



FOR IMMEDIATE RELEASE

The U.S. Supreme Court has just issued a major decision rejecting federal preemption and preserving access to justice! The Court held 6 to 3 today in *Wyeth v. Levine* that federal law does NOT preempt -- i.e., wipe out -- lawsuits against drug manufacturers for failing to warn of their drug's dangers.

The Court's powerful decision, authored by Justice Stevens, emphasizes that "the purpose of Congress is the ultimate touchstone in every pre-emption case" and that "in all pre-emption cases, ...we start with the assumption that the historic police powers of the States were not to be superseded unless that was the clear and manifest purpose of Congress." It notes that the federal Food, Drug, and Cosmetic Act (FDCA) never contained any provision *expressly* preempting injured consumers' claims against drug manufacturers and emphatically rejects the drug companies' argument that drug failure-to-warn claims are *implicitly* preempted. It also rejects the U.S. Food and Drug Administration's new pro-preemption position under President Bush, holding that it "does not merit deference."

The Court rebuffs the drug companies' arguments in plain and simple terms, stating "Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue. The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary."

The Court emphasizes, as our *amicus* brief did, the important role damage suits play in protecting the public. It says, "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. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times."

Finding no pre-emption, the Court concludes, "Congress has repeatedly declined to preempt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight."

This is an enormously important decision that preserves access to justice for millions and will terminate many of the pre-emption battles now being fought in drug litigation nationwide, which took off after the Bush Administration switched the federal government's position. It has major implications for future preemption battles in numerous areas.

Of particular significance is Justice Thomas's concurrence, which advocates eliminating the type of "implied conflict pre-emption" that the Court has found in some past cases and the drug companies pushed for here. It says, "Because such a sweeping approach to pre-emption leads to the illegitimate - and thus, unconstitutional - invalidation of state laws, I can no longer assent to a doctrine that preempts state laws merely because they 'stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives' of federal law as perceived by

this Court."

To read the Supreme Court's decision in *Wyeth v. Levine*, [click here](#).

To read the *amicus* brief filed by Public Justice on the NEJM's editors' and writers' behalf, [click here](#).

Wyeth v. Levine was filed on behalf of a professional guitarist, Diana Levine, who lost an arm after an injection of the nausea drug Phenergan. She claims Wyeth failed to adequately warn of the drug's risk and won a judgment of \$6.8 million in a Vermont trial. The Vermont Supreme Court upheld the verdict, saying that the FDA's approval of the drug's label should not affect her ability to sue for her terrible injuries, which could have easily been prevented by a proper warning label. The Court affirmed that ruling today.

Congratulations and thanks to Gerson H. Smoger, the President of the Public Justice Foundation, who authored the brief with assistance from Public Justice Staff Attorney Leslie Brueckner and me.

Congratulations and thanks to plaintiffs' counsel David Frederick of Kellogg, Huber, Hansen, Todd & Evans, PLLC, in Washington, DC. He won a great victory.

Congratulations and thanks, too, to the other *amici* and great advocates in this case.

Together, we must defeat federal preemption and preserve access to justice for all.