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THE IMPLICATIONS OF THE *WYETH V. LEVINE* DECISION

On March 4, 2009, in a long-awaited decision, the U.S. Supreme Court ruled that [patients](#) who are injured by a drug *can* sue the drug's manufacturer for damages, even if the drug has been granted Food and Drug Administration (FDA) approval. The ruling has become quite controversial because the decision turned on the long-standing question of “pre-emption,” whereby federal regulations generally trump state actions.

FACTS OF THE CASE

The Petitioner, Wyeth, manufactures an anti-nausea drug, Phenergan. The labeling on this drug had previously been approved by the FDA.

During the course of medical treatment for a migraine, the Respondent, Levine, was injected with Phenergan by an “IV-push” method, which injects the drug directly into the patient’s vein. As a result of being administered with the drug by this method, Levine developed gangrene in her forearm, which was subsequently amputated.

After settling claims against the health center and clinician, Levine brought a state-law damages action against Wyeth, alleging that Wyeth had failed to provide an adequate warning about the significant risks of administering Phenergan by the “IV-push” method. Levine brought her action for damages against Wyeth, relying on common-law negligence and strict-liability theories.

Although Phenergan’s label warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that the labeling was defective because it failed to instruct clinicians to use the “IV-drip” method of intravenous administration instead of the higher risk “IV-push” method. More broadly, she alleged that Phenergan is not reasonably safe for intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug’s therapeutic benefits.

THE LOWER COURT'S RULING

After hearing the evidence, the jury found (1) that Wyeth was negligent, (2) that Phenergan was a defective product as a result of inadequate warnings and instructions, and (3) that no intervening cause had broken the causal connection between the product defects and the plaintiff's injury. The jury awarded total damages of \$7.4 million, which the court reduced to account for Levine's earlier settlement with the health center and clinician.

After the trial, Wyeth filed a motion for judgment as a matter of law. The trial court denied Wyeth's motion, rejecting Wyeth's pre-emption arguments. The trial court determined that there was no direct conflict between FDA regulations and Levine's state-law claims because those regulations permit strengthened warnings without FDA approval on an interim basis and the record contained evidence of at least 20 reports of amputations similar to Levine's since the 1960's. The court went on to say that state tort liability in this case would not obstruct the FDA's work because the agency had paid no more than passing attention to the question whether to warn against "IV-push" administration of Phenergan. In addition, the court noted that state law serves a compensatory function distinct from federal regulation.

The Vermont Supreme Court upheld the trial court's decision.

THE SUPREME COURT DECISION

Wyeth filed a petition for certiorari with the United State Supreme Court. The Supreme Court granted the petition on the issue of whether the FDA's drug labeling determinations pre-empt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.

Wyeth made two separate pre-emption arguments: (1) that it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law and (2) that recognition of Levine's state tort action creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress because it substitutes a jury's decision about drug labeling for the expert judgment of the FDA.

In the Supreme Court's Opinion, written by Justice Stevens, the Court made clear that it is unrealistic to expect the FDA to have close oversight over every specific label that gets put onto a drug vial or medical device and placed the burden of ensuring label accuracy in the hands of manufacturers.

The Supreme Court rejected Wyeth's first argument, saying that it based upon a "cramped reading" of the FDA regulations and that Wyeth could have strengthened the warnings and then sought retroactive FDA approval. With regard to Wyeth's second argument, the Supreme Court stated that there was "no merit in this argument," which was based on "an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law."

The opinion concluded by saying, “It is not impossible for Wyeth to comply with its state and federal law obligations and that Levine’s common-law claims do not stand as an obstacle to the accomplishment of Congress’ purposes in the FDCA. Accordingly, the judgment of the Vermont Supreme Court is affirmed.”

WHAT EFFECT WILL THIS DECISION HAVE?

The obvious effect of the Supreme Court’s ruling will likely to lead to a rash of similar lawsuits around the country (assuming the relevant state laws allow for it). In the past, attorneys may have rejected cases similar to Levine’s based upon the assumption that compliance with the FDA labeling requirements would trump any state claim of inadequacy. Under the *Levine* decision, manufacturers will now be held accountable for including all necessary warnings, even if they have previously obtained FDA approval without the same.

In addition, although this decision is relatively narrow in that it only evaluated the question of pre-emption with regard to the FDA labeling regulations, there is no doubt that the Supreme Court’s decision in *Levine* will be relied upon in the future for arguments against the pre-emption of state claims by other governmental regulations.

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