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WLF Urges Supreme Court To Hear Important Pharmaceutical Preemption Case

(Janssen Pharmaceuticals v. A.Y.)

“The Superior Court applied a non-existent presumption against preemption and then proceeded to ignore the legal distinction between warnings for on-label use of prescription drugs and warnings for off-label use of prescription drugs.”

—John Masslon, WLF Senior Litigation Counsel

WASHINGTON, DC—Washington Legal Foundation (WLF) today urged the U.S. Supreme Court to hear a case in which the Superior Court of Pennsylvania placed state law over federal law. WLF argues that the decision below ignores Supreme Court precedent on the presumption against preemption and federal court decisions on failure-to-warn claims for off-label use of prescription drugs.

The case arises from Janssen’s alleged failure to warn of the risks of side effects for young boys taking Risperdal. At the time A.Y. took Risperdal, it was not approved for pediatric use. Because use by children was off-label, federal regulations barred Janssen from unilaterally adding a warning to Risperdal’s label. Despite a federal law that barred Janssen from altering the label, a jury awarded A.Y. and his mother tens of millions of dollars in damages for not changing the label. The Superior Court affirmed that verdict.

In its *amicus* brief supporting Janssen, WLF argues that the Superior Court applied a non-existent presumption against preemption. History, case law, and logic do not support the presumption against preemption. WLF also argues that the Superior Court’s decision conflicts with federal court decisions. In an almost identical case from New York, a federal court held that a failure-to-warn claim against Janssen for the same conduct was preempted by federal law. Similar decisions for class III medical devices likewise suggest that the plaintiffs’ claims are preempted by federal law.

Finally, WLF’s brief explains the potential consequences of allowing the Superior Court’s decision to stand. Many pharmaceutical companies are subject to general jurisdiction in Pennsylvania. If these companies can be held liable for following federal law, they are unlikely to invest in developing life-saving drugs. WLF therefore urges the Supreme Court to hear this case and reaffirm the supremacy of federal law.

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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