



TO: Editorial Page Editors and Writers
FROM: Thomas McGarity, Member Scholar, Center for Progressive Reform
RE: FDA and Preemption of State Tort Laws: *Wyeth vs. Levine*
DATE: October 29, 2008

On November 3, the U.S. Supreme Court will hear oral arguments in a case that could provide a boost to the Bush Administration's ongoing backdoor effort to protect industry from litigation over defective products – "tort reform," as its backers call it. The case before the Court involves a Vermont woman who sought medical treatment for migraine headaches, but ended up having an arm amputated because a pharmaceutical company had inadequately labeled an anti-nausea drug.

At its core, *Wyeth v. Levine*, is about whether the Food and Drug Administration's labeling requirements preempt state tort law, under which Diana Levine, a professional guitarist, brought her suit against Wyeth, a pharmaceutical company that manufactures Phenargen, an anti-nausea medicine. Eight years ago, Levine went to a clinic with a migraine, and received an injection of the drug. The drug's label cautioned that one method for administering the drug – the so-called "Push IV" method of direct injection into a vein – was risky because of the danger that the drug could be injected into an artery instead of a vein. But the label did not instruct doctors *not* to use the technique. Indeed, Wyeth knew well that the potential hazards of direct injection were serious: if the drug hit a vein – as it did in Levine's arm – it could kill tissue, forcing amputation or worse. Nevertheless, rather than instructing health care providers to use the safer intravenous drip method, Wyeth's label only cautioned care. The worst happened, and Levine's arm had to be amputated.

She sued Wyeth over its failure to provide adequate warning of the dangers of the drug, and in court, Wyeth argued that because its label had been approved by the FDA, it could not be sued under state tort law. Indeed, Wyeth further maintains that it could not legally have distributed the drug with any additional labeling information, without prior approval from FDA. Not only were medical professionals adequately warned, the company maintains, but warning them more explicitly would have violated the law.

The argument that Wyeth cannot be sued for using an FDA-approved label relies on a misreading of the law – but it is a misreading the Administration has promoted, and toward which the Supreme Court majority has shown some sympathy. The relevant law is the Federal Food, Drug and Cosmetic Act, which gives FDA authority to approve drugs for use in the market. Nothing in the now 70-year-old statute suggests that it preempts state tort laws, and FDA has long expressed the view that it did not. Neither has Congress seen fit to expand FFDCA law to preempt tort laws. In fact, when

Congress debated the 1938 Act, it considered creating a federal claim for damages, but was dissuaded at least in part on the argument that state law already permitted such actions.

That made good policy sense then, and still does today. The FDA is underfunded and overextended. Its information is imperfect, reliant as it is on industry to identify relevant safety issues and to provide data on them. Simply put, manufacturers know more about their products than the FDA does or ever will. Those that choose to hide or avoid taking action to protect consumers from hazards their products pose ought not be able to hide behind the FDA's skirts.

Civil litigation creates a powerful disincentive for such corporate misbehavior. It helps hold manufacturers accountable and provides victims with an opportunity to receive some compensation for the harm done to them.

In the case of *Wyeth vs. Levine*, for example, Ms. Levine's career as a guitarist is effectively over because Wyeth made a decision not to issue a stronger warning label. Contrary to its assertions in court, it is not only permitted but required to provide additional warnings to doctors when it learns that its products have such possible adverse consequences; it must seek approval concurrently.

That notwithstanding, FDA now takes the position that its label approvals preempt state tort laws. If regulatory agencies were perfect, common law liability might be unnecessary. A long record clearly indicates otherwise. And, more specifically, if FDA were perfect, Wyeth's label would have carried an adequate warning.

Ms. Levine deserves compensation. Wyeth deserves to be held accountable. Americans deserve the protection from such corporate irresponsibility that litigation helps provide.

I hope you'll find space on your editorial pages for this important issue. If you'd like more information, please feel free to contact Matthew Freeman in the Center for Progressive Reform's media office at 301-762-8980, or by email at mfreeman@progressivereform.org.

Thanks very much for your consideration.