IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
900 Ridgebury Road
Ridgefield, CT 06877

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201;

DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration,
5600 Fishers Lane
Rockville, MD 20857;

KRISTA M. PEDLEY, in her official capacity as Director of the Office of Special Health Initiatives,
5600 Fishers Lane
Rockville, MD 20857;

MICHELLE HERZOG, in her official capacity as Acting Director of the Office of Pharmacy Affairs,
5600 Fishers Lane
Rockville, MD 20857;

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201; *and*

HEALTH RESOURCES AND SERVICES ADMINISTRATION,

Civil Action No. _____

5600 Fishers Lane
Rockville, MD 20857

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim" or "BI") brings this action against Defendants Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services; Diana Espinosa, in her official capacity as Acting Administrator of the Health Resources and Services Administration; Krista M. Pedley, in her official capacity as Director of the Office of Special Health Initiatives; Michelle Herzog, in her official capacity as the Acting Director of the Office of Pharmacy Affairs; the U.S. Department of Health and Human Services ("HHS"); and the Health Resources and Services Administration ("HRSA") (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. This case is about an agency attempt to dramatically expand a federal program in a manner that is divorced from the statutory text. The 340B Drug Pricing Program, 42 U.S.C. § 256b ("Section 340B"), created in 1992, sets discounted prices that drug manufacturers must provide for out-patient medicines sold to certain healthcare facilities, defined in Section 340B of the Public Health Service Act as "covered entities." Congress carefully defined the "covered entities" that are eligible for the drug discounts by listing in the statute fifteen specific categories of "covered entities" that all, to some extent, serve underserved populations in various ways.

2. The statutorily-defined "covered entities" do not include for-profit pharmacies, such as CVS or Walgreens. Yet HRSA has attempted to require that manufacturers like Boehringer Ingelheim provide 340B discount drugs to such pharmacies or allow them to be transferred to such

pharmacies by covered entities if the pharmacies have various types of contracts with the covered entities. This case challenges the legal validity of HRSA's current interpretation of the statute, which purports to extend 340B discount prices to drugs provided to contract pharmacies, even though they are not within the scope of the statute or the entities that the statute was enacted to benefit.

3. Congress did not grant the federal agency charged with administering the 340B program—HRSA—authority to alter Congress's statutory list of covered entities, and indeed provided HRSA with only narrow regulatory authority regarding the program. Yet HRSA has attempted to require manufacturers to provide, as a practical matter, 340B discount drugs to contract pharmacies via claimed "informal guidance." *AstraZeneca Pharms. v. Becerra*, No. 1:21-cv-00027-LPS, 2021 WL 2458063, at *7 (D. Del. June 16, 2021) ("[T]hroughout the past 25 years, [HRSA] has dramatically expanded how covered entities may purchase 340B drugs.").

4. HRSA's guidance has shifted over the years. First, in the mid-1990s, HRSA promulgated guidance purporting to allow covered entities to select a *single* outside "contract pharmacy" that could receive 340B discounted drugs for dispensing, based on HRSA's recognition that some covered entities do not have an in-house pharmacy for dispensing drugs. *See* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996). In doing so, HRSA expressly rejected comments requesting that the agency authorize the use of multiple contract pharmacies. *Id.* at 43,551.

5. In 2010, HRSA altered its guidance to purport to allow covered entities to enter into arrangements with an *unlimited* number of contract pharmacies to receive 340B discounted drugs.

See HRSA, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010).

6. HRSA's policy change led to a huge increase in the role of contract pharmacies under the 340B program. Retail pharmacies developed business models to take advantage of the 340B program by signing up covered entities across the United States as partners under different types of arrangements. Under one model, the contract pharmacies replenish their inventory with drugs purchased at 340B discounts from manufacturers for drugs that the contract pharmacies already dispensed to customers, based on an assumption that a certain number of those customers had a relationship with a covered entity sufficient to have justified a 340B discount. *See* Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program*, at 5 (Oct. 2020) (explaining that pharmacies use "sophisticated software algorithms" to make these determinations).[1]

7. As a result, contract pharmacies on a large scale received *post hoc* drugs at the 340B discounted price that the pharmacies claimed based on drugs they already had purchased at the undiscounted price and already had dispensed to customers. *Id.* at 3; *see also* Examining Oversight Reports on the 340B Drug Pricing Program: *Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 115th Cong. 11 (May 15, 2018) (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation and Inspections, Off. of Inspector Gen. ("OIG")) ("OIG Testimony") (testifying that "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory.")

[1] *Available at* https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

8. This practice led to newfound and substantial profits for the contract pharmacies. Contract pharmacies are able to generate substantial revenues based on any previously filled prescription that their algorithm asserts was eligible for the 340B discounted price. Although contract pharmacies have not publicized the share of the 340B discount that goes into their pockets, the available data indicate that often little or none of the benefit reaches underserved patient populations. *See* U.S. Gov't Accountability Off. ("GAO"), *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at 30 (June 2018) ("2018 GAO Report"); *see also* OIG, *Contract Pharmacy Arrangements in the 340B Program*, No. OEI-15-13-00431 at 14 (Feb. 4, 2014) ("2014 OIG Report") (finding that many covered entities "do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements."). Thus, contract pharmacies can generate significant profit margins for themselves by charging patients and their insurers the full retail price for a drug when they dispense it, and then later adding to their general inventory drugs they receive from manufacturers at the 340B discounted price. Those 340B discounts are based on the status of a covered entity with which the contract pharmacy has an arrangement—but the pharmacy retains significant portions of the profit from the discounted pricing.

9. By 2020, contract pharmacy participation in the 340B program had exploded. Between April 1, 2010 and April 1, 2020, the number of contract pharmacy arrangements increased by more than 4,000%, from 2,321 to 100,451. Vandervelde et al., *supra*, at 4. And by 2020, a covered entity was contracting with an average of 22 contract pharmacies, far from the model of contracting with one pharmacy envisioned by the 1996 guidance. *Id.* at 7. The number of individual pharmacies participating in the 340B program now exceeds 27,000. *Id.* And the number of claims for manufacturers to provide 340B discounts tripled between 2014 and 2019. *See* Adam

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