Press Release

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FOR IMMEDIATE RELEASE September 20, 2018

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WLF Urges Supreme Court to Preempt State-Law Liability for Branded Drug Label

(*Merck, Sharpe & Dohme Corp. v. Albrecht*)

"Merck has shown decisively not merely that the FDA *would have* rejected a stronger Fosamax warning, but that the FDA *did* reject a stronger Fosamax warning. A clearer showing of impossibility preemption under the Supremacy Clause is hard to imagine."
—Cory Andrews, WLF Senior Litigation Counsel

WASHINGTON, DC—Washington Legal Foundation filed an *amicus curiae* brief with the U.S. Supreme Court today, urging the Court to decide that federal law preempts a plaintiff's state-law failure-to-warn claim in cases where it can be shown that the Food and Drug Administration (FDA) rejected the drug manufacturer's request to alter its label to include the very warning needed to avoid liability.

In *Merck Sharp & Dohme Corp. v. Albrecht*, the Supreme Court will revisit the issue of federal preemption for branded drug manufacturers for the first time since its 2009 *Wyeth v. Levine* decision. In *Levine*, the Court denied a preemption defense to a branded drug manufacturer in the absence of "clear evidence" that the FDA would have rejected a stronger warning label. The *Albrecht* case will put that "clear evidence" rule to the test.

The case arises from a multi-district litigation (MDL) combining lawsuits by more than 1,200 users of Fosamax, an FDA-approved prescription drug for treating osteoporosis in older woman. 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 the FDA's 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 while it studied the issue more closely. Nonetheless, 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 because the only way it could avoid liability under state law was to violate federal law by misbranding Fosamax with an FDA-rejected label, the plaintiffs' claims were preempted. But the U.S. Court of Appeals for the Third Circuit disagreed. It held that a reasonable jury could find that the FDA might have approved a differently worded label, so the question of preemption is one for a jury, not the court. It also held that Merck must prove its preemption defense by a "clear-and-convincing-evidence" standard of proof.

WLF's brief argues that by focusing on what the FDA might have done rather than on what the FDA did, the appeals court's decision dilutes *Levine* beyond all recognition. As the record shows and the government itself has confirmed, the FDA's rejection of Merck's proposed label turned solely on the available scientific data, not on Merck's choice of words. WLF's brief cautions that if the Court were to adopt the Third Circuit's view of conflict preemption on this record, it would render the Supremacy Clause a dead letter.

Celebrating its 41st 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.