



Supreme Court Tells Drugmakers 'Label Is No Shield'

By Peggy Peck, Executive Editor, MedPage Today
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WASHINGTON, March 4 -- FDA approval of a drug and its label does not shield its maker from lawsuits brought by patients injured by use of the drug, according to a 6-3 decision today by the Supreme Court.

The ruling upholds the \$6.7 million awarded by a Vermont jury to Diana Levine, a musician who lost her arm when gangrene developed following injection of the anti-nausea drug promethazine (Phenergan) by IV push.

Wyeth, maker of the drug, argued that FDA approval indemnified the company from state lawsuits.

The Vermont jury agreed with the plaintiff's argument that Wyeth failed to provide a clear warning about the dangers of IV push administration of the drug.

In Levine's case, the injection hit an artery, gangrene developed, and her right arm was amputated.

Wyeth appealed that decision and was supported in its appeal by the Bush administration. Their argument was that a warning label approved by the FDA could only be changed by the FDA.

Consumers, the company argued, cannot seek relief in state courts.

In the majority opinion, Justice John Paul Stevens brushed aside that argument and said Wyeth could "unilaterally strengthen its warning."

Stevens said he was persuaded that until a recent change by the FDA, the agency "traditionally regarded state law as a complementary form of drug regulation" because it monitors 11,000 drugs.

Justice Samuel Alito wrote a dissent that was joined by Chief Justice John Roberts and Justice Antonin Scalia.

Alito said tragic facts of the case had resulted in "bad law" that allows a state tort jury, rather than the FDA, to be "responsible for regulating warning labels for prescription drugs."

Stevens said the ruling was not a carte blanche for those seeking to sue drug companies, adding that there were circumstances where such suits should not be allowed. For example, he wrote, if the FDA had considered and rejected a stronger warning label, a lawsuit would not be allowed.

Stevens said that was not the case with the IV-push of promethazine.

Justice Stephen Breyer, who agreed with the majority, said in a brief separate opinion that it was "possible that state tort law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions."

Late today, Wyeth issued a statement saying the Supreme Court decision was "disappointing, not only for Wyeth, but for patients and public health in general."

The company said patients were "best served by a national standard for the labeling of prescription medications." A standard, the company said, that should be set by the FDA.

"When lay juries are permitted to second-guess the experts at FDA on the benefits and risks of particular medicines, the result is uncertainty for patients and doctors alike about how and when to use prescription drugs," the company said.

Bert Rein, of Wiley Rein, the D.C. law firm that represented Wyeth, said the labeling "provided clear instructions and warnings about its use, including clear warnings about the very risk at issue in this case."

Rein said "medical and scientific experts at the 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."

The case became a cause célèbre for American medicine when four current and two former editors of the *New England Journal of Medicine* signed onto an amicus brief filed last August in support of Levine's position. The brief called the issue "one of immense importance from the perspective of public health and safety." (See: [In Supreme Court Brief, Journal Editors Fault FDA Safety Record](#))

The brief, which was joined by Paul D. Stolley, M.D., formerly of the University of Maryland; Harlan M. Krumholz, M.D., S.M., of Yale; Stuart Rich, M.D., of the University of Chicago; and Eric J. Topol, M.D., of Scripps School of Medicine -- all researchers who have multiple publications in *NEJM* -- also charged that contrary to Wyeth's premise, "the FDA is in no position to ensure the safety of prescription drugs."

Levine was also supported by an amicus brief filed by 47 states' attorneys general, as well as a brief from the Texas Medical Association, the Texas Medical Liability Trust, and the North Carolina Medical Association.

Two former FDA commissioners, David Kessler, M.D., and Donald Kennedy, Ph.D., also backed her.

In addition, there were briefs supporting Levine filed by a number of individual physicians, a handful of union health and welfare funds, and the consumer advocacy group Public Citizen.

By contrast, the American College of Emergency Physicians and [the Washington Legal Foundation](#) had filed a brief supporting Wyeth's argument that the FDA approval preempts state tort claims.

Praising today's decision, Public Citizen said that "Diana Levine lost her arm because Wyeth did not take a simple step to warn her doctors of an avoidable risk of gangrene that was well known to the company -- that its anti-nausea drug should not have been administered via the IV-push method. Today's decision is a huge victory for Diana, for patients across the country, and for public health."

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