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

J. Fein, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020).[2]

10. In order to ensure that 340B discounts actually benefit covered entities or their underserved patients, Section 340B prohibits covered entities from reselling or otherwise transferring a 340B discounted drug to an individual or entity who is not a patient of the covered entity—a practice known as "diversion." Multiple government reports have identified the high risk of diversion under the 340B program associated with the use of contract pharmacies. The GAO found that contract pharmacies are incentivized to deem more prescriptions 340B-eligible because many of the contract pharmacies charge the covered entities fees under their contracts "based on a percentage of revenue generated for each 340B prescription." 2018 GAO Report at 25. To date, HRSA has taken no meaningful action to attempt to remedy this problem, and the problem continues to grow.

11. In view of the statutory structure, which does not provide for contract pharmacies; the substantial increase in the role of contract pharmacies; documented abuses; and HRSA's lack of action, various drug manufacturers announced certain changes in their policies this past year, including not providing 340B discounted drugs to or through contract pharmacies (subject to some exceptions) and limiting the types of contract pharmacies to which they would voluntarily provide drugs at the 340B discounted price.

12. In the summer of 2020, HRSA officials acknowledged that HRSA's prior guidance regarding contract pharmacies was not enforceable against manufacturers. *See, e.g.*, Michelle M. Stein, *HRSA Urges Pharma to Continue 340B Discounts at Contract Pharmacies*, Inside Health Policy (Aug. 20, 2020) (HRSA explained that "[w]ithout comprehensive regulatory authority,

[2] https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

HRSA is unable to develop enforceable policy to ensure clarity in program requirements across all the interdependent aspects of the 340B program");[3] *cf. AstraZeneca*, 2021 WL 2458063, at *6.

13. HRSA changed position in the following months. *See* Letter from HRSA to President and CEO of 340B Health (Dec. 9, 2020).[4]

14. On December 30, 2020, the Chief Legal Officer of HHS issued a legal opinion interpreting the text of the 340B statute to be unambiguous and declaring that "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." Advisory Opinion 20-06 On Contract Pharmacies Under the 340B Program at 1 (Dec. 30, 2020) ("Advisory Opinion"); *AstraZeneca*, 2021 WL 2458063, at *6 ("[T]he [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies.").

15. The December 30, 2020, Advisory Opinion was subsequently challenged in litigation by an affected pharmaceutical manufacturer. *See AstraZeneca*, 2021 WL 2458063. Despite the pendency of that litigation, in May of 2021, HRSA issued threats of enforcement in a series of letters to various drug manufacturers that had recently implemented limits on the drugs that they would provide to contract pharmacies at the 340B discounted price.

16. On June 16, 2021, the federal district court entered an order declaring the Advisory Opinion unlawful and noting that, contrary to the Advisory Opinion's reasoning, the 340B statute

[3] https://insidehealthpolicy.com/daily-news/hrsa-urges-pharma-continue-340b-discounts-contract-pharmacies.

[4] Second Am. Compl., Ex. L, *Eli Lilly*, ECF No. 103-13.

does not unambiguously obligate drug manufacturers to provide 340B discounted drugs to contract pharmacies. *Id.* at *8–9.

17. HRSA withdrew the Advisory Opinion on June 18, 2021. *See* Notice of Withdrawal from Daniel J. Barry, Acting Gen. Counsel, HHS (June 18, 2021),[5] ("Advisory Opinion Withdrawal") ("The Office of the General Counsel (OGC) is withdrawing Advisory Opinion 20-06 . . . ."). HRSA did not, however, withdraw its letters threatening enforcement, and instead represented in the litigation that the proper way to dispute those letters was via the pending litigation.

18. Shortly after issuance of the court order in the *AstraZeneca* case rejecting HRSA's interpretation of the statute, Plaintiff here, Boehringer Ingelheim, announced that effective August 1, 2021, it would provide drugs at the 340B discounted price to up to one commercial contract pharmacy for certain covered entities—namely those that do not have an in-house pharmacy. As described below, the policy also contained a number of exceptions, designed to ensure patient access to BI's medicines. HRSA sent a letter to BI on July 20, 2021, which contended that the statute requires BI to provide 340B discount drugs to all contract pharmacies and referenced potential civil monetary penalties. Ex. 1.

19. BI responded to HRSA's letter on July 29, 2021, explaining why HRSA's interpretation is foreclosed by the statute, and requesting that HRSA reconsider its interpretation. Ex. 2. In subsequent correspondence with BI, HRSA has continued to assert its same interpretation of the statute.

20. HRSA sent a second letter to BI on September 8, 2021 stating that BI's July 29, 2021 letter did not address HRSA's concerns expressed in its July 20, 2021 letter. HRSA stated

[5] Notice, Ex. 1, at 2, *Eli Lilly*, ECF No. 119-1.

that it was conducting an analysis of BI's policy and "w[ould] make a determination as to any potential action, which includes whether a violation of the 340B statute has occurred and the potential for civil monetary penalties." Ex. 3, at 1.

21. BI responded to that letter on September 15, 2021, stating that it respectfully continued to disagree with the agency's interpretation of the statute. Ex. 4. On October 4, 2021, HRSA sent a third letter to BI that stated HRSA had completed its review of BI's policy regarding contract pharmacies and that it "determined" that "BI's actions have resulted in overcharges and are in direct violation of the 340B statute." Ex. 5, at 1 (the "October 2021 Letter" or "the Letter"). HRSA reiterated its position that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities."

22. The October 2021 Letter also demanded that "BI must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* The Letter also instructed BI to reimburse covered entities for overcharges that the agency claims have resulted from the policy and threatened civil monetary penalties if BI continues its policy.

23. To date, HRSA has not altered its view of the statute. Accordingly, BI has no recourse but to bring this lawsuit, to obtain a binding determination that the 340B statute does not require BI to provide 340B discount drugs to contract pharmacies.

JURISDICTION AND VENUE

24. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706.

25. This Court has authority to grant declaratory and injunctive relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, the APA, 5 U.S.C. § 702, and the Court's inherent equitable powers.

26. HRSA's October 2021 Letter, which "determined" that BI's policy has resulted in overcharges and violates Section 340B, and which threatened civil monetary penalties against BI, is a final agency action, as discussed further below. The Letter is therefore judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

27. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e)(1) because this action seeks relief against federal agencies and officials acting in their official capacities, some of whom reside in this District, and a substantial part of the events or omissions giving rise to the claim also occurred in this District.

PARTIES

28. Plaintiff Boehringer Ingelheim is a corporation organized under the laws of the State of Delaware with its principal place of business in Ridgefield, Connecticut. Boehringer Ingelheim is a pharmaceutical company that researches, develops, manufactures, and markets novel treatments for human and veterinary medicine. Boehringer Ingelheim participates in the 340B program.

29. Defendant Xavier Becerra is the Secretary of HHS. His official address is in Washington, D.C. He has ultimate responsibility for oversight of the activities of HRSA, including

the administration of the 340B program and the actions complained of herein. He is sued in his official capacity.

30. Defendant Diana Espinosa is the Acting Administrator of HRSA. Her official address is in Rockville, Maryland. Acting Administrator Espinosa is directly responsible for the administration of the 340B program and the actions complained of herein. Acting Administrator Espinosa, among her other duties, has ultimate responsibility for the Office of Pharmacy Affairs, which is headed by Acting Director Michelle Herzog and, as a constituent part of HRSA, is involved directly in the administration of the 340B program. Acting Administrator Espinosa issued the October 4, 2021 Letter, which is a final agency action that is the subject of this complaint. Acting Administrator Espinosa is sued in her official capacity.

31. Rear Admiral Krista M. Pedley was formerly the Director of the Office of Pharmacy Affairs, which is a constituent part of HRSA. Then-Director Pedley issued the July 20, 2021 letter, which is one of the final agency actions that is the subject of this complaint. Director Pedley is now the Director of the Office of Special Health Initiatives, the parent office of the Office of Pharmacy Affairs. Director Pedley is sued in her official capacity.

32. Defendant Michelle Herzog is the current Acting Director of the Office of Pharmacy Affairs. Her official address is in Rockville, Maryland. The Office of Pharmacy Affairs is a constituent part of HRSA and is involved directly in the administration of the 340B program. Acting Director Herzog is sued in her official capacity.

33. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C., and is responsible for HRSA and the 340B program.

34. Defendant HRSA is an administrative agency within HHS headquartered in Rockville, Maryland, and is responsible for administering the 340B program.

FACTUAL BACKGROUND

A. The 340B Program

35. The 340B Drug Pricing Program was established by Congress through statute in 1992. Congress designed it to assist statutorily-defined covered entities that "provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992), 1992 WL 239341.

36. Section 340B instructs that HHS enter into "agreement[s]" with pharmaceutical manufacturers providing that the price that the manufacturers offer to certain statutorily defined "covered entit[ies]" can be no more than a certain ceiling price for the manufacturer's covered outpatient drugs. 42 U.S.C. § 256b(a)(1). That ceiling price is determined by calculating the difference between the manufacturer's Average Manufacturer Price and the Medicaid unit rebate amount for the covered outpatient drug, as determined under the Medicaid drug rebate statute. *Id.* § 256b(a)(1)-(2), (b). Section 340B requires manufacturers to offer this discounted price to covered entities, but it does not create any obligation for manufacturers to offer that price or provide 340B discounted drugs to any other parties, such as contract pharmacies, or require that manufacturers otherwise engage with contract pharmacies.

37. Section 340B lists 15 specific categories of covered entities that must be offered the benefit of purchasing drugs at the discounted price under the 340B program. 42 U.S.C. § 256b(a)(4).

38. Congress selected these covered entities because they "generally care for underserved populations." *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020).

39. The phrase "contract pharmacy" does not appear in Section 340B. The term "contract pharmacy" generally is understood in this context to refer to a for-profit pharmacy that,

as HRSA has admitted, does not qualify as a "covered entity" under Section 340B but has entered into an arrangement with one or more covered entities. *See* Email from Rear Admiral Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA to Lilly USA, LLC (June 11, 2020)[6] ("Contract pharmacies . . . are only a mode for dispensing 340B drugs and not independent covered entities.").

40. The agreement that HHS enters into with pharmaceutical manufacturers under the statute is known as the Pharmaceutical Pricing Agreement and Addendum ("PPA"). The terms of the PPA are not negotiable. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011). Indeed, "[t]he statutory and contractual obligations, in short, are one and the same." *Id.* Nothing in the PPA requires manufacturers to sell to, distribute to, or otherwise deal with contract pharmacies, third-party administrators, or any party other than covered entities. The PPA defines "covered entity" specifically to refer to healthcare entities described in Section 340B(a). *See* Sample PPA.[7]

41. Congress gave HHS tools to enforce its PPAs with pharmaceutical manufacturers, including the authority to impose substantial "civil monetary penalties" on a manufacturer who "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds" the statutory ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi), (d)(1)(B)(vi)(III).

42. Although it is nominally optional for pharmaceutical manufacturers to participate in the 340B program, *see Astra*, 563 U.S. at 117–18, manufacturers have no choice as a practical matter. If a manufacturer does not participate in the 340B program for any of its covered drug

[6] Second Am. Compl., Ex. C, *Eli Lilly*, ECF No. 103-4.

[7] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

products, all of the manufacturer's prescription drug products are ineligible for coverage under the Medicaid and Medicare programs. 42 U.S.C. § 1396r-8(a)(1), (5).

43. Congress included a number of statutory provisions to guard against abuse in the 340B program.

44. First, Congress prohibited covered entities from taking certain actions that would be inconsistent with the purpose of the 340B program, namely causing "duplicate discounts" or engaging in "diversion." A covered entity cannot cause "duplicate discounts or rebates," which occur when a covered entity purchases from the manufacturer a unit of covered outpatient drug at the discounted 340B price and then also seeks a Medicaid rebate on that same unit to be invoiced to the manufacturer. The covered entity cannot dispense discounted 340B drugs to Medicaid beneficiaries (which thereby triggers a manufacturer rebate obligation to Medicaid) without taking certain steps to prevent a duplicate discount. *Id.* § 256b(a)(5)(A). Covered entities also are prohibited from "resell[ing] or otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

45. Second, Congress required covered entities to permit both HHS and the 340B drug manufacturers to audit "the records of the entity that directly pertain to the entity's compliance with" the bars on duplicate discounts, reselling, and transfers. *Id.* § 256b(a)(5)(C).

46. Third, Congress instructed HHS to implement improvements in covered entity compliance with the statutory bars on duplicate discounts, reselling, and transfers. *Id.* § 256b(d)(2)(B). Among other things, HHS must have a process for imposing sanctions on covered entities that violate these statutory prohibitions. *Id.* § 256b(d)(2)(B)(v).

B. HRSA Guidance on Contract Pharmacies

47. Following the creation of the 340B program in 1992, until 1996, there was no HRSA guidance purporting to authorize contract pharmacies, and instead the only activity contemplated was that covered entities would purchase and dispense 340B discount drugs exclusively through their in-house pharmacies.

1. 1996 Guidance

48. In 1996, HRSA issued guidance that led to contract pharmacies participating in the 340B program in a narrow way and in limited numbers. *See* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

49. The guidance explained that covered entities could contract with a single pharmacy location for the purpose of "facilitat[ing] program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." 61 Fed. Reg. at 43,551; *see also* HRSA Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007) (confirming that the 1996 guidance provided that a "covered entity could contract with *only one* pharmacy to provide all pharmacy services for any particular site of the covered entity" (emphasis added)). The 1996 guidance did not obligate manufacturers to sell or provide prescription drugs to contract pharmacies at the 340B price; instead, it put forth HRSA's non-binding interpretation of how covered entities may choose to do business under the 340B program. *See* 61 Fed. Reg. 43,550 ("We believe that these guidelines create no new law and create no new rights or duties."); *see also* Stein, *supra*, at 1.

50. HRSA's guidance did not identify any statutory support for its conclusion that use of a contract pharmacy is permissible. Instead, HRSA acknowledged that "[t]he statute is silent

as to permissible drug distribution systems" but asserted that it does not contain "a requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." 61 Fed. Reg. at 43,549. HRSA asserted that its 1996 guidance was lawful because, in its view, it was "clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* HRSA recognized that, even under its reading of the statute, however, any obligation to deal with a contract pharmacy must be predicated on the existence of an agency relationship between the covered entity and the contract pharmacy. *See* 61 Fed. Reg. at 43,550.

51. The 1996 guidance included multiple important limits on the ability of contract pharmacies to dispense 340B discounted drugs. For example, in HRSA's view at that time, a contract pharmacy should dispense a 340B discounted drug based only on an explicit, individualized, advance determination that the prescription-holding patient is an eligible patient receiving relevant treatment from a covered entity, based on (a) "presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) *after* "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient." *Id.* at 43,556. HRSA specified those guidelines because "[t]he contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program." *Id.* at 43,553.

52. The limited nature of the 1996 guidance helped to deter 340B program abuse, particularly because the single contract pharmacy that a covered entity used would typically

maintain a separate inventory of 340B drugs that it would dispense to the covered entity's patients. The guidance emphasized that "[t]his situation is akin to a covered entity having its own pharmacy." 61 Fed. Reg. at 43,550.

2. 2010 Guidance

53. In 2010, HRSA changed positions and issued guidance that altered its policy. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

54. HRSA's 2010 guidance took the position that covered entities could enter into an *unlimited* number of contract pharmacy arrangements that would enable the contract pharmacies to obtain 340B discount drugs. *Id.* at 10,273.

55. HRSA did not identify a statutory basis for its interpretation, but claimed it "impose[d] [no] additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law." *Id.*

56. The 2010 guidance further stated that covered entities were required to include certain "essential elements" in their contract pharmacy arrangements, including that "[t]he covered entity . . . purchase the drug, maintain title to the drug and assume responsibility for establishing its price." *Id.* at 10,277. Therefore, the guidance rested on the legal fiction that contract pharmacies would operate as a vessel for covered entities. For example, the guidance provided that "[t]he contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity." *Id.* at 10,278. HRSA took no action, however, to confirm these elements were incorporated into contract pharmacy arrangements entered into by covered entities.

57. In particular, HRSA did not alter its guidance or take enforcement action even after it learned that contract pharmacies often operate on a model that has been referred to as the "replenishment" model—where drugs purchased at the 340B discount price are placed in the contract pharmacy's general inventory and are dispensed to customers without regard for whether they are, in fact, a patient of a covered entity. *See* 2014 OIG Report at 14 (noting that many "covered entities use administrators that determine 340B eligibility *after* drugs [are] *dispensed*, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible" (emphasis altered)).

58. HRSA acknowledged that its 2010 policy was not binding in an August 20, 2020 article in *Inside Health Policy*, where HRSA stated that it "strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements," but that "[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy to ensure clarity in program requirements across all the interdependent aspects of the 340B Program." Stein, *supra*, at 1.

59. HRSA admitted that its policy was not binding against the backdrop of a court ruling that HRSA lacked general rulemaking authority under the 340B statute. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 41–45 (D.D.C. 2014). The district court in that case had explained that Section 340B authorized HRSA to conduct only three specific types of rulemaking: (1) to establish an administrative dispute resolution process; (2) to issue standards of methodology for calculating ceiling prices; and (3) to impose monetary sanctions. *Id.* at 41.

C. Increased Use and Abuse of Contract Pharmacy Arrangements

60. In 2018, the GAO found that, since HRSA issued its 2010 guidance, use of contract pharmacies had "increased more than fifteen-fold, from about 1,300 to approximately 20,000 [as

of 2018].” 2018 GAO Report at 10. A more recent study put the increase at 4,228%, with now “more than 27,000 individual pharmacies (almost one out of every three pharmacies)” participating in the 340B program as contract pharmacies. Vandervelde et al., *supra*, at 4. And instead of contracting with just one pharmacy, by 2020, a covered entity was contracting with an average of 22. *Id.* at 7.

61. This explosion in the number of contract pharmacies has coincided with a sharp divergence from the contract pharmacy model envisioned by HRSA’s 1996 guidance, where a single contract pharmacy was “akin to a covered entity having its own pharmacy.” Under that guidance, covered entities and contract pharmacies were instructed to use an arrangement where the covered entity purchased the drugs at the 340B discount price and directed that those drugs be shipped to the contract pharmacy for dispensing from that specific inventory of 340B drugs only to customers who were determined to be a patient of that covered entity. *See* 61 Fed. Reg. at 43,552. Contract pharmacy arrangements now, however, do not use such an arrangement but, instead, involve a very different, so-called “replenishment model.”

62. Under the replenishment model, the contract pharmacy makes no effort to keep 340B discounted drugs separate from its other physical inventory or to identify patients of 340B covered entities at the time they dispense drugs. When the pharmacy receives 340B discounted drugs, it places them in its single, undifferentiated inventory from which it dispenses prescription drugs to all of its customers. Moreover, at the time the contract pharmacy dispenses a drug to an individual customer, it does not determine whether the customer is a patient of a 340B covered entity, whether the drug is eligible for the discounted price, or even whether the drug it is dispensing was purchased at the 340B price—ignoring the various anti-diversion safeguards set forth in HRSA’s guidance. *See* OIG Testimony at 11 (testifying “many contract pharmacies

dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory").

63. Under the replenishment model, contract pharmacies do not determine whether a customer is eligible to receive a covered outpatient drug purchased at the 340B price at the time the pharmacy dispenses the drug to the customer. Instead, such a determination purportedly is made after the covered outpatient drug has already been dispensed, often by third-party administrators that are paid by the covered entity and contract pharmacy, but that is not a system that confirms the eligibility of each specific prescription. The third-party administrator, instead, typically uses a black-box algorithm to determine whether it can somehow link each customer to a covered entity. Vandervelde et al., *supra*, at 5. The contract pharmacy then uses this determination to have drugs purchased from the manufacturer at the 340B discount price that it then places in its general inventory.

64. HRSA does not regulate or prescribe the process for identifying the prescriptions that are claimed to be eligible to be filled with 340B discounted drugs. Nor have covered entities, contract pharmacies, or third-party administrators made their algorithms public, precluding HRSA and drug manufacturers from understanding the algorithms and assessing their accuracy.

65. Contract pharmacies profit through arrangements with covered entities in multiple ways. Typically, the contract pharmacy will charge its customers and their insurers the full retail price and not pass on to them any of the savings from the 340B discount. *See* GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108 at 4 (Dec. 2019) (explaining that under the 340B program, drugs can be purchased "at the 340B price for all eligible patients regardless of the patients' income or insurance status" and purchasers "receiv[e] reimbursement from patients' insurance that

may exceed the 340B prices paid for the drugs"). The difference between the full retail price that the contract pharmacy receives from their customers and their insurers, and the heavily discounted 340B price that the contract pharmacy pays for new drugs to "replenish" its general inventory, generates substantial revenue, and a significant portion of that is kept by the contract pharmacy (and thus not provided to the covered entity). For the time period "between 2013 and 2018, the [National Community Pharmacists Association] reported that the average gross margin on all prescription medicines ranged between 22% and 23%." *Id.* For drugs purchased at the 340B price, in contrast, industry experts have estimated the average gross margin to be 72%. *Id.*

66. Many contract pharmacy arrangements are based on a percentage-based profit sharing scheme, where the contract pharmacy is paid a fee by the covered entity that it calculates as "a percentage of revenue generated for each 340B prescription." 2018 GAO Report at 25. In 2018, the GAO found that the fees that covered entities paid to contract pharmacies based on a percentage of revenue "ranged from 12 to 20 percent of the revenue generated." *Id.* at 27. Alternatively, or sometimes in addition to the percentage-based fee, the contract pharmacy may require the covered entity to pay a flat fee for each prescription that the contract pharmacy dispensed that it later relied on to secure a 340B discount. *Id.* at 26. Some flat fees are as high as $1,750 for certain brand drug prescriptions. *Id.*

67. Third-party administrators take another portion of the 340B profits generated by contract pharmacy arrangements by charging the covered entities an additional fee, often on a per-prescription basis. 2018 GAO Report at 28–30. Notably, in many instances, the third-party administrator is paid only for prescriptions that the administrator's analysis determines to be eligible to be filled with a 340B discounted drug. In addition, the fees that covered entities are charged by third-party administrators are sometimes based on a percentage of the 340B discount.

Id. These fee structures create an obvious incentive for administrators' algorithms to identify as many already-dispensed prescriptions as possible, as well as higher-value prescriptions, as eligible for a 340B discount in order to justify claiming a 340B discount on subsequent "replenishment" orders.

68. The massive profits generated by contract pharmacy arrangements with covered entities are frequently not shared with the underserved patients whom covered entities are meant to serve. The GAO found that only 54% of covered entities who responded to its request for data reported offering some discount on 340B drugs to low-income, uninsured patients in their contract pharmacy arrangements. 2018 GAO Report at 30.

69. Although Congress enacted the statute to benefit the covered entities that it identified in that statute, the "profits on 340B purchased medicines are now distributed across a vertically integrated supply chain that includes . . . pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." Vandervelde et al., *supra*, at 7. Of the approximately 27,000 contract pharmacies participating in the 340B program, more than half of all profits realized by contract pharmacies are made by just four large, for-profit pharmacy chains: Walgreens, CVS, Walmart, and Cigna's Accredo specialty pharmacy. *Id*. at 7; *see also* 2018 GAO Report at 20 (stating the majority (75%) of 340B contract pharmacies are chain pharmacies). Strikingly, the five largest pharmacy chains "represented a combined 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide." 2018 GAO Report at 21. At least one national pharmacy chain has disclosed that 340B profits are so significant as to be material to its business operations. Walgreens Boots Alliance, Inc. Form 10-K, at 23 (Oct. 15, 2020), https://bit.ly/2MoLX9d.

70. The exponential increase in use of contract pharmacies also creates serious concerns about the integrity of the 340B program, including by multiplying the chances that statutorily-prohibited diversion will occur.

71. Although there is little transparency regarding how contract pharmacy customers are retrospectively identified as patients of covered entities with prescriptions covered by the 340B program, third-party administrators have a strong incentive to broadly interpret which contract pharmacy customers would have been patients of covered entities under the 340B program because the administrators' fees are typically based on the number of prescriptions that they identify as purportedly eligible for the 340B discounted price. Notably, while the statute uses the term "patient," it does not define the term. HRSA has attempted to provide guidance, but the GAO has observed: "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. . . . The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly." GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 22 (Sept. 2011) ("2011 GAO Report"), https://www.gao.gov/assets/gao-11-836.pdf.

72. The publicly-available evidence confirms that this system with its perverse incentives has led to widespread abuses of the 340B program. As detailed in a GAO report, HRSA

has identified hundreds of instances of diversion. 2018 GAO Report at 37; *see also* 2011 GAO Report at 28 ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately two-thirds of violations for diversion that HRSA uncovered through audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

73. HRSA is aware that the contract pharmacy participation in the 340B program generates a large revenue stream for national for-profit chain pharmacies that the 340B statute was not enacted to provide.

74. In 2017, the Director of HRSA's Office of Pharmacy Affairs testified that contract pharmacy profiteering from their arrangements with covered entities was "a business matter between the parties and their contract." *Examining HRSA's Oversight of the 340B Drug Pricing Program; Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 115 Cong. 79 (July 18, 2017) (testimony of Capt. Krista M. Pedley, Director, Off. of Pharmacy Affairs, HRSA). She noted that HRSA does not prohibit covered entities from sharing with contract pharmacies the financial spread between the heavily discounted 340B prices paid and the full, undiscounted reimbursements received from insurance companies. *Id.*

75. HRSA knows that contract pharmacy arrangements create a substantial risk of statutorily-prohibited diversion and duplication. *See* 75 Fed. Reg. at 10,274 (commenter noting that the 2010 guidance "d[id] not adequately describe safeguards that will combat drug diversion and duplicate discounts").

76. For example, HRSA previously advised covered entities to implement multiple audit and other programs to police their contract pharmacy arrangements and halt diversion and

other abuses, but as HHS's Inspector General reported in 2014: "[M]ost covered entities [it studied] do not conduct all the oversight activities" HRSA recommends. *See* 2014 OIG Report at 2. The upshot is that, as the GAO concluded, HRSA "does not know the scope of the assessments [conducted by covered entities] and whether they are effective at identifying the full extent of non-compliance." 2018 GAO Report at GAO Highlights. "Given these weaknesses," the GAO concluded, "HRSA does not have a reasonable assurance that covered entities adequately identified and addressed non-compliance with 340B Program requirements." *Id.*

77. Moreover, although covered entities and contract pharmacies are supposed to implement plans to ensure 340B compliance, HRSA reviews these plans only if it conducts an audit, and HRSA typically audits only around 1.5% of covered entities. *Opportunities to Improve the 340B Pricing Program: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce*, 115th Cong. 31–32 ("July 11, 2018 H. Subcomm. Hearing") (testimony of Debra Draper, Director, Health Care Team, GAO). As a GAO witness summarized, HRSA has left the "method of ensuring compliance . . . up to the covered entities." *Id.* at 43.

78. HRSA has disclaimed legal authority to regulate arrangements between contract pharmacies and covered entities—while simultaneously asserting that manufacturers somehow are obligated by statute to provide discounted 340B covered outpatient drugs to contract pharmacies. *Id.* at 40 ("The other issue is that HRSA doesn't have legal authority over these arrangements. They discuss it as a private business matter between the covered entity and contract pharmacies and third-party administrators.").

79. For example, in responding to GAO concerns about 340B program abuses relating to contract pharmacies, HRSA asserted that "[w]hile HHS appreciates the recommendations to issue guidance, we would face challenges with issuing guidance on 340B policy matters in cases

where our enforcement authority is quite limited. HHS notes that HRSA currently lacks explicit general regulatory authority in the 340B statute to issue regulations on most aspects of the 340B Program." 2018 GAO Report at 69.

80. Likewise, in the audits conducted by HRSA in fiscal year 2019, HRSA officials reported to GAO that there were instances where HRSA "did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use." GAO, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 15-16 (Dec. 2020).

81. If HRSA lacks authority to regulate arrangements between contract pharmacies and covered entities, that only underscores the agency's lack of statutory authority to require manufacturers to provide 340B discount drugs to contract pharmacies.

82. HRSA's lack of oversight of contract pharmacy arrangements is important for multiple reasons. *First*, it underscores the flaws of HRSA's statutory interpretation—there is no plausible basis to interpret the statute as mandating that manufacturers provide 340B discounted drugs to contract pharmacies, yet simultaneously as not authorizing HRSA to engage in meaningful oversight of those pharmacies. *Second*, it illustrates that HRSA does not police the detailed contractual relationships between covered entities, third-party administrators, and contract pharmacies—and therefore is not aware of whether they even constitute the type of principal-agent fiduciary agreements that the agency's Chief Legal Officer opined was required to trigger a manufacturer obligation to provide 340B discounted drugs to contract pharmacies. *See* Advisory Opinion at 1 ("[T]o the extent contract pharmacies are acting as agents of a covered entity, a drug

manufacturer in the 340B program is obligated to deliver its covered drugs to those covered pharmacies . . . ." (emphasis added)).

83. Even where HRSA audits covered entities and discovers violations, HRSA does "not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit." July 11, 2018 H. Subcomm. Hearing at 54 (statement of Rep. H. Morgan Griffith). In the limited cases where HRSA conducted re-audits of covered entities that had compliance issues, HRSA found repeated instances of noncompliance. *Id.* at 55 (GAO witness testifying that HRSA should require "more rigorous information . . . from the covered entities as to what they've done"). To BI's knowledge, HRSA has never directly audited any third-party administrator or contract pharmacy to address compliance concerns under HRSA's contract pharmacy policies. *See* 42 U.S.C. § 256b(a)(5)(C).

D. HRSA's 2020 Advisory Opinion

84. On December 30, 2020, HHS's General Counsel issued an Advisory Opinion on contract pharmacies. In the Advisory Opinion, HHS opined for the first time that drug manufacturers are "*obligated*" to provide 340B discounted drugs to an *unlimited* number of contract pharmacies, if the contract pharmacies are "acting as agents of a covered entity." Advisory Opinion at 1; *AstraZeneca*, 2021 WL 2458093, at *6 ("The [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies."). The Advisory Opinion did not point to any evidentiary basis for concluding that any contract pharmacy acts as an agent of a covered entity, much less that all 27,000 contract pharmacies currently receiving 340B discounts do so. *Id.* Even if HRSA had authority to determine whether contract pharmacies are acting as agents of a covered entity, this would be a massive task, requiring the government to review thousands of

contract pharmacy and third-party administrator agreements, to assess the application of state agency law in each circumstance, and to make specific findings for each such contract pharmacy arrangement. The Advisory Opinion did not purport to make any findings regarding the agency relationship between contract pharmacies and covered entities, and to BI's knowledge, HRSA has not attempted to do so. Nor has HRSA provided any mechanism for drug manufacturers to evaluate in advance whether any contract pharmacy is in fact the agent of a covered entity or the terms or scope of any such agency.

85. Despite HRSA's prior statements that Section 340B was silent on the matter, the Advisory Opinion asserted that the statute unambiguously requires manufacturers to accede to contract pharmacy arrangements because the statute requires manufacturers to "offer" covered 340B drugs at or below the ceiling price for "purchase by" covered entities. Advisory Opinion at 2. The Advisory Opinion claimed that a covered entity purchases and holds "title" to the 340B drugs even when they are delivered to a different party, such as a contract pharmacy, for inclusion in an undifferentiated inventory of products that is dispensed to customers without regard to whether they are patients of the covered entity. *See id.* at 3. According to the Advisory Opinion, covered entities take title regardless of whether the delivery location is "the lunar surface, low-earth orbit, or a neighborhood pharmacy." *Id.*

86. Among other flaws, the Advisory Opinion relied upon two erroneous assumptions: that contract pharmacies or other third parties are in fact agents of covered entities; and that the covered entities have title at all times to drugs purchased at the 340B price that are part of a contract pharmacy's general inventory and dispensed by the contract pharmacy to its customer—even though such drugs are not segregated from other inventory, and even though the contract pharmacy

does not determine whether a customer or a prescription is 340B-eligible at the time it dispenses the 340B discounted drug.

87. The Advisory Opinion expressly endorsed the so-called replenishment model that is widely used by contract pharmacies. *Id.* at 6 n.6. But the Advisory Opinion did not explain, even on its own terms, how that could be reconciled with the core assumptions that formed the basis of the Advisory Opinion. In reality, under the so-called replenishment model, the 340B discounted drugs that are provided to the contract pharmacy are placed by the contract pharmacy in its general inventory and dispensed to customers without regard to whether they are patients of a covered entity with a 340B covered prescription. *See AstraZeneca*, 2021 WL 2458063, at *11 n.19 ("Under the now-prevalent 'replenishment model' . . . . [t]he covered entities never physically possess the drug.").

E. Litigation Challenging the Advisory Opinion

88. Various suits have been brought by pharmaceutical manufacturers against HRSA and HHS, challenging their interpretation of the 340B statute and response to manufacturer policies limiting the contract pharmacies to which they provide drugs at the 340B discounted price. *See Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. filed Jan. 12, 2021) ("*Eli Lilly*"); *AstraZeneca Pharms. v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-00634-FLW-LHG (D.N.J. filed Jan. 12, 2021); *Novo Nordisk Inc. v. HHS*, No. 3:21-cv-00806-FLW-LHG (D.N.J. filed Jan. 15, 2021); *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479-DLF (D.D.C. filed May 31, 2021) ("*Novartis Pharms.*"); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. filed June

23, 2021) ("*United Therapeutics*"); *Kalderos, Inc. v. United States*, No. 1:21-cv-02608-DLF (D.D.C. filed Oct. 6, 2021).

89. To date, one of those federal district courts has substantively addressed claims regarding the Advisory Opinion. It found the agency's Advisory Opinion is "legally flawed" because that Advisory Opinion wrongly concluded that the contract pharmacy framework was mandated by the statute. *AstraZeneca*, 2021 WL 2458063, at *8.

90. On June 18, 2021, following issuance of the court decision concluding the Advisory Opinion was "legally flawed," *see id.*, HHS withdrew the Advisory Opinion, purportedly "in the interest of avoiding confusion and unnecessary litigation." *See* Advisory Opinion Withdrawal at 2.

91. Despite withdrawing the Advisory Opinion, HRSA is persisting in its interpretation of the statute as requiring manufacturers to provide 340B discounted drugs to contract pharmacies for their general inventories. *See, e.g.*, HRSA Combined Mem. in Opp'n to Pl.'s Mot. for Summ. J. and in Supp. of Defs.' Mot. for Summ. J. at 17–30, *United Therapeutics* (July 17, 2021), ECF No. 16-1; HRSA Combined Reply in Support of Defs.' Mot. for Summ. J. and in Opp'n to Pl.'s Mot. for Summ. J. at 1–8, *Novartis Pharms.* (July 16, 2021), ECF No. 24.

F. Boehringer Ingelheim's Policy

92. On June 30, 2021—after the district court in *AstraZeneca* ruled that the Advisory Opinion was legally flawed and after HRSA withdrew its Advisory Opinion—BI announced that, beginning August 1, 2021, it would enact a new policy with regard to contract pharmacies (attached as Exhibit 6). Specifically, BI indicated that it would provide drug products at the 340B discount price to only one commercial contract pharmacy for each covered entity that lacks an in-house pharmacy, with some voluntary exceptions. BI's policy provides that covered entities

without an in-house pharmacy capable of dispensing 340B purchased drugs to their patients can designate a single contract pharmacy location to which BI will provide drugs at the price of the 340B discount. BI's policy includes three other voluntary exceptions, that although not required by the statute are recognized by BI because of its commitment to provide access to its products for vulnerable patient populations

93. First, BI's policy provides that BI will continue to provide drugs at the 340B discount price to commercial contract pharmacies that contract with federal grantees—i.e., those covered entities that are specifically identified in the 340B statute at 42 U.S.C. § 256b(a)(4)(A)–(K).

94. Second, BI's policy provides that it will provide drugs at the 340B discount price to contract pharmacies that are wholly owned by, or under common ownership with, 340B covered entities.

95. Third, if the limitation to one contract pharmacy creates access concerns for patients of a covered entity, BI's policy includes a case-by-case process to address those concerns, and BI has granted limited exceptions pursuant to that process.

96. BI's voluntary exceptions are designed to facilitate access to BI's medicines by underserved populations, consistent with the company's support of that policy objective. For example, the exception for federal grantees recognizes the unique role played by those grantees in supporting access for underserved and vulnerable populations.

97. BI implemented its policy on August 1, 2021, and has continued to implement it since that date.

G. HRSA's July 2021 Letter

98. HRSA sent a letter to BI on July 20, 2021, regarding BI's policy (attached as Exhibit 1) (the "July 2021 Letter").

99. Despite HRSA's withdrawal of the Advisory Opinion and the federal court ruling in *AstraZeneca* that the Advisory Opinion is legally flawed, HRSA's Letter continued to interpret the statute as requiring that manufacturers provide 340B discounted drugs to any and all contract pharmacies.

100. HRSA's July 2021 Letter did not indicate when or where HRSA "stated previously" this understanding of the statute, and given the multiple conflicting positions HRSA has taken on this issue, it is unclear to which prior statement(s) HRSA is referring.

101. HRSA's July 2021 Letter suggested that "BI's proposed limitation of the number of contract pharmacies a covered entity can use to obtain 340B discounts" would not "comply with [BI's] obligations under section 340B(a)(1)." HRSA indicated that if BI implemented its policy, "HRSA will conduct a full analysis of the policy to determine whether there is a violation of the 340B statute and the potential for civil monetary penalties in accordance with applicable legal authorities."

102. HRSA's July 2021 Letter did not quote any statutory text or otherwise explain what supported its assertion that the statutory text requires manufacturers to provide 340B discounted drugs to an unlimited number of contract pharmacies.

103. HRSA's July 2021 Letter indicated that HRSA believes that contract pharmacies provide "a vital function." However, HRSA's Letter provided no evidentiary support or citations for its claims regarding the purported benefits of an unlimited number of contract pharmacies.

HRSA's July 2021 Letter also did not discuss the significant concerns relating to contract pharmacies under the 340B program, including those relating to diversion.

104. HRSA's July 2021 Letter indicated that HRSA believes that a manufacturer can address concerns relating to contract pharmacies by conducting audits and using the administrative dispute resolution process. But HRSA's July 2021 Letter provided no justification as to why a manufacturer must provide unlawful 340B discounts, and then seek to recoup costs through an audit and administrative dispute resolution process. HRSA also did not acknowledge the practical and legal flaws with its audit and administrative dispute resolution processes, which render them woefully insufficient to address the contract pharmacy issue. Moreover, a federal district court recently granted a preliminary injunction against a rule that HRSA promulgated for use of administrative dispute resolution proceedings to resolve certain disputes regarding the 340B program because HRSA violated the Administrative Procedure Act's notice-and-comment requirements when it promulgated the rule. *See Eli Lilly Co. v. Cochran*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 981350, at *8–10 (S.D. Ind. Mar. 16, 2021).

105. HRSA's July 2021 Letter did not indicate that there was any process available by which the Letter could be challenged administratively, nor did HRSA's Letter invite further discussion or indicate that HRSA's views were amenable to change.

H. Boehringer Ingelheim's Response to HRSA's Letter and Further Correspondence

106. BI responded to HRSA's Letter on July 29, 2021 (attached as Exhibit 2).

107. BI's response letter explained that its policy fully complies with the 340B statute, which does not require manufacturers to provide 340B discounted drugs to contract pharmacies. BI's response letter discussed the recent decision by the federal court in *AstraZeneca*, the statutory

text, and various principles of statutory construction, and explained why those show that the statute does not extend to contract pharmacies.

108. BI also explained that the exceptions to its policy go above and beyond what the statute requires to promote access to BI's medicines, particularly for vulnerable and underserved populations.

109. BI further explained that the administrative dispute resolution rule had been preliminarily enjoined by a federal court, and that as a practical matter there are serious problems with relying on the audit and administrative dispute resolution process to address contract pharmacy abuses.

110. While BI expressed its willingness to work with HRSA, it noted that HRSA should reconsider its improper interpretation of the statute.

111. On September 8, 2021, HRSA sent another letter to BI (attached as Exhibit 3). That letter asserted that BI's July 29 letter "did not address the concerns" of HRSA, and indicated that HRSA "has begun conducting an analysis of BI's policy and upon completion of that analysis, . . . will make a determination as to any potential action, which includes whether a violation of the 340B statute has occurred and the potential for civil monetary penalties in accordance with applicable legal authorities." Ex. 3, at 1. HRSA's letter contained no substantive analysis.

112. BI responded on September 15, 2021 (attached as Exhibit 4). BI explained that it continued to disagree with HRSA's interpretation, and would continue to implement its 340B policy regarding contract pharmacies.

I. HRSA's October 2021 Letter

113. On October 4, 2021, HRSA sent a third letter to BI that stated HRSA had completed its review of BI's policy regarding contract pharmacies and "determined" that "BI's actions have resulted in overcharges and are in direct violation of the 340B statute." Ex. 5, at 1.

114. HRSA reiterated its position that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* In HRSA's view, "the 340B statute requires manufacturers to honor … purchases" made by covered entities through the manufacturer's distribution agreements with wholesalers "regardless of the dispensing mechanism." *Id.*

115. The October 2021 Letter did not acknowledge the agency's prior positions in its 1996 and 2010 guidance documents or its December 2020 Advisory Opinion. The October 2021 Letter also did not address the recent decision from the District of Delaware in *AstraZeneca*, 2021 WL 2458063, at *8, nor did it address the statutory interpretation arguments BI presented in its July 29, 2021 Letter.

116. The October 2021 Letter similarly did not acknowledge or respond to BI's concerns that the administrative dispute resolution process is not an adequate alternative mechanism to address concerns about contract pharmacy abuse of the 340B program.

117. Based on its apparent view of the statute, HRSA instructed that "BI must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." Ex. 5, at 2. HRSA further instructed that BI "must . . . credit or refund all covered entities for overcharges that have resulted from BI's policy." *Id.* The Letter

also stated that continued failure to provide the 340B price to covered entities using contract pharmacies could result in civil monetary penalties.

HRSA'S LETTER CONSTITUTES FINAL AGENCY ACTION

118. HRSA's October 4, 2021 Letter constitutes final agency action reviewable under the APA.

119. HRSA's July 20, 2021, September 8, 2021, and October 4, 2021 letters (collectively, "HRSA's Letters") were not issued in a vacuum: as noted, in May 2021 the agency had issued letters to six other manufacturers asserting that manufacturers must provide contract pharmacies with 340B discounts under the statute, and threatening civil monetary penalties. Moreover, HRSA has defended that same position in multiple separate pending court proceedings brought by those manufacturers.

120. HRSA's July 20, 2021 Letter to BI adopted an interpretation of the 340B statute that would require manufacturers to provide 340B discounted drugs to multiple contract pharmacies, regardless of how those contract pharmacies purchase and account for 340B prescriptions. HRSA reasserted that interpretation in its September 8, 2021 Letter and in its October 4, 2021 Letter.

121. HRSA's October 2021 Letter makes a final determination that BI's policy is a "direct violation of the 340B statute." Ex. 5, at 1. This final and conclusive determination is the culmination of an agency process, as HRSA indicated in its September 2021 Letter that it would make a determination "upon completion" of its analysis of BI's policy. Ex. 3, at 1. Therefore, the agency has taken the final position that the statute requires 340B discounted drugs be provided to multiple contract pharmacies.

122. HRSA's October 2021 Letter also threatened civil monetary penalties against BI, if BI were to move forward with implementing its policy.

123. Civil monetary penalties may be issued under 340B only if there is a "knowing[] and intentional[]" violation of the statute. 42 U.S.C. § 256b(d)(1)(vi)(III). BI vigorously disputes the suggestion that its contract pharmacy policy change constitutes a knowing and intentional violation of the 340B statute. By adopting the view that BI's conduct violates the statute, HRSA's Letter has increased the risk that if BI's conduct is found to violate the statute, the violation could be determined to be knowing and intentional. HRSA's Letter thus creates an "increased risk of prosecution and penalties" and further confirms that the Letter constitutes final agency action. *Ipsen Biopharms. v. Azar*, 943 F.3d 953, 957 (D.C. Cir. 2019).

124. BI does not have an adequate alternative for seeking review of HRSA's interpretation of the statute, as set forth in its July 20, 2021 Letter, reiterated in its September 8, 2021 Letter, and definitively "determined" in its October 4, 2021 Letter. The 340B statute does not contain a provision for review of a letter of this type, nor do the Letters themselves indicate that they may be appealed or otherwise formally contested administratively. Thus, in the absence of review by this court, BI will be forced to either (1) run the risk of civil monetary penalties by continuing to implement its policy, or (2) halt implementation of its policy, which would require it to provide 340B discounted drugs to an unlimited number of contract pharmacies in conflict with the requirements of the statute.

125. HRSA's October 2021 Letter suggests that its Administrative Dispute Resolution ("ADR") process that implements section 340B(d)(3)(A) is an alternative avenue for BI to address concerns arising over program integrity issues relating to diversion and duplicate discounts involving contract pharmacies. But a court has already concluded that the rule HRSA promulgated

to govern ADRs (the "ADR Rule") is likely unlawful because it was not promulgated through the required notice-and-comment procedures. *Eli Lilly & Co. v. Cochran*, 2021 WL 981350 (S.D. Ind. Mar. 16, 2021). As the federal district court explained, the government's actions in promulgating the ADR rule were "ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice" under the APA. *Id.* at *10. In addition, because the 340B statute does not require manufacturers to provide 340B discounted drugs to contract pharmacies, nothing in the statute prohibits manufacturers from taking action with regard to contract pharmacies to address program abuses. *See also AstraZeneca*, 2021 WL 2458063 at *7 (rejecting argument that manufacturers must go through ADR proceedings to challenge HRSA's new interpretation of the statute, which was set forth for the first time in its December 30, 2020 advisory opinion).

126. The ADR process is also not an adequate alternative avenue to address concerns about program integrity because the ADR Rule is unconstitutional. The ADR panelists are principal officers because they make final decisions for the agency without review by a superior executive officer. *See United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021) (holding that administrative patent judges were principal officers because they had "power to render a final decision on behalf of the United States" without "review by a superior executive officer"). Section 340B and the ADR Rule both provide that a panel decision is a "final agency decision" that is "precedential and binding." 42 U.S.C. § 256b(d)(3)(C); 42 C.F.R. § 10.24(d). The ADR panelists' appointments therefore violate the Appointments Clause of the U.S. Constitution since the panelists are not appointed by the President and confirmed by the Senate. Moreover, the ADR Rule violates Article III because it allows ADR panels to impermissibly exercise judicial power.

127. Requiring manufacturers to go through an audit process is flawed for other reasons. There is no statutory requirement that manufacturers provide 340B discounted drugs to entities

that are not "covered entities," and then only later recoup those unlawful discounts via an audit process. As the *AstraZeneca* court noted, there are "serious concerns" about the ability of manufacturers "to conduct effective audits of covered entities," and there is "no indication that the government ever grappled with these practical problems with the ADR process." 2021 WL 2458063, at *7 n.12.

CLAIMS FOR RELIEF

COUNT I: Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(C)
(Agency Action Taken In Excess of Statutory Jurisdiction or Authority)

128. Plaintiff incorporates by reference paragraphs 1–127 as if fully set forth herein.

129. The APA provides that the Court "shall . . . hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).

130. HHS and HRSA are "agencies" under the APA, 5 U.S.C. § 551(1), and the Letters constitute final, reviewable "agency action for which there is no other adequate remedy in a court," 5 U.S.C. §§ 551(13), 704.

131. The 340B statute does not require manufacturers to provide 340B discounted drugs to contract pharmacies. *AstraZeneca*, 2021 WL 2458063 at *11. Instead, the 340B statute requires manufacturers to offer drugs at discounted 340B prices only to "each covered entity." 42 U.S.C. § 256b(a)(1). The statute further specifies that drugs must be "purchased by a covered entity" to be eligible for a 340B discount, *id.*, and it expressly prohibits covered entities from transferring drugs purchased at the 340B discount to any person—including for-profit commercial entities—that is not a patient of a covered entity, *id.* § 256b(a)(5)(B).

132. Congress defined "covered entities" to consist of 15 types of entities that are specifically identified in the statute. Contract pharmacies are not within this statutory definition of "covered entities."

133. Congress knew how to include entities with a contractual relationship with a covered entity within the scheme of the statute if it so desired. In earlier versions of the 340B bill, Congress would have covered drugs "purchased and dispensed by, or under a contract entered into for on-site pharmaceutical services with" a covered entity. H.R. 5193 (as amended by the Senate, Oct. 1, 1992). Congress did not enact that provision.

134. Moreover, other parts of the 340B statute refer to different types of representatives of covered entities, and another part of the law that originally established the 340B program expressly referenced "a commercial entity operating under contract." Thus, "[i]f Congress intended to include agents or contract arrangements within the definition of 'covered entity,' it evidently knew how to do so," but the statute as enacted does not. *AstraZeneca*, 2021 WL 2458063 at *10.

135. The statute thus does not require manufacturers to make 340B discounted drugs available to contract pharmacies.

136. HRSA lacks any authority to impose such a requirement. "[A]n agency literally has no power to act, . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). Congress expressly declined to provide HRSA with broad rulemaking authority with regard to the 340B program, and confined agency rulemaking powers to specific aspects of the statute, none of which authorizes expansion of the statutorily identified covered entities. *See PhRMA v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014). The 340B statute does not authorize HRSA to alter the statute's text through enforcement action or subregulatory

guidance, nor has Congress delegated "gap-filling" authority to HRSA. *See generally Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995).

137. Indeed, if HRSA were understood to have such authority, that interpretation would raise a serious issue under the nondelegation doctrine, since the 340B statute lacks any "intelligible principle[s]" that would guide the agency's policymaking decisions with respect to contract pharmacies. *See, e.g.*, *Gundy v. United States,* 139 S. Ct. 2116, 2123 (2019) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)).

138. HRSA's interpretation is not entitled to deference because Congress has not delegated authority to the agency to address contract pharmacy issues, and because HRSA has altered its interpretation of the statute without engaging in notice-and-comment or other meaningful process.

COUNT II: Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
(Arbitrary and Capricious Agency Action)

139. Plaintiff incorporates by reference paragraphs 1–138 as if fully set forth herein.

140. The APA provides that a court "shall . . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

141. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its

decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

142. HRSA's Letter is arbitrary and capricious for a number of reasons, including the following.

143. *First*, the Letter "is based on the 'unjustified assumption' that Congress imposed [HRSA's] interpretation as a statutory requirement" and is therefore "legally flawed." *AstraZeneca*, 2021 WL 2458063, at *11 (quoting *Am. Lung Ass*'n *v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)). The October 2021 Letter concludes that "BI's actions . . . are in *direct violation* of the 340B statute," purportedly because the statute "*requires* that manufacturers" provide 340B drugs without restriction and because manufacturers have signed PPAs obligating their compliance "with these [statutory] *requirements*." The Letter further contends that HRSA "has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute *requires* manufacturers to honor such purchases regardless of the dispensing mechanism." Because it is apparent that HRSA "wrongly believes that [its] interpretation is compelled by Congress," the Letter must be vacated. *See Astrazeneca*, 2021 WL 2458063, at *11 (quoting *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006)).

144. *Second*, HRSA has repeatedly shifted course in its guidance regarding contract pharmacies, but none of HRSA's letters to BI even acknowledge those past changes. In 1996, HRSA interpreted the statute as authorizing only a *single* contract pharmacy per covered entity. HRSA's 2010 guidance was "directed towards covered entities," pre-dated a statutory amendment making clear that manufacturers must "offer *each covered entity*" drugs at or below 340B prices, and did not engage in any meaningful statutory interpretation that could support concluding that the statute requires manufacturers to provide 340B discounted drugs to multiple contract

pharmacies. *AstraZeneca*, 2021 WL 2458063 at *2-3. Thus, the December 2020 Advisory Opinion was "the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies." *AstraZeneca*, 2021 WL 2458063 at *6. Moreover, HRSA *withdrew* that Advisory Opinion on June 18, 2021, purportedly "in the interest of avoiding confusion and unnecessary litigation," yet continued to threaten enforcement actions based substantially on the same contentions expressed in that guidance.

145. HRSA's failure to even mention this history in its Letters means that the agency has failed to "at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). By definition, that failing renders HRSA's Letters arbitrary and capricious.

146. *Third*, HRSA's Letters do not explain why the agency's interpretation is permissible under the statute. HRSA's unclear reference to prior HRSA statements is wholly inadequate, given the multitude of conflicting past positions HRSA has taken on this issue. Furthermore, HRSA's October 2021 Letter contains a conclusory analysis of the statutory text that does not address the textual arguments or the legislative background that BI raised in its July 29, 2021 Letter. Because HRSA's Letter lacks adequate explanation, it is necessarily arbitrary and capricious. *See CSI Aviation Servs. v. DOT*, 637 F.3d 408, 414-416 (D.C. Cir. 2011) (agency violation letter, including its interpretation of the statute, must be adequately explained, such that a court can "evaluate the agency's rationale at the time of decision" (citation omitted)).

147. *Fourth*, HRSA has not provided any evidentiary or other support for its factual assertions relating to the supposed benefits of contract pharmacies. Because HRSA's Letter relies

on these factual claims as purportedly supporting its interpretation of the statute, yet provides no evidentiary or other support for those claims, the Letter is necessarily arbitrary and capricious.

148. *Fifth*, HRSA has failed to account for multiple important aspects of the problem, including: the substantial growth of contract pharmacies in recent years; the evidence that such contract pharmacies are facilitating diversion and not providing benefits to underserved patients but rather are reaping windfall profits through the 340B program; and the serious flaws in the audit and ADR processes that render them insufficient to address these issues.

COUNT III: Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(D)
(Agency Action Taken Without Observance of Procedure Required by Law)

149. Plaintiff incorporates by reference paragraphs 1–148 as if fully set forth herein.

150. The APA provides that the Court "shall . . . hold unlawful and set aside agency action" taken "without observance of procedure required by law," 5 U.S.C. § 706(2)(D), or that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).

151. HHS and HRSA are "agencies" under the APA, 5 U.S.C. § 551(1), and the Letters constitute final, reviewable "agency action for which there is no other adequate remedy in a court," 5 U.S.C. §§ 551(13), 704.

152. HRSA has adopted a new interpretation of the statute as requiring that manufacturers provide 340B discounted drugs to an unlimited number of contract pharmacies.

153. HRSA is treating that interpretation as binding on manufacturers, and has threatened manufacturers who do not abide by HRSA's interpretation with civil monetary penalties.

154. HRSA's new interpretation thus amounts to a legislative rule under the APA: it is "an agency statement of general or particular applicability and future effect designed to implement,

interpret, or prescribe law or policy," 5 U.S.C. § 551(4), and the purportedly binding nature of that interpretation renders the rule legislative, not interpretive, in nature. *See, e.g.*, *Nat'l Council for Adoption v. Blinken*, 4 F.4th 106, 114 (D.C. Cir. 2021) (agency guidance was legislative rule where it created new legal obligations and "expose[d] [parties] to enforcement actions").

155. HRSA did not provide for notice and comment prior to announcing its new interpretation, and thus violated the APA's notice-and-comment requirement. 5 U.S.C. § 553.

156. HRSA also lacks statutory authority to impose a legislative rule of this type. *See PhRMA v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014).

COUNT IV: Unconstitutional and Unauthorized Taking of Private Property

157. Plaintiff incorporates by reference paragraphs 1–156 as if fully set forth herein.

158. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, . . . found to be . . . contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

159. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

160. The Takings Clause applies to personal property. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015).

161. HRSA's actions amount to a confiscatory taking: it forces BI to transfer its property—the drugs it manufactures—to contract pharmacies, at significantly under-market prices, without just compensation.

162. That is not only a taking, but a taking that is unauthorized both by the U.S. Constitution and by statute.

163. As a constitutional matter, "it has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005). Therefore, the Constitution prohibits the government from taking BI's personal property for the sole purpose of transferring it to other private parties, even if just compensation is paid.

164. As a statutory matter, HRSA has no authority to effect a taking of this nature. No statute gives HRSA authority to require BI to transfer its personal property to other private parties.

165. Moreover, HRSA's actions cannot be justified by virtue of BI's "voluntary" participation in the 340B program. As noted above, BI's participation is hardly voluntary in light of the reality that manufacturers must agree to participate in the 340B program regarding *all* of their drugs in order for *any of* their drugs to be eligible under Medicare and Medicaid. Moreover, the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to participate in a government program. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013)

166. HRSA's actions amount to an unconstitutional and coercive condition, by forcing BI to either provide its property to contract pharmacies at a significantly below-market price, or alternatively be precluded from participating in Medicare and Medicaid, which represents a massive market for BI's products.

167. At a minimum, the serious constitutional concerns raised by HRSA's actions require a narrow construction of the statute, and thus weigh heavily against HRSA's latest interpretation that requires BI to transfer certain products to contract pharmacies at the 340B discount price.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Declare that the October 4, 2021 Letter is in excess of statutory authority, without observance of procedure required by law, is arbitrary, capricious, and is contrary to law on the grounds recited above;

B. Vacate the October 4, 2021 Letter on the grounds recited above;

C. Declare that Boehringer Ingelheim is not required to provide 340B discounted drugs to anyone other than a covered entity, and specifically not to contract pharmacies;

D. Declare that Boehringer Ingelheim's policy, as set forth in its June 30, 2021 Letter, complies with Section 340B;

E. Issue permanent injunctive relief preventing Defendants from implementing or enforcing the Letter, through ADR proceedings or otherwise;

F. Issue permanent injunctive relief preventing Defendants from imposing civil monetary penalties against Boehringer Ingelheim based on the Letters;

G. Award Plaintiff reasonable attorneys' fees and costs, plus interest accruing thereon, to the extent available under the law; and

H. Award such other relief as the Court may deem just and proper.

Dated: October 25, 2021

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