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Wyeth: The Plaintiff's Perspective

By Lawrence Goldhirsch and Taylor Asen

The Supreme Court's decision in *Wyeth v. Levine* recognizes that the FDA's approval of a drug label does not preempt state law failure-to-warn claims.

THE ISSUE WITH PHENERGAN

Rarely has a defendant in a drug case been able to compile such a favorable set of facts to present to the Court. Phenergan, marketed since the 1950s, is an anti-nausea prescription medication. Injectable Phenergan is supposed to be administered intramuscularly (into a muscle) or intravenously (into a vein.) The drug can be introduced directly into a vein by injection, called the IV-push method, or by an IV drip in which the drug is mixed with a hanging bag of saline solution connected to the patient by an IV with a needle inserted into the vein.

The drug is very dangerous if it gets into an artery; it can cause gangrene resulting in amputation of the limb. The drug can enter an artery in two ways: The medical practitioner can inject Phenergan into an artery, thinking it is a vein, or the drug can escape from the vein into the surrounding tissues, extravasation. The dangers of Phenergan are well known to Wyeth, the FDA and the medical profession. (A drug manufacturer has a duty to warn medical professionals.) Though the FDA and Wyeth discussed the possibility of implementing strong warnings regarding intra-arterial injections, the FDA never banned the IV-push method. By 2000, the year in which the plaintiff was injured, the FDA had ordered that the label must say "inadvertent intra-arterial injection can result in gangrene of the affected extremity."

THE MAJORITY DECISION

Despite the language on the label and the available literature, a physician assistant performed an IV-push into the plaintiff's antecubital area and later testified that she had no idea that such an injection could hit an artery. (Justice Alito, in his dissent, wondered how a stronger warning would have helped the plaintiff under these circumstances.) Even so, the jury found that the warnings were insufficient, that there should have been a more explicit warning about IV-push administration, and that Levine's injury would not have occurred had an adequate warning existed. The jury concluded that there was no other intervening cause of the injury, such as the assistant's conduct, as Wyeth had argued. The majority decision dismissed the defendant's arguments on proximate cause and malpractice by curtly saying in a footnote that the only question it had to decide was whether federal law pre-empts plaintiff's state law claims.

WYETH'S ARGUMENT

Wyeth argued that it was entitled to pre-emption because it was impossible for it to comply with both the common law duty to warn and the FDA labeling requirements. Wyeth claimed it had to comply with what the FDA approved in the label and could only change it, even to strengthen it, with the approval of the FDA. The Supreme Court disagreed and held that Wyeth, under existing regulations, could have revised its labels to include a stronger warning as soon as there was reasonable evidence of an association of a serious hazard. It did not have to await FDA approval.

Wyeth alternatively argued that the plaintiff's tort claims should be pre-empted because Congress had entrusted an expert agency to make decisions to strike a balance between competing objectives. Once the FDA has approved a drug's label, Wyeth urged, a state-law verdict may not deem the label inadequate. The Court rejected that argument, saying that if Congress thought state lawsuits posed an obstacle to its objectives, it would have enacted an express pre-emption provision as it did in 1976 for medical devices. (State law failure-to-warn claims are expressly pre-empted.)

ANALYSIS

Wyeth v. Levine is a major victory for consumer advocates and champions of the civil justice system — not solely because it allows victims to continue to bring failure-to-warn suits against negligent pharmaceutical companies, but more importantly because the Court explicitly acknowledges the enormous value of lawsuits in both protecting the rights of consumers and in shedding light on safety issues the FDA overlooks. "State tort suits," writes Justice Stevens

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in his majority opinion, “uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.” Lawsuits shift some of the burden off the immensely overworked, under-funded and, of late, oft-embarrassed FDA and onto the shoulders of the drug manufacturers. Indeed, Justice Stevens underscores that, notwithstanding Wyeth’s argument that the FDA has primary authority, it “has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of the label at all times.” Unfortunately, aside from FDA orders, lawsuits have proven to be the only method by which drug companies can be persuaded to assume this responsibility. Wyeth’s

Larry Goldhirsch, a member of this newsletter’s Board of Editors, is trial counsel to Weitz & Luxenberg, PC, in New York. He may be contacted at 212-558-5500. **Taylor Asen** is a paralegal at the Washington, DC office of Cuneo Gilbert & LaDuca, LLP

contention — which was swiftly rejected by the Court — was that by voluntarily strengthening Phenergan’s warning they could have been accused by the FDA of misbranding. This will sound all too familiar to plaintiffs’ attorneys who have always found it ironic that drug companies who aggressively “negotiate” the labels of their drugs for months on end with the FDA suddenly cover at the prospect of changing their label when it comes to strengthening, rather than watering down, warnings. Justice Stevens found this argument “difficult to accept” as well, since Wyeth failed to “identify[] a case in which the FDA has” punished a drug company for strengthening the warning on a drug label. He observed that, rather than state and federal laws being irreconcilable, as Wyeth claimed, “state law offers an additional, and important, layer of consumer protection that complements FDA regulation.”

Following on the heels of the nation’s overwhelming rejection of the past administration, the Supreme Court’s decision is also an unambiguous and explicit rebuke of a 2006 attempt by the FDA to preclude state court actions. Stevens

admonishes the FDA for a preamble to a new regulation in which the agency proclaims that the labeling it approves pre-empts conflicting or contrary state law, thereby protecting drug manufacturers from state law litigation. Articulating a sweeping pre-emption without offering States or other interested parties notice or opportunity for comment, Stevens said, was a procedural failure that made the FDA’s views on pre-emption inherently suspect.

The fact that the particulars of the case at hand favored the defendant, as Mr. Conko rightly points out, only emphasizes the Court’s eagerness to express its disagreement with the FDA and industry’s contention that state suits should play no part in the protection of citizens’ safety for approved drug warnings. The Supreme Court’s decision not only rightly continues the availability of such common-law suits, but has given encouragement to those pursuing such cases by characterizing state tort claims as the partners, rather than the adversaries, of the federal regulators.

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