IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK SHARP & DOHME LLC
126 East Lincoln Ave.
P.O. Box 2000
Rahway, NJ 07065

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201

XAVIER BECERRA, Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

CAROLE JOHNSON, Administrator of U.S. Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Merck Sharp & Dohme LLC ("Merck") brings this lawsuit against Defendants U.S. Department of Health and Human Services ("HHS"), Xavier Becerra, in his official capacity as Secretary of HHS; U.S. Health Resources and Services Administration ("HRSA"), an agency within HHS; and Carole Johnson, in her official capacity as Administrator of HRSA (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. This Administrative Procedure Act ("APA") suit arises against the backdrop of this Court's decisions in *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479-DLF and *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF, 2021 WL 5161783 (D.D.C. Nov. 5, 2021) ("*Novartis/UT*"), in which this Court vacated and declared unlawful agency actions that are strikingly similar to the agency action challenged here.

2. In *Novartis/UT*, this Court considered the validity of so-called "violation letters" sent by Defendant HRSA to two pharmaceutical manufacturers, Novartis and United Therapeutics. In those letters, which were separately sent but essentially identical to one another, HRSA asserted that certain policies adopted by those manufacturers violated the 340B statute, 42 U.S.C. § 256b, which in broad strokes requires drug manufacturers to offer their "covered outpatient drugs" at deeply discounted prices to certain health care providers (identified and defined in the 340B statute as "covered entities") as a condition of having the drugs covered under Medicaid and Medicare Part B.

3. This Court resolved *Novartis/UT* by granting declaratory relief to the manufacturers and vacating the violation letters HRSA had sent to them. The Court explained that "[t]he Violation Letters contain legal reasoning that rests upon an erroneous reading of Section 340B." *Novartis/UT*, 2021 WL 5161783, at *9. The Court accordingly "declar[ed] that the [manufacturer] plaintiffs' policies do not violate Section 340B under the positions advanced in the Violation Letters and developed in this litigation. The plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities." *See id*.

4. Plaintiff Merck respectfully submits that the Court should enter similar relief in this case with respect to a letter that Defendants recently sent to Merck. The letter sent to Merck is identical in all relevant respects to the violation letters invalidated by this Court in *Novartis/UT*.

5. Like the manufacturers in that case, Merck has adopted policies designed to respond to the potential for increased 340B Program noncompliance—such as duplicate discounts and drug diversion—that, as several government reports have found, arises and is at a heightened risk of occurring when covered entities order discounted 340B drugs for shipment directly to third-party pharmacy entities ("contract pharmacies"). Merck has attempted at all stages of its policy development to work collaboratively with HRSA and with covered entities, including through a July 2020 telephone call with HRSA and an initial effort to adopt its 340B Program integrity initiative on a purely voluntary basis. Merck has also worked diligently to communicate with HRSA regarding Merck's policies and the reasons why they are lawful, necessary, and appropriate, including through written communications to HRSA, each of which unsuccessfully requested a further meeting with HRSA. *See* Ex. A, C, E, G, I.

6. Similar to the policy adopted by United Therapeutics, an aspect of Merck's initiative involves a request that certain 340B covered entities that wish to use contract pharmacies provide limited claims-level transactional data through a third-party vendor, so that these transactions can be appropriately vetted. Merck regards this approach as consistent with longstanding HRSA guidance, which HRSA has not withdrawn, advising that manufacturers may include conditions with respect to 340B pricing offers "that address customary business practice, request standard information, or include other appropriate contract provisions." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Entity Guidelines, 59 Fed. Reg. 25,110, 25,113–14 (May 13, 1994) ("1994 Guidance"). The provision of claims data is

commonplace in the healthcare industry and is routinely used for verifying eligibility for pricing and in connection with payments, rebates, and discounts. Consistent with these common industry practices, Merck, its customers, and its business partners use claims data in a variety of contexts to verify that customers receive the right price or the correct discount or rebate for a transaction.

7. The precise information requested depends on the transaction involved, but it frequently involves claims-level data similar to the information requested under Merck's 340B initiative. As an example, in Merck's contracts with pharmacy benefit managers and health plans, and especially in the managed care context, Merck requires claims-level data to ensure rebates are accurately and appropriately paid on Merck products. Such data helps Merck confirm important information, such as (among other things) confirming that the utilization is by an eligible health plan member, confirming the specific products and quantity dispensed, confirming whether the products are being purchased directly or indirectly from Merck, and confirming that rebates are not paid on duplicate or multiple claims. In the 340B context, Merck's initiative facilitates this type of review using a third-party platform called 340B ESP™. And, as Merck has noted in its correspondence with HRSA and HHS on these matters, a number of agencies, including the HHS Centers for Medicare and Medicaid Services and the HHS Office of Inspector General, have acknowledged that 340B duplicate discounts can be identified and prevented through the use and review of claims-level data. *See, e.g.*, Letter from Phil Rinnander, Executive Director, Finance, Merck, to Alex M. Azar, Secretary, U.S. Department of Health and Human Services, at 1 (Aug. 3, 2020) (Ex. B).

8. Importantly, and as Merck has repeatedly emphasized to HRSA, Merck's initiative permits *all* covered entities to purchase Merck's covered outpatient drugs at or below the 340B

ceiling price, *regardless* of whether they provide the requested claims-level data for contract pharmacy transactions.

9. Merck's initiative does not affect the many covered entities that do not use contract pharmacies. According to HRSA's 340B Program website, "[t]he overwhelming majority (82 percent) of covered entities do not contract with pharmacies." HRSA/OPA, *340B Drug Pricing Program: Contract Pharmacy Oversight* (Feb. 6, 2014, Date Last Reviewed: Apr. 2017), https://www.hrsa.gov/opa/updates/contract-pharmacy-2014-02-05.html (last visited July 8, 2022).

10. Moreover, even among the covered entities that choose to use contract pharmacies, Merck's current policy only applies to purchases by a confined subset of 340B covered entities: hospital entities and community health center entities (*i.e.*, entities enrolled in the 340B program as a consolidated health center program). And for hospital and community health center covered entities that agree to provide the limited claims-level data that Merck has reasonably requested, Merck's policy permits them to use unlimited contract pharmacies if they choose to do so, without any numerical or geographic limitations.

11. If a hospital or community health center covered entity elects to use contract-pharmacy arrangements *and also* declines to provide the requested claims-level data, Merck's policy still permits that covered entity to purchase covered outpatient drugs at or below the 340B ceiling price, consistent with Merck's commitment to meet its statutory obligation to offer all of its covered outpatient drugs for purchase by all covered entities at or below the 340B ceiling price. Merck's policy also permits a hospital or community health center covered entity that declines to provide claims-level transactional data to utilize any contract pharmacy that it wholly owns or holds through common ownership, provided that the pharmacy is registered with HRSA as a contract pharmacy of that covered entity. And, if a hospital or community health center covered

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