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High Court Eases Way to Liability Lawsuits

By [JESS BRAVIN](#)

WASHINGTON -- The Supreme Court said drug makers can be sued in state court over alleged defects, even if the Food and Drug Administration has approved a medication's use.

The 6-3 ruling undercuts years of business efforts to block state suits over the safety of products from motorcycle brakes to railway cars. "This is a very sweeping decision, with significant implications for areas other than the regulation of prescription drugs," said Jay Lefkowitz, a former policy adviser to President George W. Bush.

Companies have long sought to establish federal rules as a single standard trumping state law, and enjoyed a push under the Bush administration to shield industries from negligence suits.

The case was brought by Vermont musician Diana Levine, who went to a clinic complaining of migraines. She was injected with anti-nausea drug Phenergan, made by [Wyeth](#). Though the drug label permitted intravenous injection, it said "extreme care" was needed to avoid hitting an artery, because "likely" complications included "gangrene requiring amputation."

That happened to Ms. Levine, whose right forearm was amputated. She sued Wyeth, alleging the label should have barred intravenous injection, and a state jury awarded her \$7.4 million. Wyeth appealed to the Supreme Court, arguing that Ms. Levine had no right to sue, because the FDA approved the drug's label.

Writing for the court, Justice John Paul Stevens concluded that Congress saw state liability laws as bolstering, not undercutting, the FDA's mission of ensuring drug safety. With 11,000 drugs on the market in the U.S., he wrote, the FDA's own advisory panels have said it lacks resources to protect the public.

A 2006 Bush regulation reversed prior FDA policy by declaring state law interfered with the agency's mission. Justice Stevens wrote that the agency's new position was "inherently suspect" because it supplied no supporting evidence and failed to follow procedures for public comment. "Congress has repeatedly declined to pre-empt state law," he wrote.

Dissenting Justice Samuel Alito argued that being covered by federal regulation gave Wyeth immunity from state law. "This case illustrates that tragic facts make bad law," he wrote.

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