CLIENT ALERT

Supreme Court Decision Raises New Questions on Impossibility Preemption in Cases Challenging Sufficiency of Drug Label Warnings

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On May 20, 2019, the U.S. Supreme Court announced that application of "impossibility" preemption to bar failure to warn claims against drug manufacturers presents a question of law to be decided by trial courts, not juries. While the Justice Breyer-authored decision resolved a decade of disagreement among the lower courts and settled the issue of whose decision governs (judge or jury), concurring opinions by Justices Thomas and Alito demonstrate that this decision raises even more challenging questions as to the scope and availability of impossibility preemption. These issues will be, for now, left to the lower courts to work out. Their resolution will likely determine the ongoing viability of this defense.

In *Merck Sharp & Dohme Corporation v. Albrecht*, 587 U.S. ____ (2019), the Court reaffirms that impossibility preemption generally applies when it is "impossible for a private party to comply with both state and federal requirements." The decision specifically addresses impossibility preemption within the framework of federal and state prescription drug regulation and purports to resolve "differences and uncertainties among the courts of appeals and state supreme courts in respect to the application" of the Court's holding in *Wyeth v. Levine*, 55 U.S. 555 (2009). *Wyeth* provided that the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations governing drug labels would not, standing alone, result in preemption of state-law failure to warn claims absent "clear evidence" that the FDA would not have approved the change to the drug's label required under state law. Prior to the decision in *Albrecht*, lower courts interpreted the "clear evidence" requirement to present either a fact question for the jury or a question of law for courts. In settling this issue, the Supreme Court unanimously agreed that "this question of pre-emption is one for a judge to decide, not a jury," and "where that is so, the judge must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflic[t].'" For purposes of demonstrating such a conflict, the majority opinion held 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.

Albrecht involved the claims of more than 500 plaintiffs who allegedly suffered "atypical femoral fractures"—stress fractures in the thigh bone that ordinarily would heal in the normal course but instead progress to complete breaks—as a result of using Fosamax, an osteoporosis medication manufactured by Merck. The plaintiffs alleged that Merck had a duty under state law to warn them about the risk of these fractures, but Merck failed to do so. Asserting the defense of impossibility preemption, Merck argued that plaintiffs' claims were preempted because it sought approval from FDA to change the Fosamax label to include warnings about the risks of such fractures, but FDA rejected Merck's proposed changes. Because a drug manufacturer is limited in its ability to unilaterally change drug labeling, and because FDA had already disapproved Merck's proposed changes, Merck argued that it would be impossible for it to comply with both federal law and state law. Merck asserted that under the Supremacy Clause of the United States Constitution, plaintiffs' claims should be dismissed because federal law on the issue trumps state law. Agreeing with Merck, the district court dismissed the failure to warn claims on summary judgment. On appeal, the Third Circuit vacated that decision, holding that *Wyeth*'s "clear evidence" requirement presented a question of fact for the jury.

In vacating the Third Circuit's judgment, the Supreme Court did not address the merits of Merck's argument. It instead remanded the case for further proceedings consistent with the opinion, leaving open certain key issues that will likely drive future litigation on impossibility preemption.

First: it is unclear from the majority opinion what efforts are required of a drug manufacturer before it can successfully invoke impossibility preemption. As Justice Breyer explained, it would not be enough for a drug manufacturer to demonstrate that the tension between federal and state requirements results in "the laws of one sovereign *permit[ting]* an activity that the laws of the other sovereign restrict or even prohibit." Rather, state law must *require* something of the manufacturer that federal law forbids. Specifically, "[t]he underlying question for this type of impossibility pre-emption defense is whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law." Thus, the "clear evidence" requirement of *Wyeth* "requires the drug manufac-turer to show that it 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 changing the drug's label to include that warning." Although this paradigm seems straightforward in the abstract, the majority and both concurring opinions demonstrate that it is not easily applied in practice.

As a threshold matter, the majority acknowledged that "meeting the standard we set forth [in *Wyeth*] would be difficult," and noted that "[i]mpossibility preemption is a demanding defense." To illustrate the difficulty of meeting the *Wyeth* standard, the Court observed that, under the FDA's Changes Being Effected ("CBE") regulation, drug manufacturers are empowered to implement a labeling change prior to obtaining FDA approval "if the change is designed to 'add or strengthen a . . . warning' where there is 'newly acquired information' about the "evidence of a causal association" between the drug and a risk of harm." Although the FDA can later reject those changes, until it actually does so, "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both."

The majority opinion and Justice Thomas's concurrence seem to suggest that unless a drug manufacturer has exhausted every effort to effect a labeling change, impossibility preemption almost always will not apply. This places a significant burden on the manufacturer, who must demonstrate that the FDA actually considered and rejected "*any and all* warnings … that would satisfy state law." That is an amorphous requirement and one likely to be exploited by plaintiffs, who in seeking to defeat impossibility preemption defenses may be incentivized to assert endless permutations of potential warnings the manufacturer could have used. If plaintiffs are successful in that effort, it would effectively undercut impossibility preemption in this context.

Second: another question Albrecht left unanswered is what form of agency action rises to the level of "federal law" capable of superseding conflicting state-law requirements. Justice Breyer identified several possibilities, but ultimately decided to avoid the issue as one not properly before the Court. The opinion vacillates, suggesting at some points that it is enough if FDA simply "informed the drug manufacturer that the FDA would not approve changing the drug's label," but in other places seeming to require a more formal process (*i.e.*, disapproval through notice-and-comment rulemaking, formal rejection of a warning label, or any "other agency action carrying the force of law"). Justice Thomas suggested this is a much more exacting requirement limited to what is understood in administrative law as "final agency action."

Justice Alito, on the other hand, thought under certain circumstances even inaction on the part of the FDA could be relevant to the preemption analysis because "Congress has 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.'" As Justice Alito explains, "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." Importantly, "[t]he FDA's duty does not depend on whether the relevant drug manufacturer . . . brought the new information to the FDA's attention" or "require the FDA to communicate to the relevant drug manufacturer that a label change is unwarranted; instead, the FDA could simply consider the new information and decide not to act." Without a majority decision on this issue, however, it will fall to the lower courts to decide what form of FDA action is necessary to establish an impossibility preemption defense.

Lower courts will no doubt wrestle with these issues and others left unsettled by *Albrecht*. The good news is that, while those issues remain unresolved, there are creative arguments available to drug manufacturers to support impossibility preemption as a defense to failure to warn claims. And because the issue of impossibility preemption is now clearly a question of law, those arguments can be advanced and potentially resolved on a dispositive motion. For example, manufacturers now have available to them certain legal doctrines (e.g., canons of construction), to argue on a dispositive motion that a plaintiff's failure to warn claim is preempted by the FDA's consideration and rejection of a risk or warning that is substantively or linguistically indistinguishable from the risk or warning advanced by the plaintiff. Or, relying on Justice Alito's concurring opinion, the defense could arguably be advanced by a drug manufacturer who did not proactively provide information to the FDA or seek to add new warnings to its label, provided the manufacturer can otherwise demonstrate that the FDA was "fully informed" of the relevant risks.

We cannot know at this point whether such arguments will persuade courts. But as these issues work their way through the judicial system, defense counsel for drug manufacturers should carefully consider asserting creative preemption arguments anytime a plaintiff asserts a failure to warn claim.

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