

September 19, 2008

The New York Times

Drug Label, Maimed Patient and Test for Court

By [ADAM LIPTAK](#)

MARSHFIELD, Vt. — When Diana Levine starts talking about her rock 'n' roll days, she plays a little air guitar, mimicking the way she used to handle her electric bass in bands like the Re-Bops and Duke and the Detours. But Ms. Levine is missing much of her right arm, which was amputated below the elbow after a medical disaster.

She sits at her kitchen table, strumming an imaginary guitar with a phantom hand.

In November, the Supreme Court will hear arguments about whether Ms. Levine may keep more than \$6 million that a [Vermont](#) jury ordered Wyeth, a pharmaceutical company, to pay her for failing to warn her adequately about the risks of one of its drugs. The case, the latest in a brisk parade of similar ones, will help define the contours of a signature project of the Roberts court.

In legal jargon, the cases concern "pre-emption," a doctrine that can bar injured consumers like Ms. Levine from suing in state court when the products that hurt them had met federal standards. The issue is less boring and more consequential than it sounds, and Ms. Levine's case is shaping up to be the most important business case of the term.

"Federal pre-emption is the fiercest battle in products liability law today," said Catherine M. Sharkey, a law professor at [New York University](#). "The court clearly recognizes this, as it has agreed to hear so many cases and seems eager to give clarity to what has been, to date, an undisputably muddled area of law."

A second pre-emption case, this one concerning cigarette labels, is scheduled for the first argument of the new term, on Oct. 6.

Business groups, often supported by the Bush administration, have vigorously pursued pre-emption arguments, hoping to build a barrier against many kinds of injury suits. Plaintiffs' lawyers oppose broad pre-emption doctrines, saying they short-circuit valid claims arising from terrible injuries.

Ms. Levine is a trim, elegant 62-year-old who now favors three-quarter length sleeves, just long enough to cover what remains of her right arm. But she gestures enthusiastically with both arms, and she retains a playful side.

Her house is jammed with whimsical toys — a papier-mâché giraffe, an enormous telephone receiver. In the control room of her recording studio, there is a copy of "Hand, Hand, Fingers, Thumb," a children's book. "It's just sarcasm," she explained.

In the spring of 2000, suffering from a migraine, Ms. Levine visited a clinic near here for a treatment she had received many times: Demerol for the pain and Wyeth's drug Phenergan for nausea.

"Nothing wrong with either drug," Ms. Levine said. "They're both safe when given the right way."

But if Phenergan is exposed to arterial blood, it causes swift and irreversible gangrene. For that reason, it is typically administered by intramuscular injection. According to Ms. Levine's lawyers, using an intravenous drip is almost entirely safe as well.

This time, though, a physician's assistant used a third method. She injected the drug into what she thought was a vein, a method known as "IV push." But the assistant apparently missed.

In the following weeks, Ms. Levine's hand and forearm turned purple and then black, and they were amputated in two stages.

The drug's label, approved by the [Food and Drug Administration](#), had warned that "inadvertent intra-arterial injection" can result in "gangrene requiring amputation." But it did not rule out administration of the drug by IV push.

Ms. Levine said no one had discussed the risks of IV push with her, or the only benefit generally associated with intravenous administration — "more potent and expeditious antinausea relief," in the words of Wyeth's brief.

"The benefit-risk is just outrageously ridiculous," Ms. Levine said. "Any child could figure this out."

Faster nausea relief, she said, is not worth the risk of losing an arm.

Ms. Levine settled a lawsuit against the clinic, and she went to trial in Montpelier, not far from here, against Wyeth. She said Wyeth should have added a stronger warning to the label that the F.D.A. had approved.

"All they had to do," Ms. Levine said, "was change the label and say, 'Don't give it this way.'"

Lawyers for Wyeth said that was not an option, at least in the absence of new information. "Wyeth could not change Phenergan's labeling to comply with Vermont law without violating federal law," they wrote in a brief. Ms. Levine's lawyers disagreed, saying that tougher warnings were always permissible.

That is the crux of the issue. Do the F.D.A. and other federal regulators set minimum safety standards that states are free to augment? Or do they make judgments about the optimal balance between risks and benefits that states must follow?

In February, in *Riegel v. Medtronic*, an eight-justice majority of the Supreme Court ruled that many suits concerning injuries caused by medical devices were pre-empted by a 1976 federal law, in so many words. Ms. Levine's suit represents the next frontier.

"Riegel boiled down to statutory interpretation," said Professor Sharkey, of N.Y.U. "Levine challenges the court to define the parameters of pre-emption outside the safe confines of the legislators' text."

The law at issue in the Levine case does not expressly require pre-emption. Rather, Wyeth and the F.D.A. argue that the company could not comply with both federal law, given its requirement that the agency approve drug labels, and the jury's verdict, which punished Wyeth for not using a different one. That conflict, they say, amounts to "implied pre-emption."

The Vermont Supreme Court rejected that argument and upheld the jury's verdict in 2006. Federal law, the majority ruled, "provides a floor, not a ceiling, for state regulation."

Chief Justice Paul L. Reiber, who dissented, wrote: "No drug is without risks. The F.D.A. balances the risks of a drug against its benefits to maximize the availability of beneficial treatments.

"A jury does not engage in a measured and multifaceted policy analysis. Rather, a jury views the safety of the drug through the lens of a single patient who has already been catastrophically injured."

But Ms. Levine said that the jury in her case was careful and conscientious and that Vermonters were not noted for their financial profligacy. The award the jury gave her, she said, was the result of a hard look at a grave wrong.

"I'm a musician," she said. "For me, it's catastrophic because it took away my whole livelihood, my whole way of expressing myself. They lopped off my hand, and they leveled my career. And it didn't have to happen."



Nathaniel Brooks for The New York Times

Diana Levine lost part of an arm after being given a drug. A jury ordered Wyeth, a pharmaceutical company, to pay \$6 million.