Press Release

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WLF Urges Supreme Court to Grant Review And End 17-Year-Long Drug-Label Preemption Saga

(*Merck Sharp & Dohme Corp. v. Albrecht*)

> **"Seventeen years of *Jarndyce*-like drift—marked by untold billable hours, financial tolls, and wasted judicial resources—compels review here."**
> —Cory L. Andrews, WLF General Counsel & Vice President of Litigation

WASHINGTON, DC—Washington Legal Foundation today filed an amicus curiae brief with the U.S. Supreme Court, urging it to revisit a dispute over whether federal law preempts a plaintiff's state-law failure-to-warn claim when it is impossible for the drug manufacturer to simultaneously comply with federal and state law.

The case arises from a 2008 multi-district litigation (MDL) combining lawsuits by more than 1,200 users of Fosamax, an FDA-approved prescription drug. When Merck—the maker of Fosamax—learned of studies suggesting a possible link between long-term Fosamax use and an unusual type of thigh-bone fracture, it sought FDA permission to warn of that risk on Fosamax's label. But after reviewing all the available scientific data, the FDA rejected Merck's revised label. Even so, Fosamax users who suffered thigh-bone fractures sued Merck under state tort law for failing to adequately warn of their injuries.

Merck successfully argued in the MDL that the only way it could avoid liability under state law would have been to violate federal law by misbranding Fosamax with an FDA-rejected label. Because that was impossible, the plaintiffs' claims were preempted. But the U.S. Court of Appeals for the Third Circuit disagreed. It held that Merck must prove preemption by "clear-and-convincing-evidence." A unanimous Supreme Court rejected that standard of proof. On remand, the district court again concluded that Merck asked for a label that disclosed the risk; the FDA said no; so preemption follows. But in 2024, the Third Circuit took yet another detour, insisting that a 'heavy presumption' defeats preemption unless the FDA's firm denial is the sole possible reading of the record.

In its amicus brief urging review, WLF argues that the Third Circuit's approach strays from *Albrecht I*'s clear path and the Supremacy Clause's mandate. It mires Merck in escalating fees and costs, denies the plaintiffs much-needed closure, and burdens the courts with more than a decade of MDL proceedings. WLF further shows why the Third Circuit's so-called presumption against preemption has no support in the Constitution's text or history. And WLF cautions that allowing the Third Circuit's decision to stand would chill the innovation of lifesaving and therapeutic drugs.

Celebrating its 48th year, WLF is America's premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.

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