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In WLF Success, Third Circuit Rejects Agency Rewrite of Federal Drug-Discount Program

(AstraZeneca v. HHS)

“As today’s ruling confirms, HHS’s 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—The U.S. Court of Appeals for the Third Circuit today rejected the Health Resources Services Administration’s (HRSA) claim under the 340B Program to broad regulatory authority that Congress never gave it. The decision was a litigation success for Washington Legal Foundation (WLF), which filed an amicus brief in the case supporting AstraZeneca.

The appeal arose from a suit by prescription-drug manufacturer AstraZeneca 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 healthcare providers for 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 AstraZeneca are barred from imposing delivery terms on uncovered third parties—including for-profit contract pharmacies.

As the Third Circuit rightly concluded today, HRSA’s recent regulatory overreach has no statutory support. “Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies,” the court announced. “So by trying to enforce that supposed requirement, the government overstepped the statute’s bounds.” The court’s opinion largely tracks statutory arguments found in WLF’s amicus brief, which accused HRSA of trying to unilaterally transform the 340B Program from “a sensible cost-saving measure” into “a constitutionally dubious wealth-transfer scheme.”

Celebrating its 46th 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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