Merck Sharp & Dohme Corp. v. Albrecht, No. 17-290

In a sequel to *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court has granted certiorari to decide whether state-law failure-to-warn claims are preempted by a decision of the Food and Drug Administration (FDA) that rejected a proposal by the defendant drug manufacturer to warn about the risk underlying the plaintiff's claims. Prior to the plaintiff's lawsuit, the drug manufacturer had presented the FDA with scientific data supporting its application to change the warning labels on its product Fosamax to warn about the risk of atypical bone fractures. The FDA rejected the application on the basis that the justification for the proposed language was inadequate. In the lawsuit, the district court granted summary judgment to the drug manufacturer on the ground that the plaintiff's failure-to-warn claims were preempted by the FDA's decision, but the Third Circuit vacated the judgment. The court of appeals accepted the plaintiff's argument that the case needed to go to a jury to decide whether the FDA had rejected the proposed revision to the warning label because the evidence was inadequate to indicate that Fosamax caused atypical bone fractures, or instead because the FDA was dissatisfied with the drug manufacturer's use of the phrase "stress fractures," which the plaintiffs argued could be misunderstood to refer to fractures less serious than those in question. The Supreme Court invited the views of the Solicitor General, who took the position that the Third Circuit had erred and that the Court should grant review. Though the question presented is narrow, the Court's decision will affect hundreds of cases in the underlying multidistrict litigation.