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Media Contact: Glenn Lammi | glammi@wlf.org | 202-588-0302

WLF Urges Ninth Circuit to Find that Federal Law Preempts State-Law Liability for Drug Label

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

“In finding the plaintiffs’ claims to be preempted, the decision below faithfully applies the Supreme Court’s preemption precedents, vindicates the FDCA’s carefully balanced labeling regime, and should be affirmed.”

—Cory Andrews, WLF General Counsel & Vice President of Litigation

WASHINGTON, DC—Washington Legal Foundation (WLF) filed an *amicus curiae* brief with the U.S. Court of Appeals for the Ninth Circuit today, urging the court to affirm a lower court’s ruling that federal law preempts the plaintiffs’ state-law failure-to-warn claim because it was impossible for the manufacturer to change the drug’s label under federal law.

The case, *Adams v. Merck Sharp & Dohme Corp.*, arises from a multi-district litigation (MDL) combining lawsuits by users of incretin-based therapies for type-2 diabetes. Novo Nordisk Inc. manufactures and markets Victoza (liraglutide). The plaintiffs complain that Victoza’s FDA-approved labeling failed to warn of an increased risk of pancreatic cancer. But as WLF argues in its brief, and the MDL court rightly found, the FDA’s “changes-being-effected” regulation allows a manufacturer to change its labeling *only* when it possesses some “newly acquired information”—material information not previously presented to the FDA but that significantly alters the drug’s risk profile. When, as here, no such information exists, that is the end of the matter. Under the Supremacy Clause, the plaintiffs’ state-law claims are preempted.

WLF’s brief also argues that the decision below should be affirmed because the plaintiffs offered no reliable evidence to establish general causation. In seeking an abuse-of-discretion reversal, the plaintiffs invite the court to disregard Rule 702 by relaxing their burden to come forward with scientifically reliable expert testimony based on accepted methodologies. Yet WLF contends that doing so would not only sweep aside Rule 702 and decades of Supreme Court precedent but—in light of the inconsistent and unreliable methodologies employed by the plaintiffs’ experts here—also inject harmful uncertainty well beyond this case.

Celebrating its 44th 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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