

# Author fears impacts of pre-emption case

The U.S. Supreme Court just heard arguments in *Wyeth v. Levine*, a case with profound implications for the health of all Americans.

The plaintiff, Diana Levine, was given Wyeth's anti-nausea drug Phenergan, then on the market for 45 years. In rare instances, Phenergan can cause gangrene if it comes in contact with arterial vessels.

And in Levine's case, Phenergan was wrongly administered. Not only was she given double the recommended dose, but the physician's assistant who injected the drug ignored Levine's complaints of intense pain. The label identifies such pain as a sign of arterial exposure.

Levine, who lost part of her right arm, successfully sued the health center and several staff members for her injury. But that was not the end of the matter. Next she sued Wyeth.

Levine's product-liability lawsuit, brought in the state of Vermont, argues that the FDA-approved label failed to provide sufficient warning about the drug's dangers. The plaintiff's lawyers claim that the FDA-approved label did not meet Vermont's requirements -- putting the state directly at odds with the FDA. A jury agreed and awarded Levine \$7.4 million which, on appeal, was upheld by the Vermont Supreme Court.

The core issue now before the Court in the *Wyeth* case is the principle of federal pre-emption, which holds that federal law pre-empts state law when the two conflict.

Wyeth has argued that it cannot comply with both state and

federal labeling requirements. The company says FDA scientists approved the warnings on Phenergan's label after extensive research. The label, which met the FDA's strict requirements, provided clear instructions for proper administration and highlighted the risk of gangrene.

Since the FDA is the ultimate public health agency in the country, pre-emption ensures that drug labeling is subject to the approval of expert scientists, not local judges, juries, or personal injury lawyers.

A ruling in favor of Levine would dramatically undermine the FDA's effectiveness. And an increase in the number of lawsuits would divert financial resources away from research and development on life-saving treatments and raise the cost of drugs.

Liability concerns also affect the availability of medicines. Three decades ago, for instance, personal injury lawyers targeted the popular morning-sickness drug Bendectin, which a *National Enquirer* article had linked to birth defects.

The claim proved entirely bogus, but the cost of endless litigation forced the manufacturer to stop selling the drug. Hospital admissions for morning sickness subsequently doubled, increasing the risk of pregnancy complications.

Liability lawsuits benefit the legal industry more than truly injured people. Most multimillion dollar payoffs end up in the pockets of lawyers, while less than 15 cents of every tort-cost dollar goes to victims.

In *Wyeth v. Levine*, the U.S.

Supreme Court has a chance to rein in unscrupulous tort lawyers and re-affirm the supremacy of federal law over state law when there's a conflict. As they consider the arguments, the justices should remember that the health of all Americans is at stake.

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