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U.S. Supreme Court says judges must decide whether preemption applies, and clarifies when it does

Opinion highlights importance of a "clear" record at FDA

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On 20 May the U.S. Supreme Court unanimously ruled that federal preemption questions arising under the Federal Food, Drug, and Cosmetic Act (FD&C Act) are for a judge, not a jury, to decide. In doing so, the court reversed a March 2017 Third Circuit decision that had revived product liability litigation regarding Fosamax and remanded the case to that court for reconsideration. The opinion in *Merck Sharpe & Dohme v. Albrecht* addresses drugmakers' preemption defense to state law failure-to-warn claims. Since the Supreme Court's 2009 decision in *Wyeth v. Levine*, a defendant is not liable for alleged inadequate warnings if there was "clear evidence" that the U.S. Food and Drug Administration (FDA) would not have approved a labeling change to address the inadequacy. Per *Albrecht*, whether that defense is viable is the province of the judge.

The *Albrecht* decision seems likely to benefit drug company defendants in two ways. One is procedural: because the decision is the province of the judge, the issue can be addressed in motions, perhaps leading to earlier resolution. The other is in avoiding the unpredictability of a jury decision on what is often a central issue in drug product failure-to-warn cases. At the same time, the decision might be seen as narrowing the circumstances under which the preemption defense will apply. The *Albrecht* decision says the "clear evidence" that FDA would not have approved the necessary labeling change must show that FDA was "fully informed" of an asserted need for the warning and rejected a proposed labeling change to address it.

The court decides viability of preemption defense

Writing for the majority, Justice Breyer offered four reasons why the preemption question is primarily an issue of law for a judge to decide without a jury:

- The question "often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute."
- Judges are better equipped "to evaluate the nature and scope of an agency's determination" because they are experienced in "[t]he construction of written instruments," such as those normally produced by a federal agency to memorialize its considered judgments, pursuant to *Markman* v. *Westview Instruments, Inc.*

- Judges are better suited than juries to understand and interpret agency decisions in light of the governing statutory and regulatory context, as they are familiar with principles of administrative law.
- Courts may have to resolve subsidiary factual disputes "that are part and parcel of the broader legal question," pursuant to *Teva Pharmaceuticals USA, Inc.* v. *Sandoz, Inc.*

Heading back to the Third Circuit, this case will now turn on the judges' determination on whether there is "clear evidence" that FDA would have rejected the subject warning.

"Clear evidence" of preemption narrowly defined

In *Wyeth*, the Supreme Court ruled that people injured by a drug product may file state failure-to-warn suits against drug manufacturers, even though the drugs involved and their labels (which include warnings) had been approved by FDA. This weakened, but did not obliterate, the preemption defense, which was still available to a defendant who could provide "clear evidence" FDA would have rejected the additional warning that a plaintiff says was necessary. *Albrecht* puts a finer point on what constitutes such "clear evidence," clarifying that a drug manufacturer must show that it "fully informed the FDA of the justifications for the warning" and the agency "informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning."

The *Albrecht* decision defines "clear evidence" of preemption not "in terms of evidentiary standards, such as 'preponderance of the evidence' or 'clear and convincing evidence' and so forth," but "as a matter of law for the judge to decide." The court explained: "the judge must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflic[t].'"

Implications for drug manufacturers

After the 2017 Third Circuit decision, we wrote that the "clear evidence" standard set by *Wyeth* might be impossible to meet, absent a "smoking gun" letter from FDA rejecting the proposed labeling change. This is likely even more true today, given the tightening of the standard. Justice Breyer acknowledged: "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." In this light, the fact that a judge will be deciding whether the preemption defense succeeds may be of limited benefit, if the defendant must show an express rejection by FDA. That said, judges are unquestionably better equipped than juries to decide factual issues surrounding preemption.

Although the precise implications of the "fully informed" standard are not clear, it seems likely that a preemption defense will need more than evidence that FDA implied through informal communications that the agency would not have permitted a given labeling change. While it likely will remain difficult to prevail on a motion to dismiss, manufacturers should be able to argue for limited, targeted discovery on the issue of preemption to support a motion for summary judgment and will benefit from having judges, rather than juries, decide whether the defense applies. With this in mind, it will be increasingly important for there to be a clear written record of communications with FDA showing that specific warnings were proposed by the company and rejected by FDA. Doing so may be challenging, given the nature of labeling negotiations with FDA; the agency often provides feedback without expressly rejecting a proposal, leading the company to revise its proposal. Being prepared to later show that FDA was "fully informed" will require thinking ahead when negotiating labeling in the context of initial approval or post-approval labeling changes.

If you have any questions about the product liability or regulatory issues implicated by the preemption defense, or more broadly about litigation or regulation in this area, please contact any of the authors of this alert, who are part of our integrated, cross-functional team serving the pharmaceutical industry, or the Hogan Lovells lawyer with whom you regularly work.

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