



TO: Editorial Page Editors and Writers
FROM: Thomas McGarity & Nina Mendelson, CPR Member Scholars
RE: *Wyeth v. Levine*: A key victory for patients and consumers
DATE: Friday, March 6, 2009

The U.S. Supreme Court's ruling on Wednesday in *Wyeth v. Levine* was a victory for consumer protection and a rebuke of backdoor efforts to deny citizens their right to hold companies accountable for wrongdoing. The decision is a reminder of the importance of state tort law in protecting patients and consumers, protections we should not let slip away.

The case was brought by Diana Levine, a professional guitarist from Vermont who lost an arm due to an improperly administered drug. The manufacturer, Wyeth, warned on the drug's label that administering it by the "Push IV" method was risky, but did not instruct doctors against using the technique. Diana Levine paid the price. Wyeth argued in court that because the FDA had approved the drug's label, the company could not be liable for failing to warn of the risk -- that the FDA's action "preempted" state tort law. The Supreme Court rightly found otherwise, noting that Wyeth knew of the significant risks, and it could and should have changed the label to meet its obligation to warn the public.

The six justices in the majority recognized several of the key reasons for ensuring that consumers retain the right to sue in court for damages from a faulty product, in this case a drug:

- "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly."
- "The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge."
- Individual tort suits "serve a distinct compensatory function that may motivate injured persons to come forward with information."
- Even the FDA has long believed that state tort suits provided a beneficial check for safety.

When Congress wrote the law that guides the FDA pharmaceutical regulation, it steered clear of explicitly preempting state tort laws. The message from the *Wyeth* ruling is that if Congress had wanted to preempt state tort laws, it needed to say so. The Court affirmed that a federal agency like the FDA can't simply preempt a state law on the strength of its own assertion.

Wyeth v. Levine is a victory to be celebrated, but hardly the end of the story in the battle over preemption, and that's why we hope you'll find space on your editorial pages for the issue. This case was one in a series of attempts by manufacturers (not just pharmaceutical companies) to

weaken consumer protections by effecting what amounts to backdoor tort “reform.” It won't be the last such attempt.

If you'd like more information, please contact Ben Somberg in the Center for Progressive Reform's media office at 202-658-8129, or by email at bsomberg@progressivereform.org.

Thanks very much for your consideration.

Some resources that might be of use:

- The Court's opinion: <http://www.supremecourt.us/opinions/08pdf/06-1249.pdf>
- CPR's scholarship on preemption issues: <http://www.progressivereform.org/preemption.cfm>
- CPR's “Truth About Torts” series: <http://www.progressivereform.org/torts.cfm>
- Information on Thomas McGarity's book, *The Preemption War: When Federal Bureaucracies Trump Local Juries*: <http://www.progressivereform.org/preemptionwar.cfm>

The Center for Progressive Reform is a nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. Visit CPR on the web at www.progressivereform.org. CPR Member Scholar Thomas McGarity is a professor of law at the University of Texas. CPR Member Scholar Nina Mendelson is a professor of law at the University of Michigan.