# Supreme Court Says Plaintiffs Can Sue Drug Manufacturers Despite FDA's Approval of the Warning Label

In a much-anticipated decision handed down this morning, the U.S. Supreme Court ruled 6-3 that the Food and Drug Administration's (FDA) approval of drug warning labels did not bar state law tort claims alleging that the drug's warning label was not adequate. In this landmark preemption decision, writing for the Court, Justice Stevens concluded that "common-law claims do not stand as an obstacle to the accomplishment of Congress' purpose" in the Federal Food, Drug, and Cosmetic Act (FDCA). Justices Alito and Scalia and Chief Justice Roberts dissented, arguing that "tragic facts make bad law." Significantly, the Court's decision allows state juries to determine whether manufacturers provided adequate warnings on prescription drugs, even after the FDA has cleared the packaging as safe.

The case, *Wyeth v. Levine*, centered on allegations concerning the misuse of a drug made by Wyeth, which resulted in serious and permanent injuries. The plaintiff in the case, Diana Levine, sued Wyeth in Vermont state court under theories of negligence and failure to warn, and a jury awarded her more than $6 million in damages. The Vermont Supreme Court affirmed the judgment, finding no conflict between the jury's decision and the FDA's approval of Wyeth's labeling. According to the court, the FDA set minimum safety standards, which states were free to augment.

This morning, the Supreme Court upheld the decision in Levine's favor. The Court held that in the absence of a direct conflict between state and federal requirements, the FDA's approval of a drug's label does not relieve manufacturers of potential liability in state failure-to-warn claims. The Court noted that regulating drugs through tort law was within states' historical regulatory powers and that the FDA regulations were not so extensive that they preempted all state regulation. Writing for the Court, Justice Stevens noted, "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision during the FDCA's 70-year history." Specifically, and notwithstanding clear language articulated by the FDA, the Court rejected reliance on the preamble to the 2006 regulation governing the content and format of prescription drug labels as a basis for preemption on several grounds, including the opinion that the preamble is at odds with the agency's long-standing position on this defense.

It was on these grounds that the Court distinguished its earlier decision, *Riegel v. Medtronic*, which shielded medical device makers from similar state law negligence claims. Central to the Court's holding was the fact that Congress had not expressly foreclosed state law claims against drug manufacturers, as it had done for medical device manufacturers. Thus, according to the Court, states remain free to effectively impose more stringent safety standards through tort law so long as they do not directly conflict with the FDA's regulatory requirements.

Because the Court's decision leaves plaintiffs with fairly robust state court remedies, it is unlikely that today's decision will prompt proposals for legislative action such as those that followed *Medtronic*. Several lawmakers are currently considering reintroducing a bill that would effectively reverse the Court's decision in that case, allowing injured plaintiffs to once again pursue their negligence claims against device manufacturers in state court. Conversely, legislative action establishing preemption for FDA-approved drug labeling appears to be unthinkable in the current Congress.

In considering the preemption issue, the Court focused on recent amendments to the FDCA, which are likely to have a profound impact on the pharmaceutical industry's practices regarding prescription labeling. Citing both the Food and Drug Administration Amendments Act of 2007 and the Changes Being Effected regulations, the Court focused responsibility on pharmaceutical manufacturers to analyze "newly acquired information" and to engage in "new analyses of previously submitted data" in assessing the adequacy of their products' warning labels. Companies will need to continue to be active in monitoring such information and data as marketing continues and to maintain ongoing communication with the FDA.

For more information on the *Levine* decision, you should consult with your regular Ropes & Gray attorney.