
In 2009 in Wyeth v. Levine [3] the Supreme Court held that federal law preempts state law failure to warn claims that a drug manufacturer failed to change a drug label if there is “clear evidence” the Food and Drug Administration (FDA) would not have approved the label change. In Merck v. Albrecht a unanimous Supreme Court held that a judge rather than a jury determines if the FDA would have approved the change.

The federal Food, Drug, and Cosmetic Act (FDCA) provides no federal remedy for unsafe and ineffective drugs but state law may in the form of a failure to warn claim. The FDA allows manufacturers to change warnings on drug labels when newer drug safety information becomes available. The Supreme Court has held if the FDA would not have approved a drug label change, which a state failure to warn law would have required, the FDCA preempts the state law claim.

In this case more than 500 people who took Fosamax suffered atypical femoral fractures between 1999 and 2010. They claimed that Merck, the drug manufacturer, violated state law by failing to include a warning on the drug label until 2011.

Merck claimed that their state law claims are preempted because the FDA would not have approved a change to the label warning about atypical femoral fractures until 2011.

Both Merck and the FDA knew from the time the drug was approved in 1995 that it could theoretically cause atypical femoral fractures. But, according to Merck, until 2011 “both Merck and the FDA were unsure whether the developing evidence of a causal link between Fosamax and atypical femoral fractures was strong enough to require adding a warning to the Fosamax drug label.” And in 2008 and 2011 the FDA rejected Merck’s suggestion to add warning language about “stress fractures” for different reasons.

The Third Circuit held that it is for a jury to decide whether the FDA, “in effect, has disapproved a state-law-required labeling change,” in which case the state law claims would be preempted. The Supreme Court disagreed in an opinion written by Justice Breyer. According to the Court, this question is a legal one for a judge and not a jury. “The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute. Moreover, judges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency’s determination.”

While juries are unpredictable they have a reputation for being more favorable to injured individuals than large, well-funded corporations. For this reason juries may be more likely than judges to conclude that the FDA would have agreed to the label change because such a ruling will make it possible for a state-law failure-to-warn claims to go forward.

Interestingly, Chief Justice Roberts and Justice Kavanaugh joined an opinion written by Justice Alito concurring only in the judgment (not the reasoning) of the majority opinion. Justice Alito agreed that
“whether federal law allowed Merck to include in the Fosamax label the warning alleged to be required by state law is a question of law to be decided by the courts, not a question of fact.” But he criticized the Court’s opinion for containing a “misleading” discussion of the facts and the law. Instead of articulating alternative reasons for coming to the same bottom line conclusion as the majority opinion, as most concurring opinion do, Justice Alito’s opinion instead critiqued numerous aspects of the majority opinion’s discussion of the law and the facts of the case.

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