



Supreme Court Issues Decision on Preemption Issues in Wyeth v. Levine: State Tort Failure to Warn Claim Found Viable



Suzanne C. Midlige
Partner
Tel: 973-631-6006
SMidlige@CoughlinDuffy.com



William J. Hoffman
Associate
Tel: 973-631-6022
WHoffman@CoughlinDuffy.com



Michael E. Carrer
Associate
Tel: 973-631-6060
MCarrer@CoughlinDuffy.com

On March 4, 2009, in the highly anticipated decision of *Wyeth v. Levine*, the Supreme Court of the United States held, by a margin of 6-3, that the Food and Drug Administration ("FDA") approval of a drug's label does not preempt state tort failure to warn claims that the labeling was inadequate. The Court concluded that drug manufacturers can comply with both state law and the federal Food, Drug and Cosmetic Act ("FDCA") without contravening the Congressional intent of the FDCA.

The plaintiff, Diane Levine, developed gangrene in her right arm after being improperly injected with Wyeth's anti-nausea medication, Phenergan, through the "IV-push" method of administration. Her arm was ultimately amputated at the forearm. Levine sued Wyeth alleging that IV-push was an unsafe method of administration that should have been removed from the drug's labeling. A nearly \$7 million jury award was affirmed by the Vermont Supreme Court in October 2006, and Wyeth appealed to the Supreme Court of the United States.

In ruling against Wyeth, the majority opinion – written by Justice Stevens and joined by Justices Kennedy, Souter, Ginsburg and Breyer – noted that the Vermont jury found that the inadequate label was both the "but-for" and proximate cause of Levine's injury. According to the Court, the jury's verdict did not mandate a change to the label, only the award of damages premised on the jury's finding that the warning, as written, was insufficient. The majority then focused on two cornerstones of a preemption analysis: (1) that "the purpose of Congress is the ultimate touchstone in every preemption case" and (2) that the Court starts with the presumption that the historic police powers of the states are not superseded by federal law unless such purpose is clear and manifest (i.e., the "presumption against preemption").

Wyeth unsuccessfully raised two (2) arguments in favor of preemption: (1) it was impossible for the drug label to conform to both federal and state law (i.e., "impossibility preemption") and (2) state tort actions create an obstacle to the "full purposes and objectives" of Congress (i.e., "implied preemption"). In connection with the impossibility preemption argument, the Court addressed the "changes being effected" ("CBE") FDA regulation, which allows a drug manufacturer to change an already approved label to incorporate new safety warnings, while the FDA reviews the revised label. The Court reasoned that the CBE regulation allowed revised label warnings to reflect "newly acquired information" prior to FDA approval, including new analyses of data previously submitted to the FDA. Although limited, there was some evidence of new information available to Wyeth in the period after it obtained FDA approval for Phenergan, allowing it to amend the label pursuant to the CBE regulation. As a result, the Court held that, "[t]he CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change." According to the Court, compliance with both federal and state law was not impossible.

As to the implied preemption argument, the Court noted that Congress specifically preserved state law remedies under the FDCA. Additionally, the Court noted that, although the portion of the FDCA dealing with medical devices contained a specific preemption provision, that portion dealing with prescription drugs did not. Finally, even in the 2007 amendments to the FDCA, "Congress did not enact a provision . . . that would have required the FDA to pre-approve all changes to drug labels."

In addition, the Court concluded that the FDA preamble to labeling regulations did "not merit deference." The preamble, which declared that FDA approved labels were both the "floor" and the "ceiling" with respect to warnings, was a "mere" assertion that FDA approval preempts state law. The Court noted that the preamble was not offered to the states or other interested parties for debate and, as such, "[t]he agency's views on state law are inherently suspect in light of this procedural failure." Further, the preamble reverses the FDA's long-standing position that FDA approval does not preempt state failure to warn tort actions. Finally, although Justice Thomas concurred in the majority's judgment, he rejected the Court's discussion of implied preemption doctrine, arguing that the doctrine is unconstitutional.

Should you have any questions or comments regarding this matter, please feel free to contact us.

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