

[NOT YET SCHEDULED FOR ORAL ARGUMENT]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Novartis Pharmaceuticals Corp.,

Plaintiff-Appellee,

v.

Carole Johnson, in her official capacity as  
Administrator of the U.S. Health  
Resources and Services Administration,  
et al.,

Defendants-Appellants.

No. 21-5299

**STATEMENT OF THE ISSUE**

This case concerns Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b. That statute requires drug manufacturers who participate in Medicaid and Medicare Part B to enter into agreements with the U.S. Department of Health and Human Services to offer covered entities “outpatient drugs for purchase at or below the applicable [statutory] ceiling price if such drug is made available to any other purchaser at any price.” 42 U.S.C. § 256b(a)(1). Covered entities, including certain hospitals and clinics, often dispense medications to their patients through third-party pharmacies. Plaintiff, a drug manufacturer, created a

policy that placed restrictions on the ability of covered entities to purchase covered outpatient drugs at the statutory ceiling price and dispense them through third-party pharmacies. On appeal, the federal defendants intend to raise the issue of whether such restrictions are prohibited under the statutory scheme.

Respectfully submitted.

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