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## Supreme Court Limits Preemptive Effect of FDA Labeling

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et seq. ("FDCA") and its underlying regulations set forth a rigorous procedure that prescription drug manufacturers must follow to obtain approval of their products from the Food and Drug Administration ("FDA"). Included in those approvals is the labeling that the manufacturer is to place on the product. The United States Supreme Court, in *Wyeth v. Levine*, recently held that a manufacturer's compliance with those regulations and the FDA's subsequent approval of the labeling did not preempt a state-court products liability action for failure to warn.

In *Wyeth*, plaintiff, a professional musician, lost her forearm to gangrene when a drug manufactured by defendant Wyeth was not administered properly. Plaintiff argued that the warnings contained on the drug were insufficient. Wyeth argued that the failure to warn claim was preempted by the FDCA because (1) it was impossible for Wyeth to comply with the state court requirement for stricter warnings without violating federal law and (2) allowing state court actions for inadequate warnings would frustrate the federal regulatory scheme. The United States Supreme Court, in a 6-3 decision, rejected those defenses.

Initially, the Supreme Court found that under FDA regulations, a prescription drug manufacturer could provide stricter warnings for a product and then submit such a warning to the FDA for approval. "Impossibility," therefore, was not a defense.

Secondly, and more importantly, the Supreme Court found that allowing state court tort actions based on inadequate warnings on prescription drugs did not frustrate the federal regulatory scheme for such products. In fact, the Court found that Congress, in enacting the FDCA, relied on such actions as an enforcement mechanism for the Act's requirements.

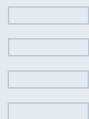
Wyeth had relied on a preamble to a 2006 FDA regulation that declared the FDCA established both a "floor" and a "ceiling" for labeling so that FDA approval of labeling preempted conflicting or contrary state law. The preamble also stated that certain state-law actions, including failure-to-warn claims, threatened FDA's statutorily prescribed role as an expert federal agency. The Supreme Court, however, refused to give any deference to the FDA finding of preemption.

In a discussion that is applicable to any assertion by a federal administrative agency that finds preemptive effect for its regulations, the Supreme Court held that the FDA, prior to the 2006 regulation, had repeatedly taken the position that such state court actions were an important enforcement tool under the FDCA and that FDA approval would not preempt state law tort claims. The FDA failed to provide any justification for the radical change in position. In addition, the Court found that the FDA's assertion of preemption was contrary to the clear Congressional intent that the FDCA not preempt state court tort actions.

The Court distinguished *Wyeth* from *Geier v. American Honda Motor Co.*, where the Court held that Department of Transportation ("DOT") regulations regarding passive restraint systems preempted a state court design defect claim based on Honda's failure to install air bags that the plaintiff claimed were required. The Court stated that in the *Geier* case, the DOT had developed a comprehensive passive restraint policy after extensive studies and formal rule-making.

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That policy had rejected the all airbag system argued by the plaintiff in favor of a gradual phase-in of a mix of passive restraints. The plaintiff's claim that Honda's failure to install the airbags, therefore, presented an obstacle to achieving the variety and mix of restraints sought by the federal regulation.

The Supreme Court found no such problem with the Plaintiff's claim in *Wyeth* and affirmed the Vermont Supreme Court's ruling that the FDCA did not preempt the Plaintiff's claim. ■

## Third Department Declines to Follow Second and Fourth Department's Expansion of the Doctrine of Primary Assumption of the Risk

In *Trupia v. Lake George Central School District*, the Appellate Division, Third Department reversed a decision from the Supreme Court of Warren County that granted the defendants permission to amend their answer to include the affirmative defense of primary assumption of risk following discovery and Plaintiffs' filing of the note of issue. The court determined that while leave to amend a pleading was within the trial court's discretion, the proposed amendment was "devoid of merit."

The Third Department found that the minor plaintiff's act of sliding down a banister of a stairway during a break between classes at summer school was not a "sport or recreational activity" to which the doctrine of primary assumption of the risk would apply. The Third Department recognized that the finding was contrary to recent decisions from the Second and Fourth Departments that have expanded the application of the assumption of risk doctrine beyond sport or recreational activities to include non-athletic activities such as entering a window, teaching a class or jumping off a concrete bench. In straying from these decisions, the Third Department placed emphasis upon the policy behind the doctrine: to "facilitate the free and vigorous participation in athletic activities." The Third Department further noted that the Second and Fourth Department's expansion of the doctrine took an approach more akin to the doctrine of contributory negligence that barred recovery from a defendant due to plaintiff's own negligence, which is no longer available in New York. ■

## Uniform Civil Rules for the Supreme and County Courts are Amended to Address Electronic Discovery

On March 20, 2009, the Chief Administrative Judge of the New York State Unified Court System amended Section 202.12(c) of the Uniform Civil Rules for the Supreme and County Courts to add a new paragraph related to electronic discovery. Under Section 202.12(c)(3), the court during a preliminary conference may now establish the method and scope of any electronic discovery if it deems it is appropriate. This includes, among other things: the method of the retention of electronic data and implementation of a data preservation plan, identification of relevant data and redaction of privileged electronic data, the anticipated cost of data recovery, proposed initial allocation of such cost for data recovery, disclosure of the programs and manner in which the data is maintained and identification of the individual(s) responsible for data preservation. ■

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