IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION,
59 Route 10, East Hanover, New Jersey 07936,

Plaintiff,

v.

Civil Action No. _____

DIANA ESPINOSA,
in her official capacity as
ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane,
Rockville, Maryland 20852,

and

XAVIER BECERRA,
in his official capacity as SECRETARY,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.,
Washington, D.C. 20201,

Defendants.

VERIFIED COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation (Novartis) brings this Complaint against Defendants Diana Espinosa, in her official capacity as Acting Administrator of the Health Resources and Services Administration (HRSA), and Xavier Becerra, in his official capacity as Secretary of the Department of Health and Human Services (HHS), and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action for preliminary and permanent injunctive relief to challenge a recent HRSA determination that Novartis's policy governing so-called "contract pharmacy" arrangements is not in compliance with the 340B statute, 42 U.S.C. § 256b, and an accompanying threat of enforcement action.

2. Under the 340B Drug Pricing Program, drug manufacturers that wish to participate in certain Medicaid and Medicare programs must offer deep discounts to specified hospitals and clinics benefiting underserved patient populations. To ensure that the discounts are appropriately targeted to the right recipients, the 340B statute carefully circumscribes the universe of hospitals and clinics that qualify as "covered entities" entitled to those steep discounts.

3. In recent years, there has been an explosion of so-called "contract pharmacy" arrangements, in which covered entities enter into contractual arrangements with third-party pharmacies—often large, national, for-profit pharmacy chains. Under a contract pharmacy arrangement, drugs are not shipped to the covered entity for dispensing at the covered entity. Instead they are shipped directly to the contract pharmacy—wherever in the country that pharmacy may be.

4. Nothing in the statute contemplates—let alone requires—that manufacturers agree to ship drugs nominally purchased by covered entities directly to "contract pharmacies" for dispensing to both patients and non-patients of the covered entity alike. And yet that is precisely what HRSA has purported to mandate here.

5. Under the plain language of the 340B statute, Novartis is not required to recognize *any* contract pharmacy arrangements. Nevertheless, in order to strike a reasonable

balance between redressing abuses of the 340B Program and serving the statute's goals, Novartis voluntarily recognizes [1] all contract pharmacies within a 40-mile radius of the covered entity, [2] all federal grantee covered entity contract pharmacy arrangements, regardless of location, and [3] an exemption to the 40-mile radius limitation when the facts and circumstances require.

6. On May 17, 2021, HRSA notified Novartis that it has concluded Novartis's policy violates the 340B statute. Exhibit 1 (the Decision Letter). HRSA demanded a response by June 1, and threatened enforcement action if Novartis did not drop its contract pharmacy policy.

7. HRSA's decision is unlawful under the Administrative Procedure Act (APA). First, it conflicts with the plain language of the statute. The 340B statute does not mandate—nor does it give the agency discretion to mandate—that manufacturers ship drugs to third-party pharmacies at the whim of covered entities.

8. HRSA's decision also is arbitrary, capricious, and an abuse of discretion. Under the agency's own guidance documents, contract pharmacy arrangements are eligible for 340B discounts only when specified requirements are met, including that the covered entity retains title to the drugs in question. But the Decision Letter made no finding that any of the covered entities at issue actually retained title to the drugs at issue. And due to limits on the ability of manufacturers to obtain even basic information about contract pharmacy arrangements, manufacturers have no way of knowing one way or the other.

9. HRSA has failed to offer an adequate explanation for its evolving position on whether and in what circumstances contract pharmacy arrangements trigger the 340B discount.

10. Absent prompt judicial relief, Novartis will suffer irreparable harm in the form of unlawful enforcement actions and significant reputational harm. The government's public

assertion that Novartis is knowingly and intentionally violating its federal obligations plainly injures Novartis's reputation.

11. For all of these reasons, HRSA's Decision Letter should be vacated and declared unlawful, and HHS should be enjoined from proceeding with its threatened actions.

PARTIES

12. Plaintiff Novartis Pharmaceuticals Corporation is a pharmaceutical company. It brings innovative medicines to market in order to enhance health outcomes for patients. Novartis is incorporated in the State of Delaware and has its principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

13. Defendant Diana Espinosa is the Acting Administrator of the Health Resources and Services Administration, an operating component within HHS. The Acting Administrator maintains an office at 5600 Fishers Lane, Rockville, Maryland 20852. The Administrator is sued in her official capacity only.

14. Defendant Xavier Becerra is the Secretary of HHS. Defendant Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201, and is sued in his official capacity only.

JURISDICTION AND VENUE

15. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiff requires a declaration of its

rights by this Court and injunctive relief to prohibit Defendants from violating laws and regulations.

16. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (e) because this is a civil action in which Defendants are officers of the United States acting in their official capacities and one of the Defendants maintains his office and conducts business in this judicial district.

FACTUAL BACKGROUND

The 340B Program

17. In 1992, Congress created the 340B Drug Pricing Program, which requires participating pharmaceutical manufacturers to provide deep discounts on their covered outpatient drugs to qualifying hospitals and clinics generally serving poor, uninsured, underinsured, or otherwise vulnerable patient groups. 42 U.S.C. § 256b(a). The stated purpose of the program was to provide "protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384 (II), at 12 (1992). As a condition of federal payment being available under Medicaid and Medicare Part B for its covered outpatient drugs, a manufacturer must agree to participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1).

18. At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a "covered entity" no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug. 42 U.S.C. §§ 256b(a)(1), (a)(4), (b)(1). A participating manufacturer must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

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