U.S. Supreme Court Rejects Complete Preemption Defense for Drug Manufacturers

Yesterday, in *Wyeth v. Levine*, the Supreme Court, in a divided opinion, rejected the view that approval of drug labeling by the Food and Drug Administration preempts state law product liability claims premised on the theory that a different labeling was necessary to make the drug reasonably safe for use. Justice Stevens delivered the opinion of the Court. Justices Breyer and Thomas wrote separate concurring opinions. Justice Alito, joined by Chief Justice Roberts and Justice Scalia, dissented.

The case involved a dispute over Phenergan, a drug manufactured by Wyeth and prescribed to the plaintiff for nausea. Levine received the drug through an "IV-push" injection, a higher risk method, which caused gangrene and ultimately required the removal of her forearm. She sued the health center and doctor and settled those claims. She also sued Wyeth, alleging common law negligence and strict liability claims, challenging the labeling as defective because it failed to instruct clinicians to administer the drug using an IV-drip rather than an IV-push method. Wyeth argued that any failure to warn claim was preempted by federal law, asserting both an "impossibility preemption defense" (i.e., that it would be impossible to comply with both federal and state requirements), and a conflict preemption defense (i.e., that state-law suits pose an obstacle to the federal drug labeling objectives). The trial judge disagreed and the case went to a jury. The jury found that Wyeth was negligent and that Phenergan was defective because of its inadequate warnings and instructions, and awarded Levine $7,400,000 in damages. The Vermont Supreme Court affirmed in a divided opinion. The Supreme Court has now affirmed as well.

After reviewing the history of federal regulation of drugs and drug labeling, the Court did not accept the impossibility preemption defense. The Court relied on the "changes being effected" regulation (21 CFR § 314.70(c)(6)(iii)(A), (C)) which permits a manufacturer to change a label to "add or strengthen a contraindication, warning, or precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," without waiting for FDA approval, but by filing a supplemental application with the FDA.

The Court did not accept Wyeth's argument that newly acquired information is necessary to supplement a label. Rather, new analyses of previously submitted data may be a sufficient basis for a change in a label. The Supreme Court also disagreed with Wyeth's argument that a unilateral addition of a warning would convert Phenergan into a new drug or render Phenergan misbranded. The Court questioned the notion that the FDA would bring an enforcement action against a

manufacturer for strengthening a warning, as well as the notion that the FDA rather than manufacturers bears primary responsibility for drug labeling.

The Court also rejected the conflict preemption defense, noting that where Congress intended to expressly preempt state-law suite, it has enacted an express preemption provision, as in the case of medical devices, but it did not enact such a provision for prescription drugs. The Court rejected reliance on the preamble to FDA's regulations in 2006, governing the content and format of prescription drug labels, calling it "an agency's mere assertion," that did not merit deference, in part because it represented a "dramatic change in position," that was at odds with FDA's "traditional recognition of state-law remedies." According to the Court, "[a]lthough we recognize that some state-law claims might well frustrate the achievement of congressional objective, this is not such a case."

Justice Breyer wrote separately to underscore that the Court was not considering the preemptive effect of a specific agency regulation bearing the force of law. Although Judge Thomas also concurred in the judgment, he wrote separately to make it clear that he did not join in "the majority's implicit endorsement of far-reaching implied preemption doctrines."

Justice Alito's dissenting opinion argues that the presence of an express preemption provision in the statute is irrelevant and that FDA's 40 years of regulating the safety and efficacy of Phenergan should have preempted a state tort suit. As Justice Alito concluded: "The FDA told Wyeth that Phenergan's label renders its use 'safe.' But the State of Vermont, through its tort law, said: 'Not so.'" Calling this a case in which "tragic facts make bad law," the dissent would have reversed the Vermont Supreme Court and found the state-law rule "squarely preempted."

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