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WLF Urges Federal Court To Reject Agency Rewrite Of Federal Drug-Discount Program *(Johnson & Johnson v. HRSA)*

“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—Yesterday, Washington Legal Foundation (WLF) urged the U.S. District Court for the District of Columbia to reject the Health Resources Services Administration’s (HRSA’s) position that drug manufacturer Johnson & Johnson cannot use a rebate model to provide 340B pricing to certain hospitals. WLF’s amicus brief was prepared with generous pro bono assistance from Thad Westbrook and Jeff Wald of Nelson Mullins.

The suit arises from a challenge to the agency’s recent threatened enforcement action under the 340B Program. The 340B Program requires drug 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 whether discounts are handled up-front or as rebates—to the parties’ free-market negotiations, HRSA has recently taken the position that manufacturers are barred from providing discounts as rebates.

In its amicus brief supporting Johnson & Johnson, WLF argued that HRSA’s recent regulatory overreach has improperly expanded this well-intended cost-reduction program far beyond anything its statutory text can sustain. According to HRSA, a drug manufacturer must receive pre-approval from the agency before employing a 340B pricing model. But this claim is belied by the text of 340B, which requires no such pre-approval. Moreover, HRSA’s argument goes against its own historical 30-year practice of tacitly approving various 340B-compliant pricing models without requiring pre-approval. Given its failure to reasonably explain its differential treatment of rebate and up-front discounting models, HRSA’s actions in this case are arbitrary and capricious and must be set aside.

Celebrating its 48th 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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