Supreme Court: FDA Approval Doesn't Bar Suits

BY ALICIA AULT

In an eagerly anticipated opinion, the U.S. Supreme Court has upheld a lower court ruling that Food and Drug Administration approval does not give pharmaceutical companies immunity from product liability lawsuits.

The justices voted 6-3 to affirm the judgment of the Vermont Supreme Court that federal law did not preempt Diana Levine's claim of inadequate warning on the label of promethazine (Phenergan). Ms. Levine received the drug by intravenous push and subsequently lost her arm. She was awarded $6.7 million by a Vermont jury.

A majority of justices rejected the argument by Wyeth Pharmaceuticals Inc., maker of Phenergan, that it was impossible for the company to simultaneously comply with both federal and state laws and regulations. Wyeth could have unilaterally strengthened the label at any time without input or clearance from the FDA, wrote the justices, concurring with the lower court opinion. And, the company's argument that following the duty to warn under state law would have interfered with the FDA's power to preempt state law was "meritless," according to the majority opinion.

Justice Clarence Thomas voted with the majority, agreeing that Wyeth could have changed its label and complied with both state and federal laws. But he said that he did not agree with the majority's more far-reaching conclusions about preemption, specifically a tendency to override state laws when they were perceived to be an impediment to enforcing federal statutes.

Justice Samuel Alito and Justice Antonin Scalia, joined by Chief Justice John Roberts, dissented, writing in their opinion that "this case illustrates that tragic facts make bad law. The Court holds that a state tort jury, rather than the Food and Drug Administration, is ultimately responsible for regulating warning labels for prescription drugs." That premise is not consistent with previous rulings, they wrote.

Indeed, just last year the U.S. Supreme Court ruled in *Riegel v. Medtronic Inc.* that FDA approval conferred special protection against product liability suits involving medical devices.

The Pharmaceutical Research and Manufacturers of America said that it was still reviewing the opinions in *Wyeth v. Levine*. "We continue to believe that the expert scientists and medical professionals at the FDA are in the best position to evaluate the voluminous information about a medicine's benefits and risks and to determine which safety information to include in the drug label," PhRMA Senior Vice President Ken Johnson said in a statement.

Consumer advocacy group Public Citizen called the ruling a broad rebuff to the industry's attempt to duck tort damages. Brian Wolfman, director of Public Citizen Litigation Group, said that the organization was "extremely gratified" that the Court "upheld the traditional right of patients harmed by defective and mislabeled drugs to sue drug companies to recover compensation for their injuries." ■

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