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HIGH COURT’S DECISION IN WYETH SPELLS TROUBLE FOR IMPLIED PREEMPTION DEFENSE TO STATE LAW TORT ACTIONS

On March 4, 2009, the Supreme Court issued its long awaited decision in Wyeth v. Levine, where the Court was presented with the issue of whether approval of a prescription drug label by FDA provides the drug manufacturer with a complete defense to a state law tort claim. The Court held (6-3) that it did not and, although the Court’s ruling arguably did not dramatically alter the landscape of federal preemption law as many expected it would, the decision signals a move towards limiting the availability of the implied preemption defense.

BACKGROUND

In April 2000, Diana Levine went to her health clinic for treatment of nausea and other symptoms relating to severe migraine headaches. To control her symptoms, the treating clinicians gave her Phenergan, an anti-nausea drug manufactured by Wyeth. The drug was administered by the “IV-push” method. One of the risks associated with the IV-push method, which Levine argued was not adequately disclosed on the FDA approved label, is that it could lead to rapid onset of gangrene if the drug makes its way into an artery instead of a vein. This is exactly what happened in Levine’s case, resulting in the loss of her forearm.

Levine sued Wyeth in Vermont state court for monetary damages, alleging that Wyeth failed to adequately warn about the dangers of administering the drug through the IV-push method. The Vermont trial judge denied Wyeth’s assertion that

Levine’s claim was preempted, stating that FDA’s approval of Wyeth’s label did not prevent the manufacturer from adding to or strengthening warnings on the label. A jury awarded Levine millions in damages. The decision was affirmed by the Supreme Court of Vermont and the Supreme Court granted certiorari. FDA, alongside Wyeth, argued that federal drug-approval and warning-label standards should preempt stricter state laws in the form of tort liability.

DECISION

Justice Stevens, writing for the majority, which included Justices Kennedy, Souter, Ginsberg, Breyer, and Thomas, held that the labeling approval by the FDA does not preempt state laws or shield

2 Justice Breyer filed a concurring opinion for the purpose of emphasizing that the majority’s decision fell short of considering the preemptive effect of an agency regulation bearing the force of law (as opposed to a statement of preemption that appeared in the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels, which the Court held here did not bear the force of law).

3 Concurring only in the judgment, Justice Thomas wrote a separate opinion to emphasize his view that preemption should be found only where expressly provided for in statutory text enacted by Congress pursuant to the Constitution and in duly authorized agency action. According to Justice Thomas, since neither the Constitution nor the FDCA specifically divest state power over civil litigation, he concurred with the majority’s decision.
companies from legal damages as part of liability claims.\(^4\)

In deciding against the application of the preemption doctrine in this case, the majority looked to Congressional purpose relating to drug labeling and began its analysis with the assumption that the police powers of the States are not preempted by Federal law unless that was the purpose of Congress. Justice Stevens’ opinion traced the long history of FDA regulations that worked alongside state law to assure the safety and effectiveness of drugs. The majority opinion emphasized that historically, the burden of ensuring label accuracy ultimately lies with the drug manufacturers.

The majority then addressed, and rejected, each argument Wyeth set forth in favor of its position that preemption should bar Levine’s state law failure to warn claims. First, Wyeth argued that (1) it was impossible to comply with both federal and state requirements, where the former approved Wyeth’s labeling related to the IV-push method, and the latter would have required a different label; and (2) Wyeth couldn’t change the label without FDA’s permission, and, therefore, it would have been impossible for it to have avoided the negligence for which the Vermont jury found liability. The Court rejected these arguments, relying on FDA’s recent “changes being effected” (“CBE”) regulation, which permits a drug manufacturer to change a drug label to strengthen its warnings without prior approval from FDA.

Second, Wyeth argued that by penalizing drug companies for using FDA approved labeling, state law tort claims like Levine’s would obstruct the purpose of the labeling regulations set forth by Congress in the Food Drug and Cosmetic Act (“FDCA”) by allowing juries to second-guess the expert risk determinations of the FDA.

Relying on historical evidence of the co-existence of FDA regulation of drug labeling and implicit Congressional approval of state tort litigation in the area of drug labeling, the Court rejected Wyeth’s arguments as a weak interpretation of congressional intent and characterized Wyeth’s claims as an overbroad view of an agency’s power to pre-empt state law.

Finally, Wyeth argued that, notwithstanding the CBE regulation, a statement by FDA in the preamble to a 2006 regulation governing the format and content of prescription drug labels was enough to preempt Levine’s claims. Specifically, the FDA preamble stated that “FDA approval of labeling . . . preempts conflicting or contrary State law.” 71 Fed. Reg. 3922 (2006). Significantly, the Court recognized that an agency regulation bearing the force of law could preempt conflicting state law requirements. However, in this case, the Court found that FDA’s proclamations in a preamble to a regulation did not carry the force of law and, therefore, Levine’s claims were not preempted by that language.

\(^4\) Chief Justice Roberts and Justice Scalia joined in the dissenting opinion written by Justice Alito.

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