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

Today, the Supreme Court unanimously held that whether the Food and Drug Administration (FDA) would have rejected a change to the labeling of a prescription drug is a question of law to be decided by courts rather than a question of fact to be decided by juries.

Background: Individuals allegedly injured by prescription drugs often assert state-law failure-to-warn claims against drug manufacturers. Federal law preempts such claims when federal law prohibited the manufacturer from issuing the warning purportedly required by state law. In such circumstances, where simultaneous compliance with state and federal law is impossible, federal law takes precedence. Accordingly, whether a particular failure-to-warn claim is preempted depends on the particular drug's regulatory history.

A prescription drug may be sold in the United States only if the FDA has approved its labeling. Generally, a drug manufacturer may not change the drug's FDA-approved labeling absent prior agency approval. But, under certain circumstances, federal law allows brand-name drug manufacturers to provisionally revise a drug's warning label without prior agency approval, if the manufacturer learns of new, scientifically valid information concerning the drug's safety. Like proposed labeling changes for which a manufacturer seeks prior approval, provisional labeling changes may be rejected by the FDA if the agency determines that they are not scientifically warranted.

Because federal law preempts state-law failure-to-warn claims only when federal law would have prevented the drug manufacturer from issuing the warning purportedly required by state law, a manufacturer's assertion of the preemption defense requires an evaluation of what the FDA would have done had the manufacturer either requested permission to change the drug's warning label or provisionally changed the label without prior approval. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court held that successful assertion of the preemption defense requires a manufacturer to present "clear evidence" that the FDA would have rejected the warning purportedly required by state law.

Issue: When a brand-name drug manufacturer contends that a state-law failure-to-warn claim is preempted by federal law because the FDA would have rejected the warning purportedly required by state law, is the question whether the FDA would have rejected that warning a question of law to be decided by the court or a question of fact to be decided by a jury?

Court's Holding: In an opinion authored by Justice Breyer on behalf of six of the Justices, the Court held that whether the FDA would have rejected a particular warning is a question of law to be decided by the court. The Court found that "judges are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context." The Court further found that placing resolution of the question in the hands of judges "should produce greater uniformity" in outcomes. Justice Thomas joined the opinion of the Court, but also wrote separately to suggest that, on his view of the record, the defendant manufacturer had not established that the FDA would have rejected the warning at issue, and thus had not established its entitlement to summary judgment. Justice Alito, writing on behalf of himself as well as Chief Justice Roberts and Justice Kavanaugh, joined in the judgment of the Court, agreeing that the question of agency disapproval is a question of law, but emphasized his view that the record supports finding preemption in this case.