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# Supreme Court Rules on *Wyeth*: State Law Claims Not Preempted

March 2009
by James W. Huston, Stacy Kaplan

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On March 4, 2009, the U.S. Supreme Court issued its eagerly awaited decision in *Wyeth v. Levine*, U.S. Supreme Court No. 06-1249, 555 U.S. ____ (2009). In a 6-3 decision delivered by Justice Stevens, the Court held that federal law does not preempt Levine's state law failure-to-warn claim concerning the adequacy of a prescription drug label. The Court also stated that a company may unilaterally add a stronger warning to a product label pursuant to the FDA's "changes being effected" ("CBE") regulation, and emphasized that a company—and *not* the FDA—bears primary responsibility for drug labeling.

**Background**

In February 2008, the U.S. Supreme Court issued a decision in *Riegel v. Medtronic*, 552 U.S. __ (2008), ruling 8-1 that the preemption clause of the Medical Device Amendments of 1976 ("MDA") bars state common law claims challenging the safety or efficacy of a medical device that received premarket approval from the FDA. *Riegel* was a clear victory for medical device manufacturers. Unlike the MDA, the drug provisions of the Food, Drug, and Cosmetic Act ("FDCA") do not contain an express preemption provision. However, in a 2006 preamble to its final rule on prescription drug labeling, the FDA declared its intent that its regulations preempt contrary or conflicting state law regarding prescription drug labeling.

**The Underlying Facts and the Decisions Below**

Plaintiff Diana Levine, a professional musician, filed the case against Wyeth in Vermont's Washington County Superior Court in 2000, after receiving an improper IV push injection of the company's anti-nausea medication Phenergan to treat a migraine headache. As a consequence of the IV push injection, she developed gangrene and had her right arm amputated. Levine claimed that the warning label on the drug—which carries the risk of gangrene when injected into arteries—was inadequate because it did not explicitly prohibit the use of an IV push injection to deliver the drug, although it did warn against that method of delivery. Wyeth argued that the FDCA, and the FDA's implementation of that Act in approving Phenergan and its labeling, impliedly preempted any state law claims over the product.

The jury in the trial court awarded a $7 million verdict in favor of Levine, and the court issued an opinion addressing preemption as a matter of law, and concluding that the jury's verdict under state law in no way interfered with the regulatory objectives of the FDA. Wyeth appealed to the Vermont Supreme Court, arguing that "(1) Wyeth would have been unable to comply with both Vermont's common law duty to foreclose IV push injection and FDA's directive, as evidenced by the drug's approved label, to retain it; and (2) the claims would obstruct the full accomplishment of FDA's risk-benefit objective to optimize use of Phenergan by imposition of a duty to foreclose IV push injection."

In October 2006, the Vermont Supreme Court upheld the jury's $7 million award to Levine, and ordered Wyeth to modify the Phenergan label. Wyeth appealed to the U.S. Supreme Court.

**The Supreme Court's Decision**

The question posed to the Supreme Court was: "Whether the prescription drug labeling judgments imposed on manufacturers by the [FDA] pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use."

The Court rejected Wyeth's argument that Levine's state law claims are preempted because it is impossible for Wyeth to comply with both the state law duties underlying those claims and federal labeling requirements. Specifically, the Court found that Wyeth unilaterally could have added a stronger warning about IV push injection to the Phenergan label pursuant to the FDA's CBE regulation. The Court emphasized that the ultimate responsibility for drug labeling belongs to the company and *not* the FDA.

Wyeth's argument that compliance with a state law duty to add a stronger warning to a label would interfere with Congress's intent to entrust the FDA with drug labeling decisions was dismissed as meritless. The Court explained that the history of the FDCA shows that Congress did not intend to preempt state law failure-to-warn claims, and stated that the FDA's 2006 preamble to its final rule on drug labeling does not merit deference.

**Significance of the Decision**

The *Levine* decision will have a significant impact on the pharmaceutical industry. Pharmaceutical companies in compliance with federal labeling requirements may still be held liable for failure to warn under state law. Accordingly, companies are likely to see an increase in products liability litigation in state court. Increased litigation may have a dampening effect on product research and development. Furthermore, in an attempt to minimize potential exposure in these litigations, companies likely will add more warnings to labels. Companies may also take steps to oversee physician compliance with labeling instructions. Finally, companies are likely to file more labeling change requests with the FDA, and as the FDA contends with this increase in filings, it may take longer for new drugs to reach the market.

For more information on this topic or to discuss a specific product liability matter, please contact Jim Huston or Erin Bosman in our San Diego office, or Grant Esposito in our New York office. For general information about our product liability experience in the pharmaceutical and medical device industries, please click here.