

# Third District Court of Appeal

State of Florida, July Term, A.D. 2009

Opinion filed December 30, 2009.  
Not final until disposition of timely filed motion for rehearing.

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No. 3D08-1563  
Lower Tribunal No. 03-9855

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**Armando Valdes, III, etc., et al.,**  
Appellants,

vs.

**Optimist Club of Suniland, Inc., et al.,**  
Appellees.

An Appeal from the Circuit Court for Miami-Dade County, Daryl W. Trawick, Judge.

Hersch & Talisman and Patrice A. Talisman; Donna B. Michelson, and Phillip D. Parrish, for appellants.

Thornton, Davis & Fein and Barry L. Davis and Michael D. Bon, for appellees.

Before RAMIREZ, C.J., and ROTHENBERG, and LAGOA, JJ.

RAMIREZ, C.J.

Armando Valdes, III and his parents, appeal the trial court's entry of final summary judgment in favor of the defendants below, McNeil-P.P.C., Inc. Because we believe the United States Supreme Court's decision in Wyeth v. Levine, 129 S.Ct. 1187 (2009), controls the issue of federal preemption presented in this case, we reverse the trial court's determination.

On April 24, 1999, Armando Valdes, III collapsed during a roller hockey game. He had to be resuscitated at the scene and was then taken to a hospital. Doctors diagnosed him with having suffered a heat stroke and cardio-respiratory arrest which resulted in a brain injury, hypoxic ischemic encephalopathy, and left him completely disabled. On the morning of his collapse, Armando took Tylenol Cold, an over-the-counter medication, for his head cold along with soda. Armando and his parents filed a negligence and products liability suit against McNeil, the manufacturer of Tylenol Cold, as well as the hockey club and equipment vendor, for Armando's injuries.

The Valdeses settled with all the defendants except for defendant McNeil for strict liability and negligent failure to warn. The Valdeses contended that the Tylenol Cold medication, which contains pseudoephedrine, increased the risk of heat-related illness and heart-related risks when ingested with caffeinated products and coupled with strenuous or athletic events in a hot environment like that of

South Florida. They asserted that McNeil's failure to warn of these risks on the labels of the Tylenol Cold packaging breached Florida state law requirements.

McNeil filed several affirmative defenses in its response to the Valdeses' complaint including federal preemption. After discovery, McNeil moved for final summary judgment arguing that federal law, which governs over-the-counter and non-prescription drugs, and the FDA's labeling requirements, which did not require McNeil to include the risk of heat-related illness on the label, preempted the state law claims in the Valdeses' complaint. 21 U.S.C. §379r. The lower court agreed and granted final summary judgment in favor of McNeil. The Valdeses appealed the decision to this Court.

Because this is an appeal from an order of summary judgment and calls for a review of an issue of law, our standard of review is *de novo*. State v. Coney, 845 So. 2d 120, 137 (Fla. 2003).

McNeil argues that federal law that governs the labeling of medication preempts state law requirements and bars state law claims from being brought against it since its label contained the FDA-approved language. The federal statute in question states that no State or political subdivision thereof may establish regulations for drugs different from those required by that chapter of the statute unless one of the listed statutory exceptions applies. 21 U.S.C. §379r(b). The exception at issue, subsection (e), states: “[n]othing in this section shall be

construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.” 21 U.S.C. § 379r(e). McNeil concedes that express preemption does not apply, but argues that implied preemption is applicable here because compliance with both state law and federal law is impossible and, even if not impossible, would frustrate the Congressional purposes and objectives behind the enactment of the statute.

The Court recently decided Wyeth, and the ruling in that case controls our decision here. See Wyeth v. Levine, 129 S.Ct. 1187 (2009). The facts in Wyeth are similar to the ones here, and the arguments made by the prescription drug manufacturer are practically identical to those advanced by McNeil. In Wyeth, the Court found that:

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices ..., Congress has not enacted such a provision for prescription drugs ... Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 1200.

McNeil argues that Wyeth is distinguishable because it dealt with prescription drugs and not over-the-counter medication like those at issue here.

We disagree with McNeil that the distinction carries the weight to allow it to circumvent the reasoning of the Court in Wyeth. After extensively detailing the historical background of the FDCA and amendments to the act, the Court found that the failure of Congress to expressly preempt the field in light of the long history since enacting the FDA leads to the conclusion that state actions like those here “lend force to the FDCA’s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protections that complements the FDA regulation.” Id. at 1202-03. Additionally, the Court, citing to the very statutory exception at issue here, stated in a footnote that the 1997 amendment to the statute “pre-empted certain state requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions. See 21 U.S.C. §§ 379r(e), 379s(d).” Id. at 1200 n.8. This further weakens McNeil’s attempts to distinguish Wyeth from the facts of this case.

Based on the Court’s holding in Wyeth, we conclude that the trial court’s entry of final summary judgment in McNeil’s favor was in error and therefore reverse. The federal law that regulates the labels of over-the-counter medication at issue here expressly saves this type of state law causes of action, and there is no

implied federal preemption that would keep the Valdeses from going forward with their suit against McNeil.

Reversed.