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U.S. Supreme Court Rejects Pre-Emption Defense in Drug-Labeling Case

Earlier this month, in a closely watched pre-emption case, the U.S. Supreme Court issued a ruling that could have a significant impact on both highly-regulated industries and, by extension, state tort litigation. In *Wyeth v. Levine*, the Court held that an FDA-approved label warning about the potential side-effects of a drug did not pre-empt a state-law tort claim challenging the adequacy of the drug maker's label.

In *Wyeth*, the drug at issue was known to cause irreversible gangrene if it entered the patient's artery. That is precisely what happened, resulting in the amputation of the plaintiff's hand and forearm. The FDA-approved label warned of this danger; however, the plaintiff claimed that the label was defective under Vermont common law because it failed to instruct clinicians to refrain from using a specific injection method, which was known to increase the risk of introducing the drug into an artery. A Vermont jury agreed, awarding the plaintiff \$6.7 million in damages against the drug manufacturer.

The Supreme Court considered two implied pre-emption theories that have gained traction in recent years: (i) impossibility – that it would have been impossible to comply with state-law tort duties and the federal label requirements; and (ii) purposes-and-objectives – that the state-law tort action would interfere with Congress's purposes and objectives of congressionally-mandated federal drug labeling regulations.

The Court rejected the defendant's impossibility pre-emption argument, explaining that the manufacturer – not the FDA – bears primary responsibility for the content of its drug label and ensuring that it is adequate. The Court emphasized that a manufacturer can strengthen its warning without prior FDA approval. Thus, neither the fact that the FDA previously approved the label or that it retains authority to later reject labeling changes, makes it impossible for a manufacturer to comply with both federal and state requirements.

The Court rejected the defendant's purposes-and-objectives argument as well, looking past the FDA's 2006 pronouncement – that its approval of a label preempts contrary state-law claims – in favor of the FDA's longstanding approach that state law provides an additional, and important, layer of protection in conjunction with its own regulations. Accordingly, the Court concluded that the plaintiff's failure-to-warn claim did not obstruct the purpose of federal drug-label regulations.

While the effect of the Supreme Court's holding outside of the FDA drug-labeling context is an open question, the *Wyeth* decision will likely be used to urge courts in state-law tort actions, affecting highly-regulated industries, to restrict the use of these *implied* pre-emption doctrines absent evidence that Congress has *expressly* authorized a particular federal agency to directly pre-empt state law. This is apparently true even when a federal agency has publicly expressed its view to the contrary. One other aspect of the Court's decision bears watching – the majority's strong endorsement of state-law tort suits in uncovering safety risks and providing compensation.

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