

U.S. Supreme Court Issues Landmark Decision Regarding Pharmaceutical Warnings

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March 4, 2009 marked a dramatic day in medical litigation across the country. On this day, the United States Supreme Court issued its long awaited decision in the watershed case of *Wyeth v. Levine*. In *Wyeth*, the Court held that the manufacturer of a prescription drug could still be sued in state court for alleged defects in the drug's warning label, *even though* that warning label was fully approved by the United States Food and Drug Administration ("FDA"). The legal term of art defining this high-stakes battle is "FDA preemption."

Prior to *Wyeth*, many pharmaceutical and medical device manufacturers argued that so-called "failure to warn" lawsuits should be dismissed because the FDA exclusively governed warning label content – not personal injury lawsuits where lay jurors serve as the arbiter. Hence, such lawsuits were "preempted" by the actions of the FDA. Many such "failure to warn" lawsuits around the country were either dismissed or on hold based on FDA preemption defenses, prior to release of the *Wyeth* decision on March 4th. Now that *Wyeth* has been decided, many lawsuits against pharmaceutical manufacturers will be given new life. Physicians or other health care providers are often sued as co-defendants in such lawsuits, as was the case in *Wyeth*.

Factually, the plaintiff in the *Wyeth* case, Diana Levine, underwent a right forearm amputation following intravenous push administration of Phenergan and subsequent gangrene. The Phenergan either extravasated, or was improperly injected into the patient's artery. Ms. Levine sued the health care clinic and its staff, and the manufacturer of the Phenergan (Wyeth). Ms. Levine settled her claims against the health care clinic and its staff, and proceeded to trial against Wyeth – leading to a \$7.4 million jury verdict in her favor in Vermont state court. This verdict was then appealed by Wyeth through several levels of appellate courts, leading ultimately to the March 4th U.S. Supreme Court decision. The majority decision was issued by Justices Stevens, Kennedy, Souter, Ginsburg, Breyer and Thomas. Justices Alito, Roberts and Scalia dissented.

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