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CLIENT ALERT

Supreme Court Holds that Judges—Not Juries—Must Decide Whether State-law Failure-to-Warn Claims Are Preempted by FDA Drug Labeling Decisions

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Yesterday, the Supreme Court unanimously held in *Merck Sharp & Dohme Corp. v. Albrecht* that judges—not juries—must decide whether the FDA would have rejected a new safety warning on a drug label, thus preempting state tort-law claims based on that failure to warn. The decision clarifies the Court's prior ruling in *Wyeth v. Levine*, 555 U.S. 555 (2009), that "'clear evidence' that the FDA would not have approved a change to the drug's label pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." But the Court split on what constitutes "clear evidence," with the majority requiring a showing that "the drug manufacturer 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 a change to the drug's label to include that warning."

The case arose when a group of individual plaintiffs sued Merck alleging that it failed to warn them that its FDA-approved osteoporosis drug, Fosamax, causes atypical femur fractures—a rare type of complete, low-energy fracture that affects the thigh bone. The plaintiffs allegedly suffered atypical femoral fractures after taking Fosamax between 1999 and 2010. Prior to 2011, the FDA-approved label for Fosamax did not warn about this risk.

Merck argued that the plaintiffs' state-law failure to warn claims are preempted by federal law because the FDA precluded Merck from warning about atypical low-energy femoral fractures before 2011. Merck pointed to its 2008 application for preapproval to add a warning that Fosamax may cause stress fractures, which the FDA rejected because it was not convinced the science showed that Fosamax caused stress fractures. Merck argued that, because the FDA rejected this proposed warning, the FDA would have also rejected a warning for atypical femoral fractures.

Citing *Wyeth,* the district court granted Merck summary judgment, finding that the FDA's rejection of Merck's proposed label change for stress fractures presented "clear evidence" that the FDA also would not have approved a change concerning the more serious, "atypical" femur fractures.

The Third Circuit reversed, reasoning that, for Merck to establish a preemption defense under *Wyeth*, the "factfinder must conclude that it is highly probable" that the FDA would not have approved Merck's proposal to change Fosamax's label, and that this "is a question of fact that must be answered by the jury."

The Supreme Court granted certiorari, and yesterday vacated the Third Circuit's holding. The Court held that a judge, not a jury, must decide *Wyeth*'s preemption question of whether there is "clear evidence" that the FDA would not have approved the new warning. Justice Breyer, writing for the Court, gave several reasons for this conclusion:

- "The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute."
- "[J]udges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency's determination," as they "are experienced in '[t]he construction of written instruments,' such as those normally produced by a federal agency to memorialize its considered judgments," "are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context," and "are normally familiar with principles of administrative law."
- Judge-issued decisions "should produce greater uniformity among courts; and greater uniformity is normally a virtue when a question requires a determination concerning the scope and effect of federal agency action."

Justice Breyer added that because "courts should treat the critical question not as a matter of fact for a jury but as a matter of law for the judge to decide," "[w]e do not further define *Wyeth's* use of the words 'clear evidence' in terms of evidentiary standards, such as 'preponderance of the evidence' or 'clear and convincing evidence' and so forth." Instead, the Court explained that "clear evidence" requires a showing that "the drug manufacturer 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 a change to the drug's label to include that warning."

Justice Thomas concurred in the decision, but wrote separately to explain his view that under "the relevant pre-emption principles," "Merck's impossibility pre-emption defense fails." He noted that "Merck's primary argument, based on various agency communications, is that the FDA would have rejected a hypothetical labeling change" concerning atypical femur fractures. But he noted that "Merck's belief that the FDA would have eventually rejected" a label change is not enough because "neither agency musings nor hypothetical future rejections constitute pre-emptive 'Laws' under the Supremacy Clause." Justice Thomas opined that Merck must point to a "statute, regulation, or other agency action with the force of law that would have prohibited it from complying with its alleged state-law duties."

Justice Alito separately concurred in the judgment, joined by Chief Justice Roberts and Justice Kavanaugh. He remarked that "the Court barely notes a statutory provision," 21 U.S.C. §355(o)(4)(A), which "imposed on the FDA a duty to initiate a label change '[i]f the Secretary becomes aware of new information, including any new safety information . . . that the Secretary determines should be included in the labeling of the drug.'" He noted that "this duty arguably affect[s] the pre-emption analysis" because "if the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." He assumed that the Third Circuit, on remand, would "consider the effects" of this statute "on the preemption issue in this case."

Future cases will further unpack the scope of the Court's preemption analysis.

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