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Wyeth v. Levine: Expanded Liability for Pharmaceutical Manufacturers?

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In *Wyeth v. Levine* the Supreme Court held that federal law did not pre-empt the plaintiff's state law claim for failure to warn. More specifically, the Supremes rejected Wyeth's argument that Levine's failure-to-warn claims were pre-empted by federal law because the drug labeling had been approved by the federal Food and Drug Administration (FDA).

Facts. Plaintiff Levine suffered from migraines with accompanying nausea. In April 2000, Levine was treated by a physician assistant with Demerol for pain and Phenergan for nausea. The Phenergan was to be administered intravenously by IV push but was inadvertently administered into an artery causing gangrene and the subsequent amputation of Levine's forearm. This tragic turn of events made even worse by the loss of Levine's livelihood as a professional musician.

The label for Phenergan at the time of administration warned that extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. It was known that intra-arterial injection causes pain, severe chemical irritation, severe spasms of distal vessels and resultant gangrene requiring amputation. Further, there was, and still is no proven successful management of this condition after it occurs. The label further provides that intravenous Phenergan should be given in a concentration no greater than 25 mg/ml and at a rate not to exceed 25 mg/minute. In the event that a patient complains of pain during intended

intravenous injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation.

The trial court established that Levine's injury would not have occurred if the Phenergan label had included an adequate warning about the risks of the IV push method of administration. The jury also determined that Levine's injury was foreseeable and found Wyeth negligent as well as strictly liable. The critical defect in the Phenergan label was the lack of an adequate warning about the risks of IV push administration.

Wyeth's Arguments. Wyeth's pre-emption arguments were two. First, that it would have been impossible for the company to comply with the state-law duty to modify Phenergan's labeling without violating federal law. Second, Wyeth argued that recognition of the state tort action created an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA.

The impossibility pre-emption argument was rejected in short because a manufacturer, not the FDA, bears the responsibility for the content of its label. An FDA regulation called the "changes being effected" (CBE) permits a manufacturer to make certain changes to its label before receiving FDA approval. Such changes include changing a



label to add or strengthen a contraindication, warning, precaution, or adverse reaction. Furthermore, the Supremes rejected the notion that the CBE regulation can only be used to reflect newly acquired information. Data previously submitted but newly analyzed can be the subject of a CBE labeling change. Moreover, risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments. Data and conclusions drawn from its interpretation is not static but evolves over time and regulatory mechanisms provide for updating labels and warnings in light of new interpretations.

Wyeth's second argument was that Congress entrusted an expert agency to make drug labeling decisions and that compliance with a state-law duty to provide stronger warnings would obstruct the purpose of that regulation. The company's contention was that the Federal Food, Drug and Cosmetic Act (FDCA) provides that once a drug label was approved by the FDA, state law cannot deem the label inadequate. In support of this contention, Wyeth relied on the preamble to a

2006 FDA regulation in which the FDA declared that the FDCA established both a floor and a ceiling so that FDA approval of labeling preempts conflicting or contrary state law. However, the Supremes rejected the FDA's statement on pre-emption as 'mere assertion' citing Congress's failure to authorize the FDA to pre-empt state law directly.

Take Home Message. Drug manufacturers cannot rely on FDA approved labeling to shield them from state-law claims. The FDA labeling regulations set a 'floor' for labeling but manufacturers must also consider their obligation to warn of hazards, precautions, contraindications and the like from a tort claim perspective. In doing so, manufacturers need to continually evaluate safety and hazard data not only for new trends but also to reinterpret older data in light of subsequent activity. Ultimately, as the Supreme Court has unequivocally stated, the manufacturer is ultimately responsible for its product labels and warnings.

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