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Supreme Court Holds That Courts, Not Juries, Must Decide Whether The FDA's Rejection Of A Proposed Warning Label Provides "Clear Evidence" To Preempt A State-Law Failure-To-Warn Claim

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

Decided May 20, 2019

Today, the Supreme Court unanimously held that courts, not juries, must decide as a matter of law whether there is "clear evidence" that the FDA would not have approved a proposed label warning about a risk of a drug, thereby preempting a state-law failure-to-warn claim based on that same risk.

Background:

Patients sued Merck for failing to warn that its prescription drug Fosamax is associated with "atypical femoral fractures." Merck moved for summary judgment, arguing that the claims were preempted because the FDA had rejected Merck's proposed label warning about the risk of the fractures. Specifically, Merck submitted to the FDA a "Prior Approval Supplement"—which requires the agency's preapproval to add language to a warning label—seeking to warn about the risk of "stress fractures," but the FDA rejected the proposal on the basis that Merck's justification was "inadequate" because "[i]dentification of 'stress fractures' may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature." Merck argued that the FDA's decision made it impossible for the company to comply with both state law and federal law and, therefore, the patients' state-law failure-to-warn claims were preempted. The district court granted summary judgment to Merck, but the U.S. Court of Appeals for the Third Circuit reversed, holding that *Wyeth v. Levine*, 555 U.S. 555

"We here decide that a judge, not the jury, must decide the pre-emption question . . . . The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute."

Justice Breyer,
writing for the Court

(2009), established an evidentiary standard of proof that required the factfinder to conclude that there is "clear evidence"—*i.e.*, that it is highly probable—that the FDA would not have approved a change to the drug's label to include the warning allegedly required under state law. And because there was a genuine issue of material fact as to why the FDA rejected Merck's proposed label, Merck was not entitled to summary judgment.

Issue:

Federal law preempts a state-law failure-to-warn claim where there is "clear evidence" that the FDA would not have approved a drug manufacturer's proposed label warning about a particular risk of using that drug. *Wyeth*, 555 U.S. at 571. "Is the question of agency disapproval primarily one of fact, normally for juries to decide, or is it a question of law, normally for a judge to decide without a jury?"

Court's Holding:

Whether there is "clear evidence" that the FDA would have rejected a proposed label warning is a question of law for the courts to decide.

What It Means:

- The Court preserved the ability of manufacturers to assert an impossibility preemption defense to state-law claims for failure to warn about a certain risk when the FDA has rejected a proposed label warning about the same risk.
- The decision clarified that the "clear evidence" phrase in *Wyeth* does not refer to an evidentiary standard of proof that applies to preemption questions, and reiterated that courts must answer such questions by asking whether state and federal law "irreconcilably conflict."
- The Court explained that state and federal law "irreconcilably conflict" in the failure-to-warn context if (i) a manufacturer fully informed the FDA of the justifications for a drug label

warning required by state law, and (ii) the FDA nevertheless disapproved of the manufacturer's proposed change to the drug's label to include the warning.

- The decision may improve the uniformity of preemption law in this area, as judges will be bound by precedent and are more familiar than lay juries with construing agency determinations.

As always, Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding developments at the Supreme Court. Please feel free to contact the following practice leaders:

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