Did the Supreme Court get *Wyeth* Right?

*by Thomas N. Tiedt**

The U.S. Supreme Court upheld the award of $6.7 million to Diana Levine March 4 in *Wyeth v Levine* – a seminally important case addressing the question of Constitutional preemption of tort litigation against FDA-approved prescription drugs.

Here are the facts of the case (No. 06-1249, argued 11/3/08): In April 2000, Diana Levine was given Wyeth's anti-nausea drug, Phenergan, with an intravenous injection. In 2004, Wyeth sold the rights for the intravenous form of Phenergan to Baxter International. Because the drug entered an artery, Levine suffered gangrene and subsequently had her forearm amputated, ending her career as a professional musician. Wyeth did not dispute these facts. The U.S. Supreme Court, as well as the lower courts, all agreed that Wyeth's inadequate label was the proximate cause of Diana Levine's injury.

This case is clearly critical to the politics of tort litigation. Industry associations and the Bush Administration sided with Wyeth's arguments to dismiss the ruling of the Vermont Supreme Court, which had affirmed a lower court's ruling that federal laws did not preempt pharmaceutical tort litigation.

Wyeth had argued that the Federal Food, Drug, and Cosmetic Act (FDCA) preempted such tort litigation and that, therefore, it was impossible for Wyeth to comply with FDA-approved labeling and conclusions by state juries that such labeling was inadequate and a cause for harm.

In a six to three decision — which many experts consider a surprising margin—the Court rejected Wyeth's arguments, concluding that the company misunderstood FDCA and FDA regulations and, instead, was trying to use FDA as a shield.

The Court ruled that FDCA and FDA regulations require that the manufacturer, not FDA, bears primary responsibility for the content of its product's label. FDA regulations permit manufacturers to strengthen safety warning prior to FDA approval, however, the court noted.

The Court ruled in favor of the 'presumption against preemption' because, it argued, Congress had not preempted pharmaceutical tort litigation, as it did in 1976 for FDA-approved medical devices, since enactment of FDCA.

The Court thus rejected Wyeth's contention that FDCA establishes both a floor and a ceiling for drug regulation. There was "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," the Court declared. The Court concluded that the history of the FDCA shows that Congress did not intend to pre-empt state-law failure-to-warn actions.

The Court gave "no weight" to FDA's support of Wyeth's arguments. "The United States' amicus brief is similarly undeserving of deference," the Court noted.

The Court concluded: "The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly."

Justice Clarence Thomas concurred with the ruling of the majority, stating: "Federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA."

Wyeth responded to the Court's ruling, stating: "The medical and scientific experts at FDA are in the best position to weigh the benefits and risks of a medicine and to assess how those benefits and risks should be described in the product's label."

In general, advisory committees and experts conclude that the budget and staff of FDA are inadequate for the discharge of existing responsibilities to protect the public. Almost weekly, dramatic stories of FDA's shortcomings and nondisclosures of critical safety information by manufacturers underscore FDA's ongoing inadequacies. FDA approval should not be a shield against tort litigation or responsible drug marketing.

Because of FDA's inadequacies and manufacturers' occasional concealment of critical safety data and/or misleading of FDA scientists, the safeguards of tort litigation are needed to protect consumers. In view of the nation's financial stakes in better health care and the need for a vibrant pharmaceutical industry and drug safety system, the Court's ruling was the right one on legal as well as practical grounds. A beneficial outcome of the Court's ruling, in the context of our current economic challenges, would be increased federal government attention to drug safety.

For more comprehensive articles on this issue by Tiedt, see 62 *Food and Drug Law Journal* 547-558 (2007) and the September/October 2008 of *Update*.

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