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Seventh Circuit: Tort Suit Against Branded Drug Manufacturer is Preempted Under Federal Law

(Dolin v. GlaxoSmithKline LLC)

“This was a clear-cut case of impossibility preemption under the Supremacy Clause. As the Seventh Circuit recognized, it was literally impossible for GSK both to comply with its federal-law duties and to avoid tort liability under Illinois law.”

—Cory Andrews, WLF Senior Litigation Counsel

WASHINGTON, DC—Earlier this afternoon, the U.S. Court of Appeals for the Seventh Circuit rejected liability in a case that attempted to hold a pharmaceutical manufacturer liable for injuries caused by a drug it neither manufactured nor sold. In reversing a \$3 million jury verdict, the appeals court held that federal law prevented the defendant from adding a warning about the alleged association between its drug, paroxetine, and suicide in adults. The decision was a victory for WLF, which filed an *amicus curiae* brief in the case.

The case arose from a suit by Wendy Dolin, who alleged that her husband’s 2010 suicide was caused by ingesting paroxetine, a selective serotonin reuptake inhibitor (SSRI) widely used to treat depression and anxiety. Although from 1992 to 2014 GlaxoSmithKline (GSK) manufactured and marketed a branded version of paroxetine named Paxil, it is undisputed that Mr. Dolin never took Paxil. Instead, he took only a generic version of paroxetine manufactured by Mylan Pharmaceuticals, a generic competitor of GSK. Nonetheless, simply because federal law requires paroxetine’s generic label to be identical to that of Paxil, Ms. Dolin sought to hold GSK liable in tort under Illinois law for injuries caused by its competitor’s drug.

But GSK had asked the Food and Drug Administration (FDA) for permission to modify Paxil’s label to warn of an increased risk of suicide. The FDA repeatedly refused that request. GSK even unilaterally added such a warning in 2006, but the FDA ordered GSK to remove it and replace it with a more general warning. In its brief, WLF argued that state court juries are in no position to second guess Congress’s carefully calibrated regulatory regime for generic and branded drugs. Instead, WLF urged the court to reject the plaintiffs’ call to alter the delicate policy balance that Congress has watchfully maintained for many decades. The appeals court agreed, holding that, under settled conflict preemption principles, federal law preempted the plaintiff’s tort claim.

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.

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