apply *Levine*, the decision appears to suggest that a preemption defense may be available where the agency considered and rejected the specific label change advocated by the plaintiff. This approach highlights the critical role that in-house counsel can play in laying the groundwork for a preemption defense. Preemption considerations should play a part in decisions about the information to be submitted to the relevant federal agency; the proposal, implementation, and timing of revised labeling, instructions, and warnings; and the preservation of a clear record of accepted and rejected changes (both pre- and postmarket).

Both in the prescription drug context and beyond, a number of strategic steps may aid the preservation and assertion of a successful preemption defense. For example, many preemption-related issues remain undecided—and different courts may take different approaches to the issue. For this reason, it is important to be wary of forum-shopping by plaintiffs, and to consider filing an early forum or transfer motion. Also, even if preemption is not available in a particular case, state regulatory compliance statutes may provide an effective means to avoid or reduce potential liability.

The implications of the Court’s decision for compliance by manufacturers regarding variability in state labeling requirements, postmarketing surveillance of drug safety issues, and addressing labeling revisions proactively will be analyzed in an upcoming Morgan Lewis LawFlash.

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