



FDA'S APPROVED LABEL OF DRUG DOES NOT PREEMPT STATE LAW CLAIM

Wyeth v. Levine, NO. 06-1249, 2009 WL 529172 (U.S. Mar. 4, 2009)

On March 4, 2009, the United States Supreme Court published its long awaited decision in *Wyeth v. Levine*, holding that the U.S. Food and Drug Administration's ("FDA") drug labeling judgments do not preempt state law product liability claims asserting inadequate warnings.

The Case

Diana Levine sued Wyeth, the manufacturer of Phenergan, alleging that Wyeth failed to provide adequate warnings regarding the risks of administration of its drug, Phenergan, by IV-push. As a result of complications, Levine suffered gangrene and her arm had to be amputated. The evidence revealed that administration of Phenergan by IV-drip would eliminate these complications, and that the physician's assistant who administered Phenergan to Levine was not even aware of the existing drug's warnings. A Vermont jury awarded over \$6,000,000 to Levine, finding that Phenergan was a defective product as a result of inadequate warnings even though Wyeth used the labeling language approved and required by the FDA. The Vermont Supreme Court affirmed the jury's verdict, finding that that the verdict "did not conflict with FDA's labeling requirements for Phenergan because [Wyeth] could have warned against IV-push administration without FDA approval and because federal labeling requirements create a floor, not a ceiling for state regulation."

The Court's Opinion

Justice Stevens delivered the opinion of the Court, rejecting Wyeth's preemption arguments. Justice Stevens reviewed Congressional intent and the history of the Food Drug and Cosmetic Act ("FDCA"), finding that, since the original enactment of the Federal Food and Drug Act in 1906, "Congress took care to preserve state law." While Congress did enact an express preemption provision for medical devices in 1976, Congress has not enacted a preemption provision for prescription drugs. As late as 2007, Congress amended the FDCA, enlarging the power of the FDA, yet still did not enact a preemption provision or any provision that would require prior approval of all changes to drug labels. Furthermore, the FDCA and the regulations issued by the FDA did not prohibit Wyeth from changing its labeling to strengthen the language pertaining to risks associated with IV-push administration of Phenergan. Under the FDA's "change being effected" ("CBE") regulations, a manufacturer is allowed to make changes to its label to add or strengthen warnings or instructions but must file a supplemental application with the FDA. Prior approval of the change by the FDA is not required.

Wyeth, who received at least 20 reports of adverse incidents similar to Levine's injury, "could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug." Wyeth had a duty to update its label and submit a CBE to provide a warning that adequately described the risk of gangrene from IV-push administration when that risk became apparent. According to Justice Stevens, while the FDA and Wyeth had made label



changes for Phenergan, the risks associated with IV-push versus IV-drip administration were not given more than ‘passing attention.’ “Absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”

Justice Stevens stressed that Congress was silent on the issue of preemption, but noted that the FDA had issued interpretive statements asserting that FDA approval of labeling preempts conflicting or contrary state law and, specifically, that state law failure to warn actions threaten the FDA’s role as the expert federal agency responsible for evaluating and regulating drugs. Justice Stevens found the FDA’s preemption statements procedurally defective because they were issued without the opportunity for public comment. Additionally, these statements were a reversal of the FDA’s own longstanding position on the issue of preemption and were made without any explanation or discussion of the conflict with state law. Accordingly, the FDA’s preemption statements were afforded no weight. The Court concluded that the FDA’s labeling decisions did not preempt state law claims that Phenergan’s label did not contain an adequate warning. The judgment of the Vermont Supreme Court was affirmed.

The Dissenting Opinion

Justice Alito offered a dissent, joined by Justice Roberts and Justice Scalia. Rather than the ‘passing’ consideration to the issue of IV-push administration, Justice Alito found the FDA’s consideration of the issue of IV-push to be extensive. The FDA “has long known about the risks associated with IV push in general and its use to administer Phenergan in particular. Whether wisely or not, the FDA has concluded—over the course of extensive, 54 year long regulatory proceedings—that the drug is ‘safe’ and ‘effective’ when used in accordance with FDA-mandated labeling.” This history revealed that the FDA specifically considered and reconsidered the adequacy of the warnings related to IV-push administration and the labeling employed by Wyeth was the FDA’s considered decision based on scientific and medical data, issued through administrative proceedings and bear the force of law. Because the majority opinion effectively allows the juries in all 50 states to contradict the FDA’s expert determinations, ‘parochialism may prevail.’

Expected Consequences

This case opens the door to state product liability actions in prescription drug failure-to-warn cases where the FDA has not considered the specific warning urged by the plaintiff. The majority’s ruling makes clear that the manufacturer has the ultimate obligation to ensure adequate warnings are included in original drug labels and strengthened as may be necessary based upon adverse incident reports and scientific and medical studies. Unless Congress enacts a preemption provision for the FDA’s drug labeling decisions, drug manufacturers cannot rely on the FDA’s labeling determinations as safety from lawsuits and possible liability as a result.

– [*Amy W. Truett*](#)



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Leon Gary, Jr.
Jones Walker
Four United Plaza
8555 United Plaza Boulevard
Baton Rouge, LA 70809-7000
225.248.2024 *tel*
225.248.3024 *fax*
lgary@joneswalker.com

Products Liability Practice Group

Ainsworth, Kevin O.	Joyce, William J.
Anada, Tarak	Leitzelar, Luis A.
Anseman, III, Norman E.	Liddick, Eric Michael
Balart, L. Etienne	Lowenthal, Jr., Joseph J.
Brehm, Sarah S.	Mann, Christopher S.
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Jenkins, R. Scott	Wynne, William P.

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