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WLF Urges Seventh Circuit to Reject Agency Rewrite of Federal Drug-Discount Program

(Eli Lilly Company v. Becerra)

“Recent regulatory overreach has improperly expanded the 340B Program far beyond anything its statutory text can sustain.”

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

WASHINGTON, DC—Washington Legal Foundation (WLF) today urged the U.S. Court of Appeals for the Seventh Circuit to reverse a federal trial-court ruling that seizes on a statute’s silence alongside its “overarching purpose” to grant the Health Resources Services Administration (HRSA) broad gap-filling authority that Congress never gave it.

The appeal arises from a suit by prescription-drug manufacturer Eli Lilly against HRSA challenging the agency’s recent enforcement action under the 340B Program. The 340B Program requires manufacturers who participate in the Medicare and Medicaid markets to offer deep discounts on prescription drugs to nonprofit safety-net providers of healthcare services to uninsured and low-income patients. Although the statute leaves the messy details of 340B transactions, including the terms of delivery, to the parties’ free-market negotiations, HRSA has recently taken the position that manufacturers like Lilly are barred from imposing delivery terms on uncovered third-parties—including for-profit contract pharmacies.

While it overturned HRSA’s violation letter as arbitrary and capricious under the APA, the district court nonetheless ratified HRSA’s expansive statutory interpretation. That error, WLF contends in its *amicus* brief, warrants reversal. As WLF shows, the district court’s statutory construction, if allowed to stand, would allow HRSA to unilaterally transform the 340B Program from a sensible cost-saving measure into a constitutionally dubious wealth-transfer scheme. This it cannot do.

Above all, WLF’s brief argues, whether to drastically expand the scope of the 340B Program in this way is a question of such economic and political magnitude that Congress would never commit it to the discretion of an agency without explicitly saying so. Because rewriting federal law is a task the Constitution reserves solely for Congress, WLF urges the appeals court to clarify that the 340B statute imposes no duty on manufacturers beyond “offering” covered entities the chance to “purchase” 340B-discounted drugs.

Celebrating its 45th 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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