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SCOTUS Opinion: Court Clarifies "Clear Evidence" Standard For Failure-To-Warn Claims

20 May 2019

Merck manufactured the drug Fosamax to combat osteoporosis in postmenopausal women. Merck's scientists theorized that use of Fosamax might cause atypical femoral fractures, but the drug label approved by the Food and Drug Administration in 1995 did not include a warning for those fractures. After 1995, evidence of such fractures started to develop. In 2008, Merck applied to the FDA for approval to change the Fosamax label to include warnings of stress fractures, but the FDA denied the application. In 2011, the FDA ordered a change to the drug's label to warn of atypical femoral fractures, and rejected Merck's request to warn for stress fractures instead. In *Merck Sharp & Dohme Corp. v. Albrecht*, a class action was filed against Merck for state law tort damages from failure to warn customers about this potential effect of Fosamax. Merck argued that the claims were preempted by federal law, and specifically because there was "clear evidence that the FDA would not have approved a change to the . . . label." The district court dismissed the case, but the Third Circuit reversed, citing uncertainty in the "clear evidence" standard, and whether the issue was to be determined by a judge or jury. The Court, in an opinion by Justice Breyer, held that the question of "clear evidence" was a question for a judge, not a jury, to decide, and that, to succeed in a preemption defense, a drug manufacturer must "show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." The case was then remanded to the Third Circuit for further consideration. Justice Thomas filed a concurrence expressing skepticism that Merck could prevail, given his conclusion that Merck could have complied with its state-law duties regardless of the FDA's actions. Justice Alito, joined by Chief Justice Roberts and Justice Kavanaugh, concurred in the judgment only, agreeing that the preemption question was one for a judge to decide, but arguing that the only issue is whether the relevant federal and state laws "irreconcilably conflict," and thus standards of proof are not relevant. A link to the opinion is here.

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