

FDA Protection Removed

The Impact of Wyeth v. Levine and the future of Pharma Product Liability Defense



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The Food and Drug Administration (FDA) regulates drug warning labels to ensure that drugs are safe for public distribution. However pharmaceutical companies have used the FDA's role as a shield in product liability lawsuits brought against them in state courts with the argument that drug safety questions are a matter for the federal government to decide.

Earlier this year the U.S. Supreme Court removed this common defense in the case of *Wyeth v. Levine*. The defense is called *federal pre-emption* and has led to several cases being thrown out of state courts before they go to trial. In this March 2009 case, the defense was rejected by the Supreme Court and the decision will likely lead to a widespread impact on how pharmaceutical manufacturers label their products and interact with the FDA going forward.

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Case Details

This case started when the claimant went to a local clinic for treatment for a migraine. The patient, Diane Levine of Vermont, was given an injection of an anti-nausea drug manufactured by Wyeth called Phenergan. The drug caused an infection and she was forced to have her forearm amputated. Ms. Levine then sued Wyeth in state court in common law negligence and strict liability, claiming that Wyeth's warnings for the drug were inadequate.

The warning label on the drug stated that the drug could cause gangrene, but it did not warn that the one method of administering, "IV-push" administration, could substantially increase the risk of intra-arterial administration resulting in gangrene.

Supreme Court Narrows Preemption

Wyeth's argument was that Ms. Levine's state law claims were pre-empted by federal law and they could not be sued under state law because the FDA had approved Phenergan's warning label, and could not unilaterally change the label. Wyeth argued that changing the warning labels to satisfy state law would have frustrated Congress's purpose in establishing the FDA as the authority on drug regulation across the U.S.

The Supreme Court said that Wyeth could have strengthened its label warnings immediately after learning that the IV-push method of providing Phenergan (as opposed to the "IV-drip" method) increases a patient's risk of developing gangrene. Wyeth could have changed its labels immediately without seeking FDA approval through the changes being effected regulation. There was no evidence in *Wyeth* that the FDA would have rejected any such modification to its label

for Phenergan. Ultimately, Wyeth had a duty to communicate the risks associated with its product.

The Court also rejected Wyeth's contention that permitting state-based liability would impede Congress' objectives in passing the federal drug laws and in vesting implementation authority with the FDA. The Court concluded that Congress did not intend FDA oversight of drug safety to supplant state tort liability rules and that Congress, the FDA and the courts historically regarded state law as a complementary form of drug regulation.

Potential Insurance Implications

The Wyeth case is of particular importance to insurers who provide product liability coverage for pharmaceutical companies, since *federal pre-emption* has been one of the main ways in which these companies have been able to settle claims without going to trial.

Wyeth does not technically create any new liability risk, but the removal of this defense creates the expectation that plaintiff lawyers will feel emboldened by the decision, will increase the prospect of cases reaching trial, and could result in increased insurers' exposure to defense costs, settlements and indemnities.

More specifically, according to the decision, Wyeth could have re-analyzed its accumulated adverse drug reaction data and decided to take the initiative themselves to add warnings, and they did not. Wyeth asserted a fear of the product being considered misbranded if they did re-label. The court rejected this argument because it is a question of fact, and the regulation would have allowed unilateral changes. When and if the FDA rejected the addition, Wyeth would not have a misbranded product as long as they complied with any subsequent FDA decision. This rationale suggests that the result won't be any more favorable to *pre-emption* in future cases. While individual facts of any case can determine how an insurance policy may respond, a possible take away from this case is that insurers may ask what an insured does with accumulated data. One aspect of the underwriting process going forward could be to consider how insurers develop and evaluate data and consider what they do to communicate changes in risk to those prescribing or consuming the product.

According to [Joseph G. Blute](#), attorney with the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo LLC, a pharmaceutical manufacturer can still raise pre-emption as a defense to a state tort claim if it can establish that the FDA considered and expressly rejected a particular warning or if the FDA mandated the particular label language at issue in the tort suit.

Given the reasoning in *Wyeth*, **pharmaceutical manufacturers should document all discussions with the FDA concerning labeling.** In addition, given *Wyeth's* emphasis on a drug manufacturer's control of its label and its duty to update that label based on new information, **drug manufacturers should react promptly to new safety information with revised labeling, and document the rationale for any decision not to change a label.**

And finally, manufacturers' regulatory personnel must be particularly careful to document disagreements with the FDA about labeling language, especially where the manufacturer and the FDA have competing positions about specific label language.

For more information regarding risk management issues for pharmaceutical companies, contact the Life Sciences Practice at William Gallagher Associates or your WGA Account Executive at info@WGAins.com.

