

Healthcare Leaders Watching Supreme Court Case

LYNNE JETER



On the eve of arguably the most important presidential election of our lifetime, the U.S. Supreme Court heard oral arguments in the most-watched landmark case of this term, referred to as simply No. 06-1249.

The court's verdict on *Wyeth v. Levine* will have a significant impact on the Federal Drug Administration (FDA) and drug regulation and could determine the future course of medical research in the United States.

"The case of *Wyeth v. Levine* isn't about consumer protection, it's about whether we'll allow trial lawyers to get rich," said Peter Pitts, president of the Center for Medicine in the Public Interest, and a former FDA associate commissioner. "If the High Court rules against Wyeth, we can look forward to a flood of lawsuits that'll bring medical innovation to a halt and drive healthcare costs through the roof. Vital medicines will disappear from the marketplace because of the threat of litigation."

Pitts said it's critical for the Supreme Court to protect the FDA's authority as chief drug regulator in the United States by ruling in favor of Wyeth and affirming the preemption of federal regulations over state ones.

"Without such a ruling, drug safety and labeling standards would be set by non-expert juries and would be different in all 50 states," he said. "Trial lawyers would have a field day with such regulatory chaos at the expense of patients waiting for the next round of innovative life-saving drugs. Let's hope the Supreme Court stands up for ordinary consumers by affirming the preemption of federal drug safety rules."

In the High Court's February 2008 decision in *Riegel v. Medtronic*, the justices held that federal law expressly preempted common-law suits against manufacturers of FDA-approved medical devices.

Background

The Wyeth case originated with Diana Levine, a Vermont songwriter and musician who visited a clinic seeking treatment for headache-related nausea. She wound up developing tissue deterioration and gangrene in her arm, ultimately leading to its amputation. How? Clinic staff administered the antihistamine Phenergen, with a physician assistant inadvertently injecting the drug into one of Levine's arteries. The problem wasn't with the drug itself, but rather with its administration via IV push. Even though Phenergen-maker Wyeth and the FDA knew the IV push created a risk of inadvertent arterial injection and gangrene, the FDA approved labeling for Phenergen that warned against — but didn't prohibit — IV push administration.

Levine claimed common-law negligence in Washington Superior Court against Wyeth, claiming Phenergen's labeling was inadequate. "All they had to do was change the label and say, 'Don't give it this way,' " Levine told the *New York Times*.

Wyeth argued the warning label use was mandated by the FDA. Partly because the court told jurors they could consider the FDA's approval of the label when making their negligence determination, the 2005 trial resulted in a jury award of \$6 million for Levine; Wyeth appealed.

In October 2006, the Vermont Supreme Court upheld the ruling 4-1, stating that because a provision of the FDCA (Food Drug & Cosmetic Act) says FDA approval isn't required to strengthen warnings, Wyeth could comply with both state and federal law.

Wyeth petitioned for certiorari, asking the court to review the "basic and fundamental doctrinal errors" made by the Vermont Supreme Court in its application of conflict preemption principles. By the court's invitation, the Solicitor General filed a brief recommending the court decide *Riegel* before rendering its decision on the *Wyeth* certiorati petition, since issues overlapped in both cases. However, several weeks before the *Riegel* decision, the court granted certiorari.

Building Momentum

The *Wall Street Journal* calls the Wyeth case "the mother of all preemption cases."

"Next, we'll see lawsuits against auto companies when someone has an accident going 90 miles per hour," wrote Jim McMahon on the *WSJ* Health Blog. "The suit will charge that the company should not have built a car capable of going so fast."

Stacey Lynch rebutted, "This suit isn't ridiculous and hopefully none of you posting negative comments about this woman and her lawyers will ever need a trial lawyer because you'll never be a victim of corporate greed."

Merrill Matthews, Jr., PhD, a resident scholar at the Institute for Policy Innovation, said the outcome of Wyeth could change how drugs are regulated in America.

"If the Supremes rule against Wyeth," said Matthews, "local juries and trial lawyers could become the de facto authority on drug safety in the United States."

The justices will determine whether the principle of preemption applies in matters of drug safety. (Preemption holds that federal law supersedes state law when there's a conflict between the two.)

"The FDA is well-suited to balance concerns about the risks and benefits associated with a drug," explained Matthews. "If trial lawyers are suddenly able to second-guess the decisions of the FDA, we'll see a huge up-tick in the number of lawsuits against drug manufacturers."

Lawsuits are expensive enterprises, emphasized Matthews.

"Even the threat of litigation can cause a company to pull its products from the market. Plus, the decision could ultimately affect whether other industries are subject to lawsuits when a manufacturer has posted, and the federal government has approved, relevant warnings about its product."

Matthews pointed to a *National Enquirer* article that erroneously linked the anti-nausea drug Bendectin to birth defects. As a result, the drug's manufacturer was forced to pull the product from pharmacy shelves. Consequently, hospital admissions for morning sickness doubled. No evidence ever emerged to back up the allegations against Bendectin.

"Without preemption, patients would lose access to necessary medicines and research into new cures would grind to a halt as drug-makers girded themselves for protracted legal battles," Matthews said. "Let's hope the Supreme Court finds in favor of patients, not trial lawyers, by affirming preemption."