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IN THIS ISSUE

Joseph J. Stroble and Stanley Blackmon report on a recent United States Supreme Court case addressing implied preemption of failure to warn claims in prescription pharmaceutical cases.

U.S. Supreme Court in Prescription Pharmaceutical Case Holds Implied Preemption is Legal Issue for Judge, Not Question of Fact for Jury

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I. Introduction

Pharmaceutical product liability plaintiffs typically allege that a medication's label failed to adequately warn of risks associated with use of the medication. Disputes over medication labeling involve the interplay between federal law/regulatory action and state law. Defense counsel must therefore strategically pursue any available preemption defenses.

Counsel's preemption analysis should now consider the U.S. Supreme Court's recent decision in *Merck Sharp & Dohme Corporation v. Albrecht*, 587 U.S. ___ (2019), wherein the Court again addressed impossibility preemption of failure-to-warn claims. That case, which originated from the Third Circuit, challenged the sufficiency of the label of Fosamax, a medication that treats osteoporosis in postmenopausal women. In *Albrecht* the Court addressed its prior holding in *Wyeth v. Levine*, 555 U.S. 555 (2009), that "clear evidence" the Food & Drug Administration ("FDA") would not have approved a change to the medication's label preempts a state law failure to warn claim.

II. Holdings and Key Practice Takeaways

The *Albrecht* Court held that what constitutes clear evidence that the FDA would have rejected a change to a medication's label, or evidence sufficient to preempt a state law claim for failure to warn, is a question of law for judges to decide, not a question of fact to be decided by juries. Defendants are better positioned after *Albrecht* to have their preemption arguments resolved at the dispositive motion stage.

Without addressing the merits of Merck's preemption arguments, the Court then went further in an effort to clarify what under *Levine* constitutes clear evidence of an agency rejection of a proposed label change. The Court held by a 6-3 majority that clear evidence is "evidence that shows the court 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." As addressed in more detail below, this separate holding generated three separate opinions suggesting varying views among the justices as to what actions or inactions by the FDA would have preemptive effect.

Particularly in multi-district litigation, plaintiffs increasingly allege multiple theories of liability and corresponding label deficiencies. Plaintiffs' theories of their case often change or evolve over the life of the litigation based upon plaintiffs' perception as to which of their arguments may have gained traction with a judge and/or jury. A pharmaceutical manufacturer can thus find itself defending its medication's label on numerous fronts. The *Albrecht* majority's definition of clear evidence may lead plaintiffs to believe that they are best positioned to survive preemption by

increasing their efforts to allege numerous labeling deficiencies.

After *Albrecht*, it is uncertain how lower courts will resolve the justices' varying views on what constitutes an agency rejection of a proposed label change sufficient to satisfy the *Levine* clear-evidence standard. It is clear, however, that what satisfies the "clear evidence" standard will be hotly contested by pharmaceutical counsel.

III. Background

The *Albrecht* plaintiffs took Fosamax for the treatment and prevention of osteoporosis and suffered atypical femoral fractures between 1999 and 2010. Plaintiffs alleged that Merck had a duty under state law to warn plaintiffs and their doctors about the risk of atypical femoral fractures associated with using Fosamax. In 2011, the FDA required Merck to add a warning about atypical femoral fractures.

In 2008, Merck sought pre-approval from the FDA to amend the Fosamax label to warn about the risk of stress fractures. Merck argued that the FDA rejected the proposed stress fracture warning via Complete Response Letter and other FDA communications. Merck contended that the FDA's rejection of the stress fracture warning established that the FDA would have rejected any attempt by Merck to add a warning to the Fosamax label about the risks of atypical femoral fractures. Merck stated that, as a result, it would be impossible for it to comply with both federal law and state law; plaintiffs' claims were therefore preempted and should be dismissed.

The District Court found that plaintiffs' claims were preempted and granted summary judgment for Merck, and Plaintiffs appealed to the Third Circuit. The Third Circuit reversed the summary judgment ruling, finding that its preemption analysis was governed by *Levine* and holding that the question of whether the FDA would have rejected a proposed label change is one of fact to be answered by a jury, rather than a judge.

The Third Circuit also observed that the *Levine* clear evidence standard had led to differing applications by lower courts and noted that further guidance by the Supreme Court on the doctrine would be helpful.

IV. Discussion of Opinion and Concurring Opinions

The Court stated that the determinative question before it was whether the question of agency disapproval was one of fact for juries to decide, or one of law for a judge to decide without a jury. The Court vacated the Third Circuit's decision and remanded the case, holding that the question of agency disapproval is a legal one for the judge. The Court reasoned that judges, given their familiarity with the principles of administrative law and the governing statutory and regulatory context, were better suited than juries to evaluate agency decisions. The Court stated that "the judge

must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflict.'"

The Court then sought to clarify what under *Levine* constitutes "clear evidence" of an agency rejection of a proposed label change. Consistent with its holding that the preemption question is an issue of law for the judge to decide, the Court did not define "clear evidence" in terms of evidentiary standards such as "preponderance of the evidence" or "clear and convincing evidence."

The Court held by a 6-3 majority that "clear evidence" is "evidence that shows the court 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." This separate holding generated three separate opinions suggesting varying views among the justices as to what actions or inactions by the FDA would have preemptive effect.

Justice Breyer's majority opinion declined to decide what sort of FDA disapproval is necessary for preemption, for example, via formal rejection of a warning label that would have been adequate under state law, via notice-and-comment rulemaking setting forth labeling standards, or rejection of labeling submitted under the Changes Being Effected or "CBE" regulation. Instead, the Court stated that "whatever means the FDA uses to exercise its authority, those means must lie within the scope of the authority Congress has lawfully delegated."

Justice Thomas in his concurring opinion concluded that Merck's preemption defense should have failed. He reasoned that Merck could have changed its label through the CBE process, and Merck's belief that the FDA would have later rejected the CBE label change did not make an earlier CBE change impossible. Justice Thomas stated that the FDA Complete Response Letter cited by Merck was not a final agency action with the force of law. The fact that Justice Thomas wrote alone may suggest that no other justice takes such a hard line on what is official FDA action sufficient to show rejection of a proposed label change.

Justice Alito (joined by Chief Justice Roberts and Justice Kavanaugh) concurred in the judgment, but his opinion expounded on the regulatory regime governing pharmaceutical labeling (including a discussion of label changes via the Prior Approval Supplement process) and Merck/FDA communications about Fosamax specifically. Justice Alito noted that the FDA's labeling duties do not depend on "whether the relevant drug manufacturer, as opposed to some other entity or individual, brought the new information to the FDA's attention" and that FDA regulations do not "require FDA to communicate to the relevant drug manufacturer that a label change is unwarranted."

Justice Alito's opinion suggests that, in light of the regulatory record, FDA had

definitively decided to reject the proposed Fosamax warning at issue years before a similar label change was implemented. Although not explicit in the separate concurrence, it appears Justice Alito, Chief Justice Roberts, and Justice Kavanaugh may have found plaintiffs' claims preempted had it been necessary to reach that question.

V. Conclusion

The *Albrecht* decision makes clear that a judge, not a jury, must decide if the FDA would have rejected a warning that plaintiffs propose was missing from a medication's label, thereby preempting a state law failure to warn claim. There should now be no dispute that a pharmaceutical defendant's preemption motion should be resolved at the dispositive motion stage. But given the justices' varying views on what constitutes an agency rejection of a proposed label change sufficient to satisfy the *Levine* clear-evidence standard, pharmaceutical counsel will continue to litigate what FDA action satisfies the "clear evidence" standard, and it will be left to lower courts to resolve the issue.

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