Legal Opinion Letter

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 18 No. 20 September 5, 2008

# HIGH COURT SHOULD UPHOLD PREEMPTION IN *WYETH v. LEVINE*

by
Robert A. Bourque

This fall, the U.S. Supreme Court will hear the case of *Wyeth v. Levine*, No. 06-1249, and will decide the critical issue of whether the Food and Drug Administration's ("FDA") approval of a prescription drug label preempts state product liability or failure-to-warn claims relating to that label.[1] This decision will be of tremendous importance because without preemption, drug manufacturers are frequently placed in the precarious position of either using FDA-approved drug labels or facing the threat of lawsuits for failing to comply with state-law failure to warn requirements. This LEGAL OPINION LETTER discusses the issues in *Wyeth* and forecasts the Court's likely ruling.[2]

The plaintiff's suit in *Wyeth v. Levine* was based on state-law negligence and failure-to-warn product liability theories. Ms. Levine alleged that Wyeth, a drug manufacturer, improperly labeled its drug, Phenergan—notwithstanding FDA approval of the label. In 1967, Phenergan's label was modified to include a warning regarding administration of Phenergan after Wyeth received a report, which it shared with the FDA, of gangrene resulting from arterial exposure to the drug. Phenergan's label warned that intravenous administration created a potential hazard that gangrene could result from exposure of Phenergan to arterial blood. Significantly, Wyeth proposed alterations to Phenergan's label regarding administration of the drug and the FDA rejected both proposals. In fact, the FDA ordered Wyeth to "[r]etain the verbiage in the current label" and later directed that "the final printed labeling for the package insert must be identical to the draft package."

Phenergan was administered to Ms. Levine via an IV-push which resulted in an inadvertent injection of Phenergan into an artery. This caused severe arterial damage and, ultimately, gangrene requiring amputation of Ms. Levine's hand and forearm. Ms. Levine's suit sought a determination that—despite FDA approval of such use—Phenergan's label should have warned medical personnel *not to use* the IV-push method of injection because of the risk of arterial contact. A Vermont jury agreed, found Wyeth liable on grounds of negligence and product liability, and awarded Ms. Levine $6,774,000 in damages.

The Vermont Supreme Court affirmed the verdict and rejected Wyeth's position that Vermont's tort laws conflicted with, and were thus preempted by, the FDA's regulation of prescription drug labels. This conclusion will likely be reversed by the Supreme Court.

---

[1]The FDA has comprehensive safety authority under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* to ensure that drugs are safe and effective. 21 U.S.C. § 393(b).

[2]The *Wyeth* decision is important because the Court recently split in *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), which presented the question of whether preemption applied in cases where drug manufacturers committed fraud on the FDA in the drug approval process. Justice Roberts recused himself and the Court split 4-4, causing the U.S. Court of Appeals for the Second Circuit's decision that there was no preemption to be affirmed.

---

**Robert A. Bourque** is a Partner in the Litigation Department of Simpson Thacher & Bartlett LLP.

The basis for preemption is found in the United States Constitution's Supremacy Clause, which states "federal law is the supreme law of the land." U.S. CONST. ART. VI, CL.2. State law that conflicts with federal law has no effect under the Supremacy Clause. Preemption can be either expressly stated in a law or implied from the law's structure and purpose. Implied preemption applies if state law conflicts with federal law such that compliance with both state and federal law is impossible. At the time of Ms. Levine's suit, there was no clause in the FDCA that expressly preempted state law and Wyeth, therefore, argued that implied preemption barred her action.

Implied conflict preemption applies in *Wyeth* because it was simply impossible for Phenergan's label to comply with federal law—directing Wyeth to use the FDA-approved label—*and* Vermont state law—requiring the label to forbid an FDA-approved use of the drug. The Vermont Supreme Court avoided conflict preemption by inappropriately relying on a regulation that allows drug manufacturers to alter a drug's label without prior FDA approval. *See* 21 C.F.R. § 314.70(c) (allowing changes in labeling "to add or strengthen a contradiction, warning, precaution or adverse reaction . . . or . . . instruction about . . . administration that is intended to increase the safe usage of the drug.") ("Section 314.70(c)"). First, the Court concluded that the FDA merely provided a floor and not a ceiling for regulation and this left room for states to regulate drug labeling. Then, the Court concluded that Section 314.70(c) allowed manufacturers to strengthen a label without FDA approval and this obviated any conflict between federal labeling requirements and state failure-to-warn claims.

The U.S. Supreme Court will likely reverse the Vermont Supreme Court's decision, first because the Vermont Court's conclusion that there is not a conflict between federal and state law is wrong. Section 314.70(c) does not allow drug makers to unilaterally change a drug's label at any time. Instead, Section 314.70(c) permits manufacturers to respond to *newly discovered* risks that the FDA has not considered. Clearly, this is not the situation in *Wyeth* where the FDA knew of the connection between arterial exposure to Phenergan and gangrene in 1967. Moreover, the FDA specifically directed Wyeth to keep Phenergan's label as written, making it impossible for Wyeth to both follow the federal law and provide the information the Vermont jury believed was appropriate. Finally, even if manufacturers are permitted to add verbiage to labels under Section 314.70(c), the FDA must ultimately review and approve the modified language, which establishes there can be no unilateral change by manufacturers in their attempt to comply with state laws. *See* 21 C.F.R. § 314.70(c)(7). Regarding Phenergan, the FDA considered Wyeth's alternative language and rejected the change. Accordingly, Wyeth could not change its Phenergan label.

In addition, the Vermont Supreme Court failed to give the requisite deference to the FDA's position on preemption. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (an agency's interpretation is entitled to deference). Indeed, in every U.S. Supreme Court case on FDCA preemption, the Court has deferred to the FDA's judgment. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 525 (E.D. Pa. 2006). The FDA's position is that preemption applies in situations such as *Wyeth*. For example, the FDA inserted a preemption preamble in its 2006 regulation on drug labeling: "[The] FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law." 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. §§ 201, 314, 601). The FDA also filed an *amicus* brief in *Wyeth* in favor of preemption. Each of these acts support preemption and reversal.



ISBN 1056 3059