Litigation Alert: The Supreme Court Upholds a Jury Verdict against Wyeth Based on a Failure-to-Warn Theory

4/3/2009

Overview

On March 4, 2009, the Supreme Court held that the Food, Drug and Cosmetic Act[1] (FDCA) and the federal drug labeling regulation[2] do not preempt a drug manufacturer's potential liability under Vermont's state tort law. *Wyeth v. Levine,* 555 U.S. ___, 129 S. Ct. 1187 (2009). *Wyeth* will affect how pharmaceutical manufacturers label their products and interact with the Food and Drug Administration (FDA).

Levine's State "Failure-to-Warn" Claim

In *Wyeth,* a physician assistant injected the plaintiff, Ms. Levine, with Phenergan, an anti-nausea medication manufactured by Wyeth. Due to the injection, Ms. Levine developed a gangrenous arm, which ultimately required amputation.

Phenergan is a highly corrosive medication. Before Ms. Levine suffered her injury, Wyeth knew that if Phenergan mixed with a patient's arterial blood, it could cause gangrene. The method used by a clinician to provide a patient with Phenergan matters. The chance that Phenergan would mix with arterial blood significantly increases when a clinician provides this medication through an IV push. If, instead, a clinician provides this medicine through an IV drip, or some other non-invasive application, the likelihood that Phenergan will mix with arterial blood significantly decreases. But, crucially, although the FDA approved Wyeth's label for Phenergan, the FDA-approved label did not specify that an increased risk of gangrene results from administering this medicine through an IV push.

After settling cases against the medical clinic and the pertinent practitioner(s), Ms. Levine sued Wyeth in Vermont state court. She alleged, among other claims, that Wyeth failed to warn her adequately about an increased risk of gangrene when Phenergan is administered through an IV push.

Wyeth's Defenses and a Trial Court Verdict

Wyeth argued, among other defenses, that Ms. Levine could not sue it under Vermont state tort law. Based on the preamble to a 2006 FDA regulation, Wyeth posited that the FDCA and implemented FDA regulations create "both a floor and a ceiling" to potential liability,

preempting any possible recovery under a state failure-to-warn theory. The FDA approved Wyeth's label for Phenergan, including the warnings concerning the risks associated with the IV-push method of administration. Therefore, Wyeth argued, it could not be liable to Ms. Levine under state tort law.

The trial court disagreed. Ultimately, a jury awarded Ms. Levine $7.4 million in damages. The Vermont Supreme Court upheld this verdict with a decision that rejected Wyeth's preemption argument. The Supreme Court granted *certiorari* to consider whether FDA labeling decisions preempt state law failure-to-warn claims.

The Supreme Court's Narrowing of the Preemption Doctrine

The Supreme Court also rejected Wyeth's preemption defense. It reasoned that Wyeth could have strengthened its label warnings immediately after learning that the IV-push method of providing Phenergan increases a patient's risk of developing gangrene. Wyeth could have changed its labels immediately without seeking FDA approval through the changes being effected regulation.[3] There was no evidence in *Wyeth* that the FDA would have rejected any such modification to its label for Phenergan. Ultimately, according to the Court, Wyeth had a duty to communicate the risks associated with its product.

The Court also rejected Wyeth's contention that permitting state-based liability would impede Congress' objectives in passing the federal drug laws and in vesting implementation authority with the FDA. The Court concluded that Congress did not intend FDA oversight to be the "floor *and* ceiling" of drug safety regulation. The Court also opined that Congress and the FDA regard state law as a complementary form of drug regulation.

Implications and Next Steps due to the *Wyeth* Decision

Wyeth does not technically create any new liability risk. But, it substantially narrows the situations in which preemption would preclude liability on a state law failure-to-warn claim.

A pharmaceutical manufacturer can still raise the preemption doctrine as a defense to a state tort claim if it can establish that the FDA considered and expressly rejected a particular warning or if the FDA mandated the particular label language at issue in the tort suit. Therefore, given the reasoning in *Wyeth,* pharmaceutical manufacturers must document all discussions with the FDA concerning labeling. In addition, because of *Wyeth's* emphasis on a drug manufacturer's control of its label and its duty to update that label based on new information, drug manufacturers should document the rationale for a decision not to change a label. Finally, manufacturers' regulatory personnel must be particularly careful to document disagreements with the FDA about labeling language, especially where the manufacturer and the FDA have competing positions about specific label language.

Endnotes

[1] 21 U.S.C. § 301 *et seq*.

[2] 21 CFR § 314.105(b)

[3] 21 CFR §§ 314.70(c)(6)(iii)(A),(C)

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