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Wall Street Journal Health Blog

Wyeth v. Levine: The Mother of All Preemption Cases

Posted by Jacob Goldstein

A Supreme Court case the drug industry is watching with baited breath lands on the [front page of the New York Times](#) this morning. The key question: Does the fact that drugs are regulated by the federal government preempt drug companies from being sued in state court?

The particulars involve Diana Levine, a Vermont musician and migraine sufferer who lost part of one arm due to side effects from Wyeth's nausea drug Phenergan.

The problem wasn't with the drug itself, but with the way it was administered. The drug causes gangrene if it comes in contact with arterial blood, so it's typically given by intramuscular injection or sometimes IV drip. But the physicians assistant who gave it to Levine via a method known as "IV push," apparently missed the vein.

Nobody talked with Levine when she was being treated for migraine symptoms about the risks from IV push, whose benefits are, at best, faster more potent relief from nausea. "The benefit-risk is just outrageously ridiculous," Ms. Levine told the Times. "Any child could figure this out."

Levine argues the label, which did warn about the risks of inadvertent intra-arterial injection, should also have clearly warned against IV push. "All they had to do was change the label and say, 'Don't give it this way,' " she told the Times.

Wyeth says the drug's label is set in accordance with federal regulators. "Wyeth could not change Phenergan's labeling to comply with Vermont law without violating federal law," the company's lawyers wrote in a brief cited by the article.

Pre-emption bonus: We've been following the case — [online here](#) — since the [Supremes agreed to hear it in January](#).

In February, the Court [ruled in favor of Medtronic](#) in a big preemption case that involved medical devices, but a federal law that applies only to medical devices was central to that decision. In June, the [Bush administration backed Wyeth](#) in the case; and in August, the [editors of the New England Journal of Medicine filed a brief](#) backing Levine.