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# Health Industry Online

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## You Can't Heed What You Don't Read - U.S. Supreme Court - *Wyeth v. Levine*

This much-anticipated opinion has put to rest a hotly contested issue of whether the FDA or a jury decides if a product label sufficiently warns physicians of a product's risk. By this case, the U.S. Supreme Court has placed the decision of how much warning a product label should contain in the hands of lay juries. *Levine* concerned Phenergan, an injectable medication used to treat nausea. At issue was the sufficiency of a warning that an "IV-push" method of administration - where the drug is injected into the patient's vein - presented a risk that the drug will enter the patient's artery and cause irreversible gangrene. Levine received an IV-push injection, the product entered an artery, she developed gangrene and lost her right forearm and her livelihood. The Court observed that "the physician's assistant who treated [Levine] ...disregarded Phenergan's label and pushed the drug into a single spot on her arm that is *most* likely to cause inadvertent intra-arterial injection." "When asked why she ignored Phenergan's label and failed to stop pushing the drug after [Levine] complained of burning pains, the physician's assistant explained that it would have been 'just crazy' to 'worr[y] about an [intra-arterial] injection...."

The question *Levine* answered was whether the FDA's drug labeling judgment "preempts state law products liability" claims and how much deference, if any, should be accorded to FDA judgment. According to the *Levine* Court, different labeling judgments are necessary to make drugs safe; the FDA determines the minimum, or floor, for the warnings that must be provided, and lay juries decide if the FDA approved warning is sufficient.

History has shown and *Levine* demonstrates that, while all medications are capable of producing adverse outcomes to some patients, the risk of harm increases when medical practitioners are not familiar with product labeling or they do not use the products as intended. After all, had the

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medical provider in *Levine* simply read and heeded the Phenergan labeling, another topic would occupy this newsletter. Yet the Vermont jury and the Supreme Court believe that had the label contained more warning, Ms. Levine would not have been injured. The Court missed an important opportunity to address the real issue of patient safety. Under the facts in *Levine*, it simply did not follow that a physician's assistant who was unaware of the current labeling could have avoided injury to Ms. Levine if the label had listed enhanced warnings. The much-anticipated *Levine* U.S. Supreme Court opinion will have profound and long-term implications for industry and litigants alike as manufacturers struggle to comply with both the requirements of federal law and the subjective requirements lay juries may impose.



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