COMMENTARY

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Supreme Court Sides with Merck in Unanimous Fosamax® Product-Liability Decision

IN SHORT

The Situation: Name-brand pharmaceutical manufacturers are often sued with claims that they should have strengthened the warnings on their labels, even where (as here) the Food and Drug Administration ("FDA") would not allow them to do so. The U.S. Court of Appeals for the Third Circuit held that, to defeat such claims as preempted by federal law, manufacturers must prove to a jury, by clear and convincing evidence, that the FDA would have rebuffed the plaintiff's desired warning. The U.S. Supreme Court granted Merck's request to review that decision.

The Result: The Supreme Court unanimously held that a judge, not a jury, should assess a manufacturer's preemption defense in these circumstances. It also held that the judge should treat that defense as an ordinary legal question, not a factual one with a uniquely difficult evidentiary burden.

Looking Ahead: Several jurisdictions had followed the Third Circuit's lead in sending these questions to a jury. Manufacturers in those jurisdictions and others can now rest assured that this key aspect of their case will be evaluated by experienced judges, not lay jurors.

Pharmaceutical company Merck recently obtained a unanimous win before the Supreme Court in a product-liability matter involving Merck's prescription medicine Fosamax®. Merck's victory will significantly help name-brand drug manufacturers fend off allegations that they should have more strongly warned against a medicine's possible side effects.

Merck's medicine Fosamax is prescribed, among other things, to prevent and treat osteoporosis in post-menopausal women. In the late 2000s, evidence began to emerge suggesting that long-term use of Fosamax and other drugs in its class might be related to an extremely unusual type of femur fracture. After telling the FDA what it knew about this possible link, Merck sought to revise Fosamax's label and suggested revisions. But the FDA said no. As its regulatory actions and its communications with Merck and the general public demonstrated, the FDA did not believe the scientific evidence supported such a warning until over a year and a half later, after an expert task force assessed the issue.

Merck got sued anyway, by thousands of plaintiffs claiming that it should have changed its warning before that task force report. Merck argued successfully in the District Court that it couldn't have changed the warning—the FDA didn't let it—and so these claims against it were preempted.

> Merck's victory restores hope to the many other pharmaceutical manufacturers facing failure-to-warn claims under state law.

But the Third Circuit disagreed. It held that such claims are preempted only if the manufacturer can prove to a jury, by clear and convincing evidence, that the FDA would have rejected a properly phrased warning. Because the Third Circuit believed some evidence suggested that the FDA had semantic rather than substantive problems with Merck's request, it held Merck

lacked the "smoking gun" to establish this defense. Merck had been successful in the trials that had gone to verdict to date, but it lost this important pre-trial defense.

The Supreme Court unanimously held that "a judge, not a jury, must decide the pre-emption question" in cases like this one, using ordinary legal burdens. Slip op. 9; *see also* slip op. 1 (Alito, J., concurring in the judgment). That question "often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute," and "judges … are better equipped to evaluate" it in the first instance. Slip op. 16; *see id*. (noting that allowing judges to decide preemption "should produce greater uniformity among courts"). Thus, questions about the preemptive effect of the FDA's actions—even "factual questions" that are "subsumed" within the analysis—go to judges, not juries. *Id*. at 17.

In keeping with this holding, the Court also explained that its prior references to "clear evidence" were not meant to serve as an "evidentiary standard," because "courts should treat the critical question … as a matter of law for the judge to decide," "simply ask[ing] himself whether the relevant federal and state laws irreconcilably conflict." Slip op. 14; *see also* slip op. 3 (Alito, J., concurring) (noting the Court's "hold[ing]" that prior usage of the phrase "clear evidence" "was merely a rhetorical flourish").

The Court vacated and remanded in light of the Third Circuit's erroneous holding to the contrary. It explained that, on remand, Merck is entitled to its preemption defense if it demonstrates 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." Slip op. 13. In conducting that analysis, courts should "obvious[ly]" focus on whether the FDA disapproved a change through action "within the scope of its [congressionally delegated] authority." Slip op. 15.

Merck's victory restores hope to the many other pharmaceutical manufacturers facing failure-to-warn claims under state law. It is now clear that manufacturers' preemption defense goes to the judge, not a jury. It is also clear (ironically enough) that "clear evidence" is not code for "impossibly difficult burden"—the judge must simply ask whether federal law prohibited what state law supposedly required.

With those two barriers out of the way, manufacturers should have an easier time convincing judges that, despite their best efforts, the FDA would not allow them to change their labels as the plaintiffs demand.

Jones Day represented Merck Sharp & Dohme Corp. in Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290 (U.S.)*.

THREE KEY TAKEAWAYS

1. Judges, not juries, must assess whether it was impossible for a manufacturer to revise its label while complying with federal law.
2. In answering any factual questions that arise in that inquiry, courts should use the ordinary preponderance standard, not a clear-and-convincing-evidence standard.
3. Manufacturers should work with counsel to identify the best way to frame their argument that the FDA's actions demonstrate the impossibility of complying with both state and federal law.


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