IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UCB, INC.,
1950 Lake Park Drive SE
Smyrna, GA 30080;

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;

CAROLE JOHNSON, in her official capacity as 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;

EMEKA EGWIM, in his official capacity as 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,
5600 Fishers Lane
Rockville, MD 20857

Defendants.

Civil Action No. 1:22-cv-02893

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff UCB, Inc. ("UCB") brings this action against Defendants Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services; Carole Johnson, in her official capacity as Administrator of the Health Resources and Services Administration; Krista M. Pedley, in her official capacity as Director of the Office of Special Health Initiatives; Emeka Egwim, in his official capacity as the 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. In November of last year, this Court vacated and set aside two letters from HRSA to pharmaceutical manufacturers that claimed the companies were in "violation of the 340B statute," 42 U.S.C. § 256b, because their policies do not provide discounted drugs to an unlimited number of contract pharmacies. *See Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479 (DLF), 2021 WL 5161783 (D.D.C. Nov. 5, 2021). The Court explained that the agency's letters "contain[ed] legal reasoning that rest[ed] upon an erroneous reading of Section 340B," *Novartis Pharms.*, 2021 WL 5161783, at *9, a statute that requires drug manufacturers to offer discounted drugs to certain "covered" healthcare providers, *see* 42 U.S.C. § 256b. The Court held that the manufacturer policies at issue—which placed certain limits on the extent to which the manufacturers would provide 340B-priced drugs to third-party entities known as "contract pharmacies"—did "not violate Section 340B under the positions advanced" in HRSA's letters. *Id.* Indeed, the "plain language, purpose, and structure of the statute" did not categorically prevent manufacturers from placing "conditions on their offers of 340B-priced drugs to covered entities." *Id.*

2. Despite this Court's ruling—and despite similar rulings from other federal courts rejecting substantively identical violation letters from HRSA to four other pharmaceutical manufacturers—the agency has not addressed the legal flaws in its actions and has continued on the same unjustifiable path. In May, HRSA issued another, substantively identical violation letter to another pharmaceutical manufacturer, the subject of a pending challenge in this Court. *See Merck Sharp & Dohme LLC v. HHS*, No. 22-cv-01986 (D.D.C. filed July 8, 2022). And in June, HRSA issued yet another substantively identical letter to Plaintiff here – UCB. Like the carbon copies that preceded it, the violation letter to UCB is agency action that is invalid multiple times over. It should be vacated, set aside, and declared unlawful.

3. Congress created the 340B Drug Pricing Program, 42 U.S.C. § 256b ("Section 340B") in 1992 to limit the price that manufacturers could charge certain healthcare providers ("covered entities") so the covered entities could purchase drugs from manufacturers at reduced prices. *See* 42 U.S.C. § 256b. The program was designed to reduce costs for the covered entities because they provide safety-net services to low-income populations. But the statute also imposes hard limits on the scope of the program. For example, covered entities "shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Covered entities also many not receive "duplicate discounts or rebates" on drugs they purchase at 340B prices. *Id.* § 256b(a)(5)(A).

4. The 340B statute defines covered entities—i.e., the designated beneficiaries of the 340B program—with a high level of specificity. The current version of the statute lists fifteen categories of covered entities. *See* 42 U.S.C. § 256b(a)(4)(A)-(O). Completely absent from that list—and completely absent from the statute—is any discussion of any third-party "contract

pharmacies," like Walgreens or CVS. *See Novartis Pharms.*, 2021 WL 5161783, at *6 (340B statute is "silent" as to any distribution requests manufacturers must accept from covered entities).

5. Four years after Congress created the 340B program, HRSA issued guidance because some covered entities lacked an in-house pharmacy, and HRSA provided that each covered entity should be allowed to select one outside "contract pharmacy" to dispense 340B-priced drugs. 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996). But the guidance recognized that the statute was "silent as to permissible drug distribution systems." *Id.* Moreover, HRSA provided that those contract pharmacies should dispense 340B-priced drugs "only" (1) "[u]pon presentation of a prescription bearing the covered entity's" identifying information or (2) based on "a prescription ordered by telephone" by a covered entity affiliate who "states that the prescription is for an eligible patient." *Id.* at 43,553. And HRSA specified that such contract pharmacies should "establish and maintain a tracking system suitable to prevent diversion." *Id*. at 43,555.

6. Nearly two decades after Congress created the 340B program, HRSA for the first time indicated that covered entities should be able to enter into 340B arrangements with an *unlimited* number of contract pharmacies through issuance of a 2010 guidance. *See* 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). That newly discovered agency view of the statute was not based on an amendment to the 340B statute, and it was contrary to the agency's position over the previous 18 years of the 340B program. The 2010 guidance had a significant economic impact, disproportionate to the size of the program created by Congress in 1992. In the ten years following the 2010 guidance, the number of contract pharmacy arrangements increased by more than 4,000%, from 2,321 in April 2010 to 100,451 in April 2020. Aaron Vandervelde et al., BRG, *For-*

Profit Pharmacy Participation in the 340B Program, at 4 (Oct 2020).[1] And by 2020, an average of 22 contract pharmacies contracted with each covered entity. Profits on 340B-priced drugs that were to benefit covered entities or patients under the framework created by Congress are now spread through payments to "pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups" "across a vertically integrated supply chain." *Id.* at 7. More than half of all the profits on 340B drugs that are paid to contract pharmacies go to just four large, for-profit pharmacy chains. *Id.*

7. The explosive growth in 340B profits for contract pharmacies involved sophisticated business arrangements aimed at maximizing contract pharmacy profits rather than ensuring program integrity. Under the widely used "replenishment model," contract pharmacies do not dispense 340B-priced drugs only to 340B patients bearing a 340B prescription that qualifies under the statute, as HRSA's 1996 guidance had specifically provided. *See* 61 Fed. Reg. at 43,553. Instead, contract pharmacies dispense 340B-priced drugs to *any* customer with a prescription from *any* prescriber. It is only after a pharmacy dispenses drugs to patients that the pharmacy then, on a periodic basis, runs its data through a nonpublic algorithm to purportedly identify, *ex post facto*, whether the pharmacy dispensed the drug to a patient of a covered entity eligible to purchase 340B-priced drugs. For each patient that the algorithm claims to be connected to a covered entity, the contract pharmacy directs the covered entity with whom it contracts to "replenish" the pharmacy's general inventory with a new 340B-discounted order. Making matters worse, contract pharmacies are often compensated by the covered entity in part based on the number of 340B-priced prescriptions they fill—so there is an economic incentive for the contract pharmacy to weight its

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

nonpublic algorithms to unearth "340B-eligible" transactions that have the most tenuous of links to the covered entity. In short, the replenishment model that contract pharmacies have created is a recipe for unlawful transfers of medications purchased at the 340B price to customers without any verified connection to the 340B program.

8. In the face of these developments—which HRSA facilitated through its 2010 guidance that provided for an unlimited number of contract pharmacies for each covered entity—the agency took no meaningful action. In 2020, in order to curb the unlawful expansion of the 340B program described above, some manufacturers announced new policies that placed limits on the extent to which they would provide 340B-priced drugs to contract pharmacies.

9. In 2020, HRSA initially took the position that because of its limited authority under the statute, the agency lacked the authority to enforce its 2010 sub-regulatory guidance against manufacturers. *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020).[2] In a December 2020 Advisory Opinion, however, HRSA declared for the first time that "drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 56 (D. Del. 2021) ("*AstraZeneca I*"). That Advisory Opinion was challenged—and struck down—in federal court. Judge Stark ruled that the Advisory Opinion was "legally flawed" because it "wrongly determine[d]" that the 340B statute "mandates . . . an unlimited number of contract pharmacies." *Id.* at 58–59.

10. HRSA was undeterred. HRSA issued a series of six violation letters to manufacturers in May 2021. Those letters were substantively identical, and they were based on the same flawed reasoning in the December 2020 Advisory Opinion. For example, they all claimed

[2] *Available at* https://340breport.com/hrsa-says-its-340b-contract-pharmacy.

that the relevant manufacturers were in "direct violation of the 340B statute" based on purported "statutory obligations" to provide 340B-priced drugs to an unlimited number of contract pharmacies.

11. In separate lawsuits before four different federal district courts, all six violation letters were vacated in whole or in part. Two district courts, including this Court, invalidated three of the letters because (like the Advisory Opinion) they were based on the incorrect understanding that the 340B statute somehow unambiguously *requires* manufacturers to provide 340B-priced drugs to multiple contract pharmacies. *See Novartis Pharms.*, 2021 WL 5161783; *AstraZeneca Pharms. LP v. Becerra*, No. 21-27-LPS, 2022 WL 484587 (D. Del. Feb. 16, 2022) ("*AstraZeneca II*"). A third district court vacated a fourth letter in light of HRSA's inconsistent positions regarding its enforcement authority. *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *22 (S.D. Ind. Oct. 29, 2021). And a fourth district court partially vacated the remaining two letters and remanded to HRSA for it to assess "the number of permissible contract pharmacy arrangements" that manufacturers could be required to supply under the 340B statute. *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 220 (D.N.J. 2021).[3]

12. On November 22, 2021, Plaintiff here, UCB, announced that effective December 13, 2021, it would provide certain drug products at the 340B discounted price to contract pharmacies only where: (1) the covered entity is a federal grantee; (2) a single contract pharmacy

[3] In the midst of this litigation, HRSA issued a violation letter to a seventh manufacturer, who challenged the letter in this Court. *See Boehringer Ingelheim Pharms., Inc. v. Becerra*, No. 1:21-cv-02826-DLF (D.D.C. filed Oct. 25). That case is currently stayed pending the outcome of the *Novartis* appeal.

is designated by a covered entity that does not have an in-house pharmacy; or (3) the contract pharmacy is wholly owned by or under common ownership with a covered entity.

13. Despite the string of adverse judicial rulings on the meaning of the statute, HRSA pressed forward without any apparent adjustment to its enforcement approach or legal justification. On May 6, 2022—well after the above opinions had been issued—HRSA issued an additional violation letter to another manufacturer that was a virtual carbon copy of the May 2021 violation letters that had been vacated.

14. On June 27, 2022, HRSA sent essentially the same violation letter to Plaintiff UCB (hereinafter, the "Violation Letter"). *See* Exhibit 1. Like the violation letters that multiple courts—including this Court—have rejected as legally flawed, the Violation Letter claimed that UCB is in "direct violation of the 340B statute" because its policy does not provide 340B-discounted drugs to an unlimited number of contract pharmacies. *Id.* at 1. As in the previous violation letters, HRSA reiterated its position—based on an erroneous interpretation of the statute—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.* And as in the previous letters, HRSA demanded that UCB "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.* at 2.

15. On July 11, 2022, UCB submitted a letter to HRSA in response to the Violation Letter. *See* Exhibit 2. UCB pointed out that HRSA's Violation Letter was "substantively identical to letters previously sent by HRSA to other pharmaceutical manufacturers that have been consistently invalidated by federal courts," including this Court, and that "[l]ike those other letters, HRSA's [Violation Letter] rests on a fundamentally flawed interpretation of the 340B statute." *Id.*

at 1. UCB relied on the quoted rationale of multiple federal court opinions—including this Court's *Novartis* opinion—holding that the 340B statute is silent regarding contract pharmacies, and that the statute does not prohibit manufacturers from establishing reasonable terms and policies in connection with their 340B sales. *Id.* at 1–2. More than two months have passed, and HRSA has not responded to UCB's letter.

16. HRSA's violation letters were invalid when they were issued in 2021. The federal court rulings that have rejected the agency's flawed reading of the 340B statute and its shifting approach to enforcement confirm that fact. Because the Violation Letter to Plaintiff UCB is arbitrary, capricious, in excess of the agency's authority and otherwise contrary to law in several respects, the Court should declare it invalid and set it aside.

JURISDICTION AND VENUE

17. 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, and the U.S. Constitution.

18. 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.

19. HRSA's Violation Letter, in which the agency purported to determine that UCB's policy has resulted in overcharges and violates Section 340B, and which threatened civil monetary penalties against UCB, is a final agency action, as discussed further below. The Letter is therefore judicially reviewable. 5 U.S.C. §§ 704, 706.

20. 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

21. Plaintiff UCB, Inc. is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. UCB participates in the 340B program. UCB is a corporation organized under the laws of the State of Delaware and headquartered in Smyrna, Georgia. UCB, Inc. is a wholly-owned subsidiary of UCB S.A., which is incorporated in Belgium.

22. 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.

23. Defendant Carole Johnson is the Administrator of HRSA. Her official address is in Rockville, Maryland. Administrator Johnson is directly responsible for the administration of the 340B program and the actions complained of herein. Administrator Johnson has ultimate responsibility for the Office of Pharmacy Affairs, which is headed by Director Emeka Egwim and, as a constituent part of HRSA, is involved directly in the administration of the 340B program. Administrator Johnson issued the Violation Letter, which is a final agency action that is the subject of this complaint. Administrator Johnson is sued in her official capacity.

24. Rear Admiral Krista M. Pedley is the Director of the Office of Special Health Initiatives, the parent office of the Office of Pharmacy Affairs. Her official address is in Rockville, Maryland. Director Pedley is sued in her official capacity.

25. Defendant Emeka Egwim is the Director of the Office of Pharmacy Affairs. His 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. Director Egwim is sued in his official capacity.

26. 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.

27. 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

28. Congress created the 340B Drug Pricing Program through statute in 1992. Congress designed it to assist statutorily-defined "covered entities," which are hospitals and other providers that offer "clinical care to large numbers of uninsured" patients. H.R. Rep. No. 102-384, pt. 2, at 12 (1992), 1992 WL 239341.

29. The 340B program addressed an inadvertent consequence of the Medicaid Drug Rebate Program ("MDRP") that was enacted in 1990. Before the MDRP, manufacturers voluntarily offered discounts on drugs that they sold to "hospitals and other safety-net providers." Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision*, 22 J. Health Care L. & Pol'y 25, 29 (2019). The MDRP, however, provided that Medicaid drug rebates would be based on the manufacturers' "Best Price," and the value of that "Best Price" was driven lower by the discounts that manufacturers provided in other circumstances. That made it unsustainable for manufacturers to continue to provide voluntary discounts to safety-net providers because those discounts had a significant effect on other pricing. *See id.* at 29–30. As a result of

this disincentive, manufacturers largely stopped offering voluntary discounts to safety-net providers. *Id.* The 340B statute addressed that problem by requiring that manufacturers whose prescription drug products are eligible for coverage under the Medicaid and Medicare programs must provide drug pricing discounts to a specified list of safety-net providers identified by the statute as "covered entities," and by providing that the 340B discounts would not factor into the "Best Price" calculation. *See* 106 Stat. at 4962 (codified at 42 U.S.C. § 1396r-8(c)(1)(C)).

30. Section 340B instructs that HHS enter into "agreement[s]" with pharmaceutical manufacturers providing that the price that the manufacturers offer to the 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 for the 340B discount is determined by calculating the difference between the manufacturer's Average Manufacturer Price ("AMP") 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). That calculation can result in a ceiling price as low as zero when the AMP increases more quickly than inflation. 82 Fed. Reg. 1,210, 1,215 (Jan. 5, 2017). In those circumstances, HHS "requir[es] that manufacturers charge . . . $0.01 [i.e., one penny] for the drug." *Id.*

31. Section 340B requires manufacturers to offer that discounted price only to covered entities listed in the statute. 42 U.S.C. § 256b(a)(4)(A)-(O). Moreover, the statute specifies that covered entities may not "resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(A), (B).

32. Section 340B's list of covered entities to whom manufacturers are required to offer drugs at the discounted price under the 340B program does not include "contract" or other third-party pharmacies. 42 U.S.C. § 256b(a)(4)(A)-(O). Congress amended the 340B statute in 2010 to

add some covered entities, Pub. L. 111-148, § 7101, 124 Stat. 119, 821 (Mar. 23, 2010) (codified at 42 U.S.C. § 256b(a)(4)), and did not include "contract" or other third-party pharmacies. *See AstraZeneca I,* 543 F. Supp. 3d at 60 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.").

33. 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 anyone other than covered entities. The PPA defines "covered entity" specifically to refer to those entities identified by Congress in Section 340B(a). *See* Sample PPA.[4]

34. Congress provided that HHS could impose "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).

35. 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 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).

[4] *Available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

36. Congress expressly prohibited covered entities from "resell[ing] or otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B).

37. Congress also provided that a covered entity cannot cause "duplicate discounts or rebates," which could occur if a covered entity purchases from the manufacturer a unit of covered outpatient drug at the discounted 340B price and then also obtains a Medicaid rebate on that same unit to be invoiced to the manufacturer. 42 U.S.C. § 256b(a)(5)(A). 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.*

38. Congress instructed HHS to implement improvements in covered entity compliance with the statutory bars on transfers, reselling, and duplicate discounts. 42 U.S.C. § 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).

39. Congress also required covered entities to permit HHS and 340B drug manufacturers to audit "the records of the entity that directly pertain to the entity's compliance with" the bars on transfers, reselling, and duplicate discounts. 42 U.S.C. § 256b(a)(5)(C). HRSA, however, has imposed a number of significant restrictions that undermine the practical benefit of the audit process. *See AstraZeneca I*, 543 F. Supp. 3d at 58 n.12 (noting "serious concerns about [manufacturers'] inability to conduct effective audits of covered entities"). For example, manufacturers must hire outside auditing firms; must submit audit work plans for HRSA approval; and may audit only one covered entity at a time. *See* 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996).

40. Under the statute, where an audit finds a violation, the manufacturer's only recourse is to initiate an administrative dispute resolution ("ADR") proceeding at the agency. 42 U.S.C.

§ 256b(d)(3)(A). But no valid regulations governing ADR proceedings exist. HRSA attempted to issue a rule establishing ADR procedures in December 2020, roughly ten years after the agency was directed to do so by statute. *See* 42 U.S.C. § 256b(d)(3)(A) (HHS "shall promulgate regulations to establish and implement an [ADR] process" "[n]ot later than 180 days after March 23, 2010"). But a court issued a preliminary injunction after finding that those rules were promulgated without going through the required notice-and-comment process. *See Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *11 (S.D. Ind. Mar. 16, 2021). No valid ADR process is currently available to address 340B program abuse or to enforce audits of covered entities.

41. HRSA's authority to promulgate regulations governing the ADR process and to impose monetary sanctions was established through statutory provisions enacted in 2010 under the Affordable Care Act ("ACA"). *See* Pub. L. 111-148, Title II, § 2501(f)(1), Title VII, §§ 7101(a)–(d), 7102, 124 Stat. 309, 821, 823. No 340B provisions—including the provisions added under the ACA—confer any authority to regulate contract pharmacies.

B. HRSA Guidance on Contract Pharmacies

42. The term "contract pharmacy" is not a statutory term, and the contract pharmacy arrangements with covered entities are nowhere authorized by Congress. The term has come to be understood in this context to refer to a for-profit pharmacy that, as HRSA has acknowledged, 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).[5]

43. From 1992—when the 340B program was established—until 1996, there was no HRSA guidance purporting to authorize any contract pharmacy. The only activity contemplated

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

was that covered entities would purchase 340B discount drugs exclusively through their in-house pharmacies to provide to their eligible patients who were treated at that location.

1. 1996 Agency Guidance

44. 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).

45. The 1996 guidance provided that a covered entity 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. The guidance set forth HRSA's non-binding interpretation of how covered entities could choose to do business. *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.

46. HRSA's 1996 guidance did not identify any statutory support for its conclusion that use of a contract pharmacy is permitted by the statute. 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.

47. The 1996 guidance included multiple important limits on the ability of contract pharmacies to dispense 340B discounted drugs. Indeed, HRSA specified the means for the covered entity and the single outside pharmacy to determine in advance of dispensing a 340B discount medication to a customer that the customer is in fact an eligible patient of a covered entity that is eligible to benefit from the discount. The 1996 HRSA guidance stated that a contract pharmacy should dispense a 340B discounted drug to a customer only after an explicit, individualized, advance determination that the prescription-holding patient is an eligible patient receiving relevant treatment from the relevant covered entity. HRSA specified that this determination by the pharmacy should be based on confirmable information that the pharmacy obtains at the time of the dispensing: either

(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) "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.

48. The 1996 guidance helped to deter 340B program abuse, particularly because the single contract pharmacy that a covered entity used would typically maintain at the pharmacy

location a separate, segregated inventory of 340B discounted drugs that it would dispense only to customers that it confirmed to be the covered entity's patients at the time the drugs were provided to the customer. The guidance emphasized that "[t]his situation is akin to a covered entity having its own pharmacy." 61 Fed. Reg. at 43,550. This structure was in place for well over a decade.

2. 2010 Agency Guidance

49. In 2010, HRSA changed its position of more than a decade and purported to find new authority that it had never previously identified. HRSA issued 2010 guidance that covered entities could enter into an *unlimited* number of contract pharmacy arrangements that would enable contract pharmacies to obtain 340B discount drugs. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010). *Id.* at 10,273. 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.*

50. The 2010 guidance stated that covered entities are 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. The guidance also 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 ensure such elements were actually incorporated into contract pharmacy arrangements entered into by covered entities.

51. In particular, HRSA did not alter its broad 2010 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. The "replenishment" model does not follow HRSA's 1996

guidance that a contract pharmacy dispense a 340B drug to a customer only if the pharmacy determines at the time it provides the drug to the customer that the customer is a patient of the covered entity with which the pharmacy has an arrangement 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) "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." 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996).

52. Rather, under the replenishment model, drugs purchased at the 340B discount price are placed in the contract pharmacy's general inventory, and the contract pharmacy dispenses the 340B discounted drugs to customers without any determination at the time the drug is transferred to the customer that the customer is a 340B-eligible patient of the covered entity. Later, at periodic intervals, the contract pharmacies employ data analysts to make after-the-fact assessments regarding which sales they deem to be prescriptions that should be covered by the 340B Program. *See* OIG, Contract Pharmacy Arrangements in the 340B Program, No. OEI-15-13-00431 at 14 (Feb. 4, 2014) ("2014 OIG Report") (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 added)). The third-party administrator typically uses a nonpublic algorithm to determine whether it can somehow link each customer to a covered entity. *See* Vandervelde et al., *supra*, at 5.

53. HRSA later acknowledged in 2020 that its 2010 policy is not binding, stating 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." 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, HRSA is unable to develop enforceable policy to ensure clarity in program requirements across all the interdependent aspects of the 340B program").[6]

54. 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 authorizes HRSA to conduct only three specific types of rulemaking: (1) to establish an administrative dispute resolution ("ADR") 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

55. In 2018, the U.S. Government Accountability Office ("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]." GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement at 10 (June 2018) ("2018 GAO Report"). Moreover, the number of claims that manufacturers must provide 340B discounted drugs 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,

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

2020). 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)" purporting to participate in the 340B program as contract pharmacies. Vandervelde et al., *supra*, at 5; *see also* Adam Fein, Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs, Drug Channels (June 15, 2021) (Fein) (estimating more than 140,000 contract-pharmacy arrangements as of June 2021).[7] By 2020, a covered entity was contracting with an average of 22 contract pharmacies—far from the *single* contract pharmacy that even HRSA recognized as a limit prior to 2010. Vandervelde et al., *supra*, at 7.

56. This explosion in the number of contract pharmacies has coincided with a sharp divergence from the contract pharmacy model provided for in HRSA's 1996 guidance, where a single contract pharmacy was "akin to a covered entity having its own pharmacy." That guidance required covered entities to purchase drugs at the 340B discount price and directed that those drugs be shipped to a single, specific contract pharmacy for dispensing from a particular inventory of 340B drugs *only* to customers who are determined by the pharmacy at the time of transfer of the medications to have a prescription that establishes they are a patient of the relevant covered entity. *See* 61 Fed. Reg. at 43,552.

57. HRSA does not regulate or address the process for contract pharmacies 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.

[7] *Available at* https://perma.cc/X3UM-ZH8C.

58. Contract pharmacies profit significantly through arrangements with covered entities in multiple ways. Typically, the contract pharmacy will charge its customers and their insurers the full retail price, and will not pass on any of the savings from the discounted price to 340B patients. *See* GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108 at 5 (Dec. 2019) (explaining that under the 340B program, drugs can be purchased by a covered entity "at the 340B price for all eligible patients regardless of the patients' income or insurance status and generate revenue by receiving reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"). The difference between the full retail price that contract pharmacies receive from their customers and their insurers and the heavily discounted 340B price that is paid to manufacturers for new drugs to "replenish" the pharmacy's general inventory generates substantial revenue, a significant portion of which is pocketed by the contract pharmacy (and thus not provided to the covered entity contrary to the reason for creation of the 340B Program). For the time period "[b]etween 2013 and 2018, the [National Community Pharmacists Association] reported that the average gross margin on all prescription medicines ranged between 22% and 23%." Vandervelde et al., *supra*, at 4. For drugs purchased at the 340B price, in contrast, industry experts have estimated the average gross margin to be 72%. *Id.* According to one estimate, "340B covered entities and their contract pharmacies generated more than $13 billion in profits from 340B[-]purchased medicines in 2018." *Id.* at 7.

59. Many contract pharmacy arrangements are based on percentage-based profit sharing, where the contract pharmacy is paid a fee by the covered entity that is calculated as "a percentage of revenue generated for each 340B prescription." 2018 GAO Report at 25. In 2018, the GAO found that the fees that contract pharmacies were paid by covered entities 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 dispenses that it later relies on to secure a 340B discount. *Id.* at 26. Some flat fees are as high as $1,750 for certain brand drug prescriptions. *Id.*

60. Third-party administrators take another portion of the 340B revenue generated for each prescription. The third-party administrators do so by charging the covered entities an additional fee, often for each prescription identified after-the-fact as eligible. 2018 GAO Report at 28–30. Notably, in many instances, the third-party administrator is paid only for prescriptions that the administrator determines after-the-fact to be eligible for 340B pricing. 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 economic incentive for administrators' algorithms to identify (and misidentify) as many "340B-eligible" prescriptions as possible in order to justify claiming a 340B discount on subsequent "replenishment" orders.

61. The massive profits generated by contract pharmacy arrangements are frequently not shared with safety-net *patients*. 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. A survey of covered entities by the HHS Office of Inspector General found that many covered entities "do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements." HHS-OIG, Stuart Wright, HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 14 (Feb. 4, 2014).[8]

[8] *Available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

62. Although Congress established the 340B program to benefit covered entities listed in the 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 5—contrary to the statute's purpose. Of the approximately 27,000 contract pharmacies purportedly 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). 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. National pharmacy chains have disclosed that 340B profits are so significant as to be material to its business operations. *See, e.g.*, Walgreens Boots Alliance, Inc., Form 10-K, at 22 (Oct. 14, 2021) ("Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce our profitability.").[9]

63. The exponential increase in use of contract pharmacies creates serious concerns about the integrity of the 340B program, including by multiplying the chances of unlawful transfers of 340B-priced drugs to non-340B patients, in direct violation of the statute's prohibition on such transfers, 42 U.S.C. § 256b(a)(5)(B)

64. The potential for diversion has been exacerbated by HRSA's failure to clearly define 340B-eligible "patients." HRSA has attempted to provide guidance, but the GAO has

[9] *Available at* https://sec.report/Document/0001618921-21-000085/wba-20210831.htm.

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").[10]

65. Publicly-available evidence confirms that the perverse incentives involved in contract pharmacy arrangements have 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; *see also id.* ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices.").

66. HRSA is aware that contract pharmacy arrangements of covered entities that participate in the 340B program generate a large revenue stream for national for-profit chain pharmacies that the 340B statute was not enacted to provide. For example, in 2017, the Director

[10] *Available at* https://www.gao.gov/assets/gao-11-836.pdf.

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). The Director noted that HRSA does not prohibit covered entities from sharing with contract pharmacies the revenue that results from the financial spread between the heavily discounted 340B prices that covered entities pay to the manufacturer and the full, undiscounted reimbursements that the covered entities receive from insurance companies. *Id.* In other words, that revenue now supports contract pharmacies and third-party administrators rather than covered entity services benefitting safety-net patients. *Id.*

67. HRSA also knows that contract pharmacy arrangements create a substantial risk of (1) statutorily-prohibited transfers of 340B-priced drugs to non-340B patients and (2) duplicate discounts in which manufacturers are unlawfully forced into paying twice the discount that is set by statute. *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"). For example, HRSA previously advised covered entities to implement multiple audit and other programs to police 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 of 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 noncompliance." 2018 GAO Report at GAO Highlights. "Given these weaknesses," the GAO concluded, "HRSA does

not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements." *Id.*

68. 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.

69. 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.").

70. 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; *see also Novartis Pharms.*, 2021 WL 5161783, at *8 ("HRSA lacks the authority to issue a legislative rule.").

71. 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).

72. HRSA has not even "issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care," and the agency "has indicated that it is not pursuing new guidance." GAO, *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212, at 30 (Jan. 2020).[11] Because there is no guidance in place, HRSA effectively does not require covered entities to address identified instances of duplicate discounts, which the GAO considered "contrary to federal law." *See id.* at 26.

73. HRSA's lack of oversight of contract pharmacy arrangements is important for multiple reasons. *First*, it underscores the flaws in HRSA's attempt to read the statute to require manufacturers to provide 340B discounted drugs to contract pharmacies. There is no plausible basis to interpret the statute to mandate that manufacturers provide 340B discounted drugs to contract pharmacies, yet simultaneously no authority for HRSA to engage in meaningful oversight of those pharmacies. *Second*, it illustrates that HRSA does not police the 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 is required in the view of the agency to trigger a manufacturer

[11] *Available at* https://www.gao.gov/assets/gao-20-212.pdf.

obligation to provide 340B discounted drugs to contract pharmacies. *See* Advisory Opinion 20-06 On Contract Pharmacies Under the 340B Program at 1 (Dec. 30, 2020) ("Advisory Opinion") ("[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)).

74. 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 UCB'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

75. On December 30, 2020, HHS's General Counsel issued an Advisory Opinion stating for the first time that drug manufacturers are "*obligated*" by the statute 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 I*, 543 F. Supp. 3d at 55–56 ("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—which has since been declared invalid and withdrawn, *see infra* ¶¶ 83–84—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 discounted drugs do so. To UCB's knowledge, HRSA has never attempted to make such findings, nor has the agency provided any mechanism for drug manufacturers to evaluate in advance whether any contract pharmacy is in fact the agent of a covered entity.

76. Despite HRSA's prior recognition that Section 340B is silent on the matter of contract pharmacies, the 2020 Advisory Opinion asserted that it now had determined that the 1992 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; *see also AstraZeneca II*, 2022 WL 484587 at *7 (D. Del. Feb. 16, 2022) ("[HRSA's] position has not been consistent over the past 25 years."). 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 that pharmacy's undifferentiated inventory of products that are transferred to customers without making any determination at that time of transfer that the customers are patients of the 340B covered entity. *See* Advisory Opinion 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.*

77. 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 retain title at all times to drugs purchased at the 340B price—even though such drugs are not segregated from other inventory of the contract pharmacy, and even though the contract pharmacy transfers drugs obtained at 340B prices to customers without any determination

at the time of transfer that the customer is a patient of the covered entity with a 340B-eligible prescription from that entity.

78. The Advisory Opinion expressly endorsed the replenishment model that is widely used by contract pharmacies. *Id.* at 6 n.6. But the Advisory Opinion did not explain how that could be reconciled with the core assumptions that formed the basis of the Advisory Opinion.

79. The Advisory Opinion's position that the 340B statute precludes manufacturers from attaching any conditions to their offers of 340B-priced drugs was also inconsistent with HRSA's historic acknowledgment that manufacturers may include reasonable terms in connection with such offers. Guidance HRSA issued in 1994, for example, made clear that in contracts with covered entities, manufacturers could include "provisions that address customary business practice, request standard information, or include other appropriate contract provisions." *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). HRSA has also endorsed manufacturers' ability to use alternate allocation procedures that involve "restricted distribution" when there is a limited supply of the drug. *See* HRSA, *340B Drug Pricing Program Notice: Clarification of Non-Discrimination Policy*, at 1 (May 23, 2012). HRSA itself publishes these restricted distribution plans on its website. *See id.* at 2.

E. HRSA's Violation Letters to Manufacturers

80. On May 17, 2021, HRSA issued substantively identical violation letters to six manufacturers: United Therapeutics, Sanofi, Novo Nordisk, Novartis, Eli Lilly, and AstraZeneca. A few months later, on October 4, 2021, the agency issued another substantively identical violation letter to Boehringer Ingelheim. Each letter claimed that the relevant manufacturer was in "direct violation of the 340B statute" because its policy does not provide 340B discounted drugs to an

unlimited number of contract pharmacies. In each letter, HRSA took the 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." And HRSA demanded that the relevant manufacturer "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." HRSA further demanded that the policies be withdrawn and that covered entities be compensated for alleged overcharges, or otherwise face civil monetary penalties.

81. The violation letters sent by HRSA to pharmaceutical manufacturers all adopted the same legally flawed interpretation of the 340B statute that was advanced by the 2020 Advisory Opinion. *See AstraZeneca II*, 2022 WL 484587 at *4 (D. Del. Feb. 16, 2022) ("The Court agrees . . . that the Violation Letter is based on the same legally flawed reading of the 340B statute that plagued the Opinion.") (internal quotation marks omitted).

F. Litigation Challenging the Advisory Opinion and Violation Letters

82. Various suits were brought by pharmaceutical manufacturers against HRSA and HHS, challenging their interpretation of the 340B statute and response to manufacturer policies, including the violation letters. *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*"); *Boehringer Ingelheim Pharms., Inc.* v. Becerra, No. 1:21-cv-2826-DLF (D.D.C. filed Oct. 25, 2021).

83. On June 16, 2021, the first federal district court to substantively address claims regarding the Advisory Opinion found that the Advisory Opinion was "legally flawed" because it wrongly concluded that the contract pharmacy framework was mandated by the 340B statute. *AstraZeneca I*, 543 F. Supp. 3d at 59.

84. Two days later, on June 18, 2021, HHS withdrew the Advisory Opinion, purportedly "in the interest of avoiding confusion and unnecessary litigation." *See* Notice of Withdrawal from Daniel J. Barry, Acting Gen. Counsel, HHS at 2 (June 18, 2021) ("Advisory Opinion Withdrawal").[12]

85. Despite withdrawing the Advisory Opinion, HRSA persisted in its same interpretation of the statute. For example, HRSA continued to issue violation letters to manufacturers, *see supra* section E, and continued to defend the validity of those violation letters in court—even though they rested on the same flawed legal reasoning that grounded the Advisory Opinion.

86. Between October 2021 and February 2022, four federal district courts issued opinions addressing claims related to the violation letters. All four district courts vacated the challenged violation letters and remanded to HRSA for further proceedings.

87. Two district courts vacated the challenged violation letters because they were based on an incorrect reading of the 340B statute. *See Novartis Pharms.*, 2021 WL 5161783; *AstraZeneca II*, 2022 WL 484587. Both district courts held that the 340B statute is silent regarding any manufacturer obligation to contract pharmacies under the 340B program, and that the statute

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

does not expressly require manufacturers to provide drugs at the 340B price to contract pharmacies. *See Novartis Pharms.*, 2021 WL 5161783, at *9; *AstraZeneca II*, 2022 WL 484587, at *6.

88. A third district court vacated the challenged violation letter in light of HRSA's inconsistent positions regarding its enforcement authority under the 340B statute. *See Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *22 (S.D. Ind. Oct. 29, 2021). The district court recognized that the 340B statute was "silen[t] both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligations imposed on drug manufacturers," but nevertheless determined that HRSA could require manufacturers to provide 340B-priced drugs to contract pharmacies. *Id.* at *14–*20.

89. A fourth district court partially vacated the challenged violation letters for HRSA to assess "the number of permissible contract pharmacy arrangements" that manufacturers could be required to provide with 340B-discounted drugs. *Sanofi-Aventis U.S.*, 570 F. Supp. 3d at 204. The district court concluded that HRSA could require manufacturers to provide 340B discounted drugs to at least one contract pharmacy per covered entity, but did not determine whether the statute required manufacturers to provide them to more than one contract pharmacy. *See id.* at 205–06.

G. UCB's Policy

90. On November 22, 2021—after multiple district courts had ruled that HRSA's interpretations of the 340B statute are legally flawed and inconsistent, and that the 340B statute is silent as to any manufacturer obligation to provide 340B-priced drugs to contract pharmacies—

UCB announced that, beginning December 13, 2021, it would implement a new policy with regard to contract pharmacies. *See* Exhibit 3.

91. In particular, UCB explained that it would continue to provide UCB products purchased at the 340B discounted price to all locations registered as 340B covered entities or child sites. UCB also continues, as a matter of policy, to offer drugs at the 340B discounted price in certain other circumstances based on the company's commitment to the healthcare safety net and the mission of the 340B program.

92. First, covered entities who are federal grantees—i.e., covered entities that are specifically identified in certain subsections of the 340B statute at 42 U.S.C. § 256b(a)(4)(A)–(K)—remain eligible to place orders of 340B-priced drugs to be dispensed through multiple contract pharmacies.

93. Second, a 340B covered entity that does not have an in-house pharmacy may designate a single contract pharmacy location to receive products purchased at the 340B price.

94. Third, contract pharmacies that are wholly owned by or under common ownership with a covered entity remain eligible to receive orders of 340B-priced drugs purchased by the affiliated covered entity.

95. UCB's policy is more generous than the 340B statute requires, and more permissive of contract pharmacy arrangements than HRSA's own pre-2010 guidance. *See supra* ¶¶ 44–48. UCB implemented its policy on December 13, 2021, and has continued to implement it since that date.

H. HRSA's February 2022 Letter and UCB's Response

96. HRSA sent a letter to UCB regarding UCB's policy on February 23, 2022. *See* Exhibit 4.

97. Despite HRSA's withdrawal of its Advisory Opinion and the federal court rulings declaring invalid HRSA's interpretation of the 340B statute, HRSA asserted in the letter that "[t]he 340B statute requires manufacturers to honor purchases by covered entities regardless of the dispensing mechanism."

98. HRSA explained in the letter that it had "reviewed the information submitted in [UCB's] November 22, 2021, correspondence," and "request[ed] responses" to a series of questions about UCB's 340B policy.

99. HRSA noted that it would "continue[] to review UCB's policy, including the responses to the questions" listed in the letter, and requested a response to the letter by March 9, 2022.

100. UCB responded to HRSA's letter on March 9, 2022. *See* Exhibit 5.

101. UCB observed that it was in compliance with its obligations under the 340B statute. UCB pointed to multiple federal court rulings and the text of the 340B statute.

102. UCB's letter included responses to HRSA's questions regarding UCB's policy. UCB explained that it "continues to strongly support the 340B program and is committed to ensuring that covered entities have access to UCB's medicines and that the program continues to benefit vulnerable and underserved populations."

I. June 2022 Violation Letter Issued to UCB and UCB's Response

103. On May 6, 2022, HRSA issued a violation letter to Merck that was substantively identical to the violation letters the agency had previously issued to other manufacturers, and which have been consistently set aside by federal courts. On July 8, 2022, Merck filed a lawsuit against HRSA in this Court, challenging the May 6 letter and the agency's continued erroneous

interpretation of the 340B statute. *See Merck Sharp & Dohme LLC*, No. 1:22-cv-01986-DLF (D.D.C. filed July 8, 2022). That case was subsequently stayed.

104. On June 27, 2022, HRSA issued a violation letter to UCB that was also substantively identical to the violation letters the agency had previously issued to other manufacturers, and which have been consistently set aside by federal courts.

105. Specifically, the Violation Letter claims that UCB is in "direct violation of the 340B statute" because its policy does not provide discounted drugs to an unlimited number of contract pharmacies. In the letter, HRSA takes the 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." And HRSA demands that UCB "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."

106. The Violation Letter rests on the same flawed analysis that this Court and other federal courts have rejected as contrary to the statute. *See, e.g.*, *Novartis Pharms.*, 2021 WL 5161783; *AstraZeneca II*, 2022 WL 484587. The Violation Letter is final agency action reviewable under the APA. *See, e.g.*, *Eli Lilly & Co.*, 2021 WL 5039566, at *15; *Sanofi-Aventis U.S.*, 570 F. Supp. 3d at 190.

107. On July 11, 2022, UCB submitted a letter to HRSA in response to the Violation Letter. *See* Exhibit 2. UCB pointed out that HRSA's Violation Letter was "substantively identical to letters previously sent by HRSA to other pharmaceutical manufacturers that have been consistently invalidated by federal courts," and that "[l]ike those other letters, HRSA's [Violation Letter] rests on a fundamentally flawed interpretation of the 340B statute." *Id.* at 1. UCB also

explained that "as currently structured by HRSA, the audit and ADR processes are wholly inadequate for addressing the abuses of contract pharmacies." *Id.* at 3. UCB emphasized that HRSA has no lawful basis to impose civil monetary penalties, which can be issued only for "knowing[] and intentional[]" overcharges. *Id.* at 4. UCB explained that its policy had not resulted in any overcharges, let alone "knowing[] and intentional[]" ones. *Id.* HRSA did not respond to UCB's letter.

CLAIMS FOR RELIEF

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

108. Plaintiff incorporates by reference paragraphs 1–107 as if fully set forth herein.

109. 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).

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

111. The 340B statute does not require UCB to provide 340B discounted drugs to contract pharmacies. *See, e.g.*, *AstraZeneca I*, 543 F. Supp. 3d at 59 ("The statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs."); *Novartis Pharms.*, 2021 WL 5161783, at *6 ("[The 340B] statute is silent as to permissible drug distribution systems . . . [and] also silent as to what distribution requests *manufacturers* must accept.").

112. The 340B statute requires manufacturers to offer drugs at discounted 340B prices only to "each covered entity" listed in the statute. 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 reselling or otherwise 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).

113. Congress defined "covered entities" to consist of 15 types of entities that are specifically listed in the statute. Contract pharmacies are not within this statutory definition of "covered entities." *See AstraZeneca I*, 543 F. Supp. 3d at 60 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.").

114. 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.

115. 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 within the definition of 'covered entity,' it evidently knew how to do so," but the statute as enacted does not do so. *AstraZeneca I*, 543 F. Supp. 3d at 60.

116. The statute thus does not require manufacturers to provide 340B discounted drugs to contract pharmacies.

117. HRSA lacks any authority to impose such a requirement on manufacturers. "[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 to specific aspects of the statute, none of which authorizes expansion of the statutorily identified covered entities. *See PhRMA*, 43 F. Supp. 3d at 41. The 340B statute does not authorize HRSA to alter the statute's text through enforcement action or sub-regulatory 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).

118. 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 the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
(Arbitrary and Capricious Agency Action)

119. Plaintiff incorporates by reference paragraphs 1–118 as if fully set forth herein.

120. 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).

121. 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.*

122. HRSA's Violation Letter to UCB is arbitrary and capricious for a number of reasons, including the following.

123. *First*, the Violation Letter "is based on the 'unjustified assumption' that Congress imposed [HRSA's] interpretation as a statutory requirement" and is therefore "legally flawed." *AstraZeneca I*, 543 F. Supp. 3d at 59–62 (quoting *Am. Lung Ass*'n *v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)); *see also AstraZeneca II*, 2022 WL 484587, at *6 (violation letter was invalid because it rested on a "flawed statutory interpretation"); *Novartis Pharms.*, 2021 WL 5161783, at *9 (violation letter's "legal reasoning . . . rests upon an erroneous reading of Section 340B"). The Violation Letter concludes that UCB'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 Violation Letter must be vacated. *See AstraZeneca I*, 543 F. Supp. 3d at 61–62 (quoting *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006)); *see also AstraZeneca II*, 2022 WL 484587, at *6; *Novartis Pharms.*, 2021 WL 5161783, at *9.

124. *Second*, HRSA has repeatedly shifted its guidance regarding contract pharmacies, but none of HRSA's letters to UCB even acknowledged those past changes, let alone provided a legal rationale for them. HRSA's 1996 guidance interpreted the statute to allow only a *single*

contract pharmacy per covered entity. HRSA's 2010 guidance concluded that the statute requires manufacturers to provide 340B discounted drugs to multiple contract pharmacies, but even that guidance was directed to covered entities, not manufacturers. *AstraZeneca I*, 543 F. Supp. 3d at 55. The December 2020 Advisory Opinion, issued more than 25 years after Congress enacted the statute, 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 I*, 543 F. Supp. 3d at 55–56. Further, whereas the Advisory Opinion claimed that contract pharmacies are entitled to 340B discounted drugs insofar as they act as agents for covered entities, *see* Advisory Opinion at 1, that justification is nowhere present in the violation letters and was seemingly abandoned without explanation or comment. Moreover, HRSA *withdrew* the December 2020 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 Advisory Opinion. *See also Novartis Pharms.*, 2021 WL 5161783, at *8 (discussing HRSA's "shifting guidance" on contract pharmacies).

125. HRSA's failure to even mention this history of its shifting position on the meaning of the statute and its policy in its Violation Letter to UCB 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 Violation Letter arbitrary and capricious.

126. *Third*, the Violation Letter does not explain how HRSA'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, the Violation Letter contains a conclusory analysis of the statute that does not address

the contrary arguments based on the statute's text and structure and the background against which the statute was enacted. Because HRSA's Violation Letter lacks adequate explanation, it is 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, is invalid unless it provides an adequate explanation, such that a court can "evaluate the agency's rationale at the time of decision" (citation omitted)).

127. *Fourth*, HRSA has not provided any evidentiary or other support for its factual assertions or assumptions. The Violation Letter claims that UCB's policy has resulted in overcharges, but identifies no specific instance or complaint involving overcharges. Similarly, although HRSA has premised its interpretation on the existence of an agency relationship between covered entities and contract pharmacies, the Violation Letter does not mention this theory or make any findings that support it. The Violation Letter is thus arbitrary and capricious because it relies on assertions that lack any evidentiary support.

128. *Fifth*, HRSA has failed to account for multiple important aspects of the policy problem associated with contract pharmacies, including: the substantial growth of contract pharmacies in recent years; the evidence that such contract pharmacies are facilitating unlawful transfers to non-340B patients and not providing benefits to underserved patients but rather are reaping windfall financial profits through the 340B program; the serious flaws in the audit and ADR processes that render them insufficient to address such issues; and various rulings from federal courts holding that HRSA's legal theories are invalid and its actions impermissible.

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

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

130. 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).

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

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

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

134. 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").

135. HRSA did not provide for notice and comment from the public on this change in the law prior to announcing its new interpretation, and thus violated the APA's notice-and-comment requirement. 5 U.S.C. § 553.

136. HRSA also lacks statutory authority to impose a legislative rule of this type. *See PhRMA*, 43 F. Supp. 3d at 41.

COUNT IV: Unconstitutional and Unauthorized Taking of Private Property Without Just Compensation

137. Plaintiff incorporates by reference paragraphs 1–136 as if fully set forth herein.

138. 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).

139. 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.

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

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

142. That is not only a taking, but a taking that is not authorized by the U.S. Constitution or by statute.

143. 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 UCB's personal property for the sole purpose of transferring it to other private parties, even if just compensation were paid.

144. As a statutory matter, HRSA has no authority to effect a taking of this nature. No statute gives HRSA authority to require UCB to transfer its personal property to contract pharmacies.

145. Moreover, HRSA's actions cannot be justified by virtue of UCB's "voluntary" participation in the 340B program. As noted above, UCB'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)

146. HRSA's actions amount to an unconstitutional and coercive condition, by forcing UCB 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 UCB's products.

147. 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 UCB to provide certain products to contract pharmacies at the 340B discount price.

COUNT V: Violation of U.S. Constitution, Art. I, § 1
(Unconstitutional Delegation of Legislative Power; Major Questions Doctrine)

148. Under Article I, § 1 of the U.S. Constitution, "[a]ll legislative powers herein granted shall be vested in a Congress of the United States." Under Article I, § 1, only Congress may engage in lawmaking.

149. "Congress is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529–30 (1935).

150. The nondelegation doctrine is grounded in the principle of preserving the separation of powers. It prohibits Congress from assigning its legislative power to another branch of government.

151. While Congress may delegate power to executive agencies, the statutory delegation must include an "intelligible principle" to guide the exercise of the relevant agency's delegated authority. *See, e.g.*, *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)).

152. 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*, 43 F. Supp. 3d at 41. The 340B statute does not authorize HRSA to alter the statute's text through enforcement action or sub-regulatory 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).

153. If HRSA were understood to have such authority, that interpretation would violate the nondelegation doctrine because the 340B statute lacks any "intelligible principle[s]" that would guide the agency's policymaking decisions with respect to contract pharmacies.

154. Relatedly, because HRSA can point to no "clear congressional authorization" for the authority it seeks to exercise, its approach runs afoul of the major questions doctrine. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022); *see also Nat'l Fed'n of Indep. Bus. v. Department*

of Labor, 142 S. Ct. 661, 668–69 (2022) (Gorsuch, J., concurring) (noting that nondelegation and major questions doctrines are "closely related" in that "[b]oth are designed to protect the separation of powers and ensure that any new laws governing the lives of Americans are subject to the robust democratic processes the Constitution demands").

155. HRSA has asserted in 2020 a previously "unheralded" authority purportedly now found in a 1992 statute to force manufacturers into an unlimited number of arrangements with contract pharmacies, which are mentioned nowhere in the statute. *See West Virginia*, 142 S. Ct. at 2610 (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). The newly discovered statutory reading has resulted in significant economic consequences, including an explosion in the size and scope of the 340B program. *See id.* at 2608 (doctrine applies in matters of "economic . . . significance") (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U. S. 120, 159–160 (2000)). The 340B statute does not confer the enforcement authority that HRSA "claim[s] to be lurking there" based on the agency's flawed interpretation of the statute. *Id.* at 2609.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Declare that the Violation 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 Violation Letter on the grounds recited above;

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

D. Declare that UCB's policy, as set forth in its November 22, 2021 Letter, complies with Section 340B;

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

F. Issue permanent injunctive relief preventing Defendants from imposing civil monetary penalties against UCB based on the Violation Letter or its rationale;

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: September 23, 2022

/s/ Beth S. Brinkmann

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