



# COUGHLIN DUFFY LLP

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## Supreme Court Hears Preemption Arguments in *Wyeth v. Levine*

On November 3, 2008, the Supreme Court of the United States heard oral argument in *Wyeth v. Levine*, a case that many legal commentators have described as having the potential to reshape the landscape of pharmaceutical litigation in the United States. The issue before the Court was whether Food and Drug Administration ("FDA") approval of a drug's label preempts state tort "failure to warn" claims alleging that the labeling was inadequate. Questions asked by the various Justices, combined with the general tenor of the argument, suggest that a split Court may find in favor of a narrowly-defined form of preemption.

The facts of *Levine*, although tragic, are straight-forward. Diana Levine developed gangrene in her right arm, which was eventually amputated at the forearm, after receiving an intravenous injection of Phenergan, an anti-nausea medication manufactured by Wyeth. Phenergan was injected into Levine's right arm via the IV-push method, whereby medication is injected directly into the patient's vein. Unfortunately, the needle penetrated one of Levine's arteries, causing gangrene to develop and leading to the amputation of her forearm.

Levine sued Wyeth in Vermont state court for its alleged failure to remove from Phenergan's label IV-push as an acceptable method of administration. According to Levine, the benefit of IV-push – faster alleviation of nausea – is far outweighed by the risk of gangrene and amputation posed by improper administration of the drug. Wyeth defended the claim by arguing that the Phenergan label, which was FDA approved, clearly warned of the risks associated with IV-push administration, including the risk of arterial injection leading to gangrene and amputation. Further, Wyeth argued that FDA approval of a drug and its labeling preempts state tort lawsuits alleging failure to warn. A jury award of nearly \$7 million in favor of Levine was affirmed by the Vermont Supreme Court in October 2006. Wyeth appealed the verdict to the Supreme Court of the United States.

During argument before the Supreme Court, Seth P. Waxman, counsel for Wyeth, argued that FDA approval of a pharmaceutical drug's label preempts state tort lawsuits that allege the label was inadequate. Mr. Waxman argued that to conclude otherwise would place a pharmaceutical company in an impossible situation: either it

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follows federal law and uses the FDA-approved label or it conforms to state tort law and adds additional warnings that were not approved by the FDA. Certain Justices did not seem convinced by Wyeth's argument. Specifically, the questions and tones of Justices John Paul Stevens, David Souter and Ruth Bader Ginsburg suggest they will likely find that FDA approval does not preempt state tort lawsuits questioning the adequacy of FDA-approved labels. Justice Ginsburg's position is not surprising in light of her dissenting opinion in *Riegel v. Medtronic, Inc.*, a Supreme Court decision issued earlier this year in which the Court found in favor of preemption of state product liability claims involving FDA-approved medical devices.

David C. Frederick argued on behalf of Levine against preemption of state tort claims. Justice Antonin Scalia asked Mr. Frederick a series of questions regarding whether the fact that the FDA-approved label allowed for IV-push as a method of administration demonstrates that the FDA considered the risks and benefits associated with IV-push and concluded that it was an allowable method of administration. Mr. Frederick disputed whether the FDA actually conducted a risk-benefit analysis specifically for IV-push, which he argued is necessary before a failure to warn claim may be preempted. Mr. Frederick agreed with Justice Samuel Alito that if the FDA, after consideration, determined that IV-push should not be contraindicated, and then approved the current label, Levine's claim would be preempted.

Our impressions at oral argument, the questions asked by the various Justices, and the Justices' prior positions on similar issues, lead us to believe that the Court will likely be split on the issue of preemption and may narrowly find in favor of preemption based on the specific facts at issue in *Levine*.

The tenor of the questions suggests that Justices Ginsburg, Stevens and Souter oppose preemption. Justice Scalia, who wrote the majority opinion in *Riegel*, will likely rule in favor of preemption. He will likely be joined by Chief

Justice John Roberts and possibly Justice Alito. Although Justice Anthony Kennedy seemed to be leaning against preemption, he may be persuaded to join in a narrowly-reasoned decision in favor of preemption. Justice Stephen Breyer may be similarly persuaded. Finally, Justice Clarence Thomas did not ask any questions, as is his custom. However, Justice Thomas often votes with Chief Justice Roberts and Justice Scalia and may vote in favor of preemption.

There is therefore a distinct possibility that the Supreme Court will find in favor of preemption of state tort actions alleging failure to warn in narrowly-defined cases in which the FDA has already considered evidence presented by the pharmaceutical company regarding the specific potential injury suffered by the patient. However, it is likely that this decision will result in a split in the Court and be accompanied by a powerful dissent against preemption.

Regardless of the Court's ruling, *Levine* is not likely to end all state tort actions against drug manufacturers. Both sides in *Levine* agree that lawsuits against pharmaceutical companies alleging withholding of information from the FDA are not preempted. Moreover, lawsuits against manufacturers who promoted "off label" use of their products or failure to warn claims involving unapproved drugs would similarly not be preempted.

The results of this year's presidential and Congressional elections will likely also have a significant impact on the preemption landscape. With the Democrats maintaining their Congressional majority, it is likely we will see attempts to enact legislation overturning or limiting any preemption decision. In fact, the United States House of Representatives Committee on Oversight and Government Reform held hearings earlier this year in connection with this very issue. The Supreme Court's decision in *Levine* will be issued before the end of its current term.

Should you have any questions or comments regarding this matter, please feel free to contact us.