Drugmakers Lose Appeal in Fight of HHS Oversight in Rebate Plans

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Summary by Bloomberg AI

- A federal appeals court ruled that the US Department of Health and Human Services properly denied proposals from drugmakers to change how health providers access steeply discounted drugs under the 340B Drug Pricing Program.
- The proposals sought to provide discounts through rebates rather than up front, which would require providers to buy medicines at full market price and then submit data to receive a rebate.
- The court concluded that the Secretary of Health and Human Services has the authority to require manufacturers to await approval before implementing a rebate mechanism, and that the manufacturers' proposals would counterintuitively let them take the lead in administering the 340B Program.

The US Department of Health and Human Services properly denied proposals from drugmakers that sought to change how certain health providers can access their steeply discounted drugs under a government program, a federal appeals court ruled Tuesday.

US health officials had the legal authority to reject proposals from Johnson & Johnson, Novartis AG, Eli Lilly & Co., and Bristol Myers Squibb Co. to discount medicines through rebates rather than up front under the 340B Drug Pricing Program, the US Court of Appeals for District of Columbia Circuit said in an **opinion**.

“Like the district court, we disagree,” Judge Bradley Garcia wrote for the court.

“Based on the statutory text and structure, we conclude that Section 340B requires the Secretary to provide for a rebate mechanism before manufacturers may implement one,” Garcia added. “And because it is undisputed that the Secretary has never authorized a mechanism encompassing the manufacturers’ rebate models, the Secretary properly required the manufacturers to await his approval while he further studied their proposals.”

The **rebate proposals** sought to significantly change how the 340B program operates.

Drugmakers under the plan currently provide up-front drug discounts to covered entities, such as qualifying safety-net hospitals, clinics, and providers that treat a disproportionate number of low-income and uninsured patients. The proposals, however, would require providers to buy medicines at full market price and then submit data to drugmakers to receive a rebate.

The four manufacturers challenged whether they needed prior approval from the government to implement their rebate models. A lower court last year **ruled** the HHS didn't act illegally when it rejected the drugmakers' bids.

The government is currently weighing **a rebate model pilot** for the second time after the first one was shot down by another federal court.

Manufacturers have long argued that requiring providers to buy medicines at commercial prices and then submit data to receive a rebate would bring more transparency to the program, which has **faced scrutiny** over its integrity, how discounts are used, or where they're provided.

The US Health Resources & Services Administration, an agency under the HHS operating the 340B program, has argued that manufacturers need prior approval from the health secretary in order to provide a back-end rebate.

"The manufacturers' reading would also counterintuitively let manufacturers, rather than the Secretary, take the lead in administering the 340B Program, rendering the Secretary's role largely reactive," Garcia said.

Judges Karen Henderson and Cornelia Pillard joined the opinion.

Hogan Lovells US LLP and Arnold & Porter Kaye Scholer LLP represent the drugmakers. The US Department of Justice represents HHS.

The cases are Johnson & Johnson Health Care Systems Inc. v. Robert Kennedy, Jr., D.C. Cir., No. 25-05236; Novartis Pharmaceuticals Corporation v. Robert Kennedy, Jr., D.C. Cir., No. 25-05177; Eli Lilly and Company v. Robert Kennedy, Jr., D.C. Cir., No. 25-05221; Bristol Myers Squibb Company v. Robert Kennedy, Jr., D.C. Cir., No. 25-05179; and Kalderos, Inc. v. USA, D.C. Cir., No. 25-05220.