IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; DANIEL J. BARRY, in his official capacity as Acting General Counsel of the U.S. Department of Health and Human Services; DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; *and* HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	C.A. No. 21-27 (LPS) ADMINISTRATIVE PROCEDURE ACT REVIEW OF AGENCY DECISION

SECOND AMENDED COMPLAINT

COMES NOW Plaintiff AstraZeneca Pharmaceuticals LP and alleges as follows:

INTRODUCTION

1. The 340B Drug Pricing Program, 42 U.S.C. § 256b (Section 340B), caps the prices that drug manufacturers can charge for out-patient medications sold to certain healthcare facilities, called "covered entities," that cater to underserved populations. Because Section 340B is targeted at assisting these vulnerable populations—not providing windfalls to for-profit corporations—Congress carefully circumscribed the types of "covered entities" that may participate in the

program, specifically identifying by statute fifteen eligible categories. Off-site, for-profit pharmacy chains (like CVS or Walgreens) conspicuously were *not* included on the list of covered entities.

2. In 2010, however, the Health Resources and Services Administration (HRSA), the agency within the U.S. Department of Health and Human Services (HHS) that administers Section 340B, issued nonbinding "interpretive" guidance suggesting a transformation of the scheme that Congress created. The guidance stated that covered entities could partner with an unlimited number of off-site, for-profit contract pharmacies that would obtain discounted prescription medicines for dispensing to eligible patients. Over the ensuing decade, use of contract pharmacies has exploded to more than 100,000 documented arrangements. That sharp increase in the role of for-profit pharmacies in the 340B program has led to the very abuses and diversion that Congress feared: 340B discounts are now rarely passed on to patients, going instead to intermediaries (including contract pharmacies themselves).

3. In response to these systemic abuses, some drug manufacturers, including AstraZeneca Pharmaceuticals LP, have limited the number of contract pharmacy arrangements they will recognize. Consistent with its statutory obligations, AstraZeneca has continued to offer 340B drugs to each covered entity on non-discriminatory terms at the 340B price; AstraZeneca has also gone beyond the requirements of the statute by permitting covered entities that lack on-site pharmacies to use an off-site contract pharmacy arrangement. But AstraZeneca has announced that, effective October 1, 2020, it no longer recognizes an *unlimited* number of contract pharmacy arrangements, instead recognizing one such arrangement per covered entity that does not maintain its own on-site pharmacy. AstraZeneca's policy is intended to bring balance back to the 340B program, by limiting the potential for abuse while also ensuring that all patients served by covered

entities have access to 340B drugs at 340B prices. And in the time that it has been in effect, 2,250 covered entities that lack an on-site pharmacy have registered a contract pharmacy, through which AstraZeneca has offered 340B pricing on 340B drugs.

4. In the months since AstraZeneca announced its policy change, HHS has tried all manner of strategies to coerce AstraZeneca into providing 340B discounts for unlimited contract pharmacy sales even though the statute does not require AstraZeneca to do so.

5. ***First***, on December 30, 2020, HHS unequivocally (but without statutory authority) took a firm stance on the contract pharmacy question: HHS General Counsel Robert P. Charrow issued an Advisory Opinion that, for the first time since the inception of the 340B program, mandated "that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." HHS Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 8 (Dec. 30, 2020) (Advisory Opinion), https://bit.ly/357nqfk.

6. ***Second***, in December 2020, after years of delay, HHS promulgated final Administrative Dispute Resolution (ADR) procedures for resolving claims related to overcharging, duplicate discounts, or diversion. *See* 85 Fed. Reg. 80,632 (Dec. 14, 2020) (ADR Rule). It did so, however, only in response to litigation that was brought by covered entities and based on a severely flawed process that does not comply with the APA. After abandoning the rulemaking process years ago, the agency based its final ADR Rule on a years-old record that wholly ignores the recent explosion of contract pharmacies and the attendant abuses of the 340B program. The Rule empowers a panel of partisan agency officials (rather than impartial

administrative law judges) to conduct one-sided quasi-trials and issue binding, precedential decisions that impose self-executing relief against the parties—and all without *any* oversight by properly appointed agency leadership.

7. ***Third***, on May 17, Diana Espinosa, the Acting Administrator of HRSA, sent AstraZeneca a letter that effectively—and prematurely—purported to resolve the same core issue as the Advisory Opinion: whether the 340B statute unambiguously requires AstraZeneca to recognize an unlimited number of contract-pharmacy arrangements. *See* Letter from Diana Espinosa to Odalys Caprisecca dated May 17, 2021 (Exhibit A). The May 17 letter asserts that "HRSA has determined that AstraZeneca's actions [under its contract pharmacy policy] have resulted in overcharges and are in direct violation of the 340B statute." *Id.* at 1. The letter further directs AstraZeneca to "provide an update on its plan to restart selling . . . covered outpatient drugs at the 340B price" through unlimited contract pharmacies by June 1, 2021,[1] and threatens to impose civil monetary penalties if AstraZeneca does not comply. *Id.* at 2.

8. Defendants' actions have caused, and are continuing to cause, substantial harm to AstraZeneca (as well other participants in the 340B program). Under Defendants' interpretation of the statute, unless drug manufacturers like AstraZeneca offer 340B discounts for all contract pharmacy sales, they risk claims of overcharging by covered entities and potential civil monetary penalties of up to $5,000 *per occurrence*; they face the potential revocation of their ability to participate in Medicare and Medicaid; and they risk penalties under the False Claims Act. Every day that HHS maintains its interpretation of the 340B statute—and its enforcement threat—AstraZeneca is exposed to the possibility of greater and greater potential liability.

[1] At AstraZeneca's request, this deadline was extended to June 10, 2021. D.I. 77.

9. Faced with that threat of an unlawful enforcement, AstraZeneca filed this lawsuit on January 12, 2021, challenging the lawfulness of the Advisory Opinion. It then amended its complaint shortly thereafter to add allegations related to the ADR Rule. On AstraZeneca's motion, the Court entered an expedited briefing schedule on AstraZeneca's motion for summary judgment and Defendants' cross-motion to dismiss, with briefing to be completed on May 24 and oral argument to be held on June 9. HRSA's May 17 letter interrupted the Court's scheduling order. In response to the May 17 letter, and on AstraZeneca's motion, the Court expedited the hearing on the parties' cross-motions for summary judgment and Defendants' motion to dismiss. It heard argument on May 27, 2021.

10. On June 16, 2021, the Court issued a Memorandum Opinion directly undercutting both the substance of Defendants' contract pharmacy stance and the procedure by which it has been implemented. The Court held that: (a) the Advisory Opinion is a "final and reviewable" agency action, D.I. 78 at 16; (b) AstraZeneca's challenge to the Advisory Opinion was timely made, *id.* at 17; (c) the Advisory Opinion was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies," *id.* at 12 (emphasis in original); and (d) the Advisory Opinion was "legally flawed," *id.* at 17, including because it was based on the "unjustified assumption that Congress imposed [the Opinion's] interpretation as a statutory requirement," *id.* at 23.

11. The Court also noted that the ADR proceedings do not provide a meaningful venue for contesting Defendants' interpretation of the 340B statute. As the Court explained: "If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained." D.I. 78 at 17.

12. The Court therefore denied Defendants' motion to dismiss and ordered the parties to submit joint briefing on "the precise relief to be granted—be it setting aside the Opinion, vacating it with respect to AstraZeneca, remanding to HHS, or something else." D.I. 78 at 23.

13. In response to the Court's Memorandum Opinion, on June 18, 2021, the Acting General Counsel of HRSA purported to withdraw the Advisory Opinion. Defendants submitted notice to the Court of this development, arguing that HRSA's withdrawal of the Advisory Opinion mooted this litigation, while at the same time asserting that "withdrawal of the Opinion does not impact the ongoing efforts of [HRSA] to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements." D.I. 81.

14. On June 30, 2021, the Court issued a Memorandum Order rejecting Defendants' position that this litigation is moot: "Because HHS and its sub-agency, HRSA, intend to act in accordance with the withdrawn Opinion, this litigation is not moot." D.I. 83 at 2. The Court further granted summary judgment on AstraZeneca's Third Claim for Relief—that the Advisory Opinion is arbitrary and capricious—and ordered that the Opinion be set aside and vacated. *Id.* at 2-3. The Court directed the Parties to meet and confer regarding the schedule for resolving claims concerning the May 17 letter, including for AstraZeneca to file an amended complaint. *Id.* at 3.

15. On July 6, 2021, the parties submitted a joint status report and proposed order that set forth filing deadlines for AstraZeneca's Second Amended Complaint, Defendants' certification of the administrative record, and the parties' respective motions for summary judgment. D.I. 84. The Court approved that briefing schedule on July 7. D.I. 85.

16. Pursuant to the Court's July 7 Order, this Second Amended Complaint now seeks further relief from this Court barring Defendants from enforcing their flawed view of Section

340B, which is found both in the vacated Advisory Opinion and in the May 17 letter. This relief flows directly from the Court's Memorandum Opinion. As the Court has explained, Section 340B itself does not require drug manufacturers, on pain of potential civil monetary penalties and other sanctions, to deliver discounted drugs to an unlimited number of contract pharmacies. Yet the May 17 letter, like the Advisory Opinion before it, purports to interpret the plain language of 42 U.S.C. § 256b to impose that obligation.

17. Even if (contrary to fact) the agency had attempted to achieve that result through programmatic gap-filling, rather than as a matter of statutory interpretation, such a rule would be invalid on several independent grounds. Despite HRSA's lack of authority to engage in general or substantive rulemaking for the 340B program, the May 17 letter purports to require manufacturers "to deliver 340B drugs to an unlimited number of contract pharmacies," a substantive requirement that is neither "contained in the statute" nor "compelled by it." D.I. 78 at 21-22. The May 17 letter also incorrectly concludes that AstraZeneca's contract pharmacy policy has "resulted in overcharges" that can be collected in ADR proceedings, Ex. A at 1, an unconstitutional process in which (as this Court noted) the result is "preordained." D.I. 78 at 16. Worse still, the May 17 letter threatens severe monetary penalties against AstraZeneca for "*knowingly and intentionally* charg[ing] a covered entity" more than the ceiling price, 42 U.S.C. § 256b(d)(1)(B)(vi)(III) (emphasis added), despite the statute's "total omission" of any requirement to honor contract pharmacy sales, D.I. 78 at 19, and despite this Court's conclusion that "AstraZeneca's view of its obligations under the 340B statute" is "permissible," *id.* at 23.

18. In issuing the May 17 letter, moreover, the agency also failed to abide by basic administrative procedure requirements. Like the Advisory Opinion, the May 17 letter "fail[s] to accept th[e] reality" that the agency has changed position, *id.* at 13, and instead persists in the view

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," Ex. A at 1 (emphasis added).

19. Both the Advisory Opinion and the May 17 letter are thus extensions of the same "flawed" legal conclusions that this Court has previously identified, D.I. 78 at 17, and they threaten the same harm. Specifically, they threaten potentially hundreds of millions of dollars in penalties *per month* if AstraZeneca does not immediately reverse its policy—on top of any credits or refunds to covered entities that the agency might seek to compel AstraZeneca to make.

20. AstraZeneca therefore seeks an order: (1) declaring that the May 17 letter violates the Administrative Procedure Act because it is in excess of statutory authority, is arbitrary and capricious, and is otherwise not in accordance with law; (2) setting aside and vacating the May 17 letter; (3) declaring that AstraZeneca is not required to deliver 340B-discounted drugs to an unlimited number of contract pharmacies; and (4) enjoining Defendants from taking any action to enforce or implement the May 17 letter or its legal conclusions, through ADR proceedings, civil monetary penalty (CMP) actions, or otherwise.

JURISDICTION AND VENUE

21. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States), 28 U.S.C. § 1346 (United States as a defendant), and 5 U.S.C. §§ 701-06 (Administrative Procedure Act). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

22. As this Court held, Defendants' issuance of *Advisory Opinion 20-06 on Contract Pharmacies Under the 340b Program* on December 30, 2020, constituted a final agency action

and was therefore judicially reviewable under the Administrative Procedure Act (APA). 5 U.S.C. §§ 704, 706; *see* D.I. 78 at 14-16.

23. The May 17 letter, which "determined that AstraZeneca's actions [under its contract pharmacy policy] have resulted in overcharges and are in direct violation of the 340B statute," Ex. A at 1, and which threatens civil monetary penalties against AstraZeneca, is also a final agency action and therefore judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

24. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1)(C) because this action seeks relief against federal agencies and officials acting in their official capacities, Plaintiff resides in this district, and no real property is involved in the action.

PARTIES TO THE ACTION

25. Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca)—a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware—is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

26. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services (HHS). His official address is in Washington, D.C. He has ultimate responsibility for oversight of the activities of the Health Resources and Services Administration (HRSA), including with regard to the administration of the 340B Program and the actions complained of herein. He is sued in his official capacity.

27. Defendant Daniel J. Barry is the Acting General Counsel of HHS. His official address is in Washington, D.C. The Office of the General Counsel of HHS issued the Advisory

Opinion that sets forth HHS's legal opinion on contract pharmacy sales under the 340B program. He is sued in his official capacity.

28. Defendant Diana Espinosa is the Acting Administrator of HRSA. Her official address is in Rockville, Maryland. Acting Administrator Espinosa is directly responsible for the administration of the 340B program and the actions complained of herein. Acting Administrator Espinosa, among her other duties, has ultimate responsibility for the Office of Pharmacy Affairs, which is headed by Rear Admiral Krista M. Pedley of the Public Health Service and, as a constituent part of HRSA, is involved directly in the administration of the 340B Program. Acting Administrator Espinosa signed the May 17 letter, which is a final agency action complained of herein. She is sued in her official capacity.

29. 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.

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

FACTUAL ALLEGATIONS

The 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

31. Section 340B of the Public Health Services Act "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide healthcare to certain underserved populations. *PhRMA v. HHS* (*Orphan Drug I*), 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (quoting *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011)). As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. *See* 42 U.S.C. § 256b(a)(1). In that agreement, the

manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III).

32. Congress enacted Section 340B "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

33. To that end, Congress imposed three requirements on covered entities. *Id.* at 16-17. First, it prohibited covered entities from receiving 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"). 42 U.S.C. § 256b(a)(5)(A). Second, it forbade covered entities from reselling or otherwise transferring such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(B). Third, it subjected covered entities to audits to verify compliance with these requirements. *Id.* § 256b(a)(5)(C).

34. Consistent with the purpose of benefiting underserved patients, covered entities under Section 340B as originally enacted were "generally disproportionate share hospitals—hospitals that serve indigent populations." *Orphan Drug I*, 43 F. Supp. 3d at 31. Congress has added to the list of 340B covered entities over time, and today there are fifteen clearly delineated categories of covered entities, including: federally qualified health centers; certain healthcare providers that receive federal grants (such as black lung clinics, hemophilia treatment centers,

urban Indian health organizations, and AIDS drug purchasing assistance programs); and certain types of hospitals (critical access hospitals, children's hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals). 42 U.S.C. § 256b(a)(4)(A)-(*O*).

35. Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259 at 1-2 (1992) (requiring manufacturer to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

HRSA Issues Non-Binding Guidance Permitting Contract Pharmacy Arrangements

36. Section 340B does not require manufacturers to deliver 340B-discounted drugs to contract pharmacies or to *any* entity not specifically enumerated in § 256b(a)(4). But over the last three decades, HRSA has issued two "guidance" documents—which HRSA concedes are non-binding "interpretive" rules—purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B. HRSA issued this non-binding guidance despite the fact that Congress did not grant HHS general rulemaking authority, authority to promulgate regulations with respect to Section 340B(a), or authority to expand the list of 340B covered entities. *See Orphan Drug I*, 43 F. Supp. 3d at 41 (identifying the specific, limited grants of rulemaking authority in Section 340B).

37. In 1996, HRSA issued guidance asserting that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a *single* outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg.

43,555 (1996 Guidance). HRSA explained that "only a very small number of the 11,500 covered entities used in-house pharmacies." *Id.* at 43,500. HRSA accordingly allowed a covered entity without its own in-house pharmacies to use a *single* affiliated outside pharmacy, an arrangement that would enable such entities to access the 340B program without having to "expend precious resources to develop their own in-house pharmacies (which for many would be impossible)." *Id.*

38. In response to questions about HRSA's authority to expand Section 340B in this manner, the 1996 Guidance acknowledged that "[t]he statute is silent as to permissible drug distribution systems." *Id.* at 43,549. HRSA thus asserted that it was "creat[ing] no new law and . . . no new rights or duties," but instead merely offering "[i]nterpretive rules and statements of policy [that] were developed to provide necessary program guidance" in view of the "many gaps in the legislation." *Id.* at 43,550.

39. HRSA recognized that some manufacturers had raised concerns that its new approach would lead to drug diversion. HRSA thus announced that it "intend[ed] to study the use of contracted pharmacy services for accessing 340B drugs to determine if there is evidence of drug diversion" and "w[ould] consider whether additional safeguards are necessary." *Id.* at 43,549.

40. In 2010, HRSA issued new guidelines designed to supersede the 1996 Guidance. The new guidance expanded its authorization of contract pharmacies under Section 340B—though again, HRSA denied that it was creating any new rights or obligations, and instead insisted that it was only issuing "interpretive guidance." 75 Fed. Reg. 10,273 (2010 Guidance). Although Section 340B's list of covered entities to which 340B drugs must be offered had not changed to allow contract pharmacies, HRSA nevertheless announced a new policy "proposal" designed to "permit covered entities to more effectively utilize the 340B program." *Id.* at 10,273.

41. Under this new policy, HRSA explained, covered entities must now be permitted to "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.* To take advantage of this new set of arrangements, HRSA announced, a covered entity merely must have a written contract in place with each contract pharmacy through which it intends to dispense 340B drugs; the covered entity need not submit these contracts to HRSA. *Id.* at 10,277; *see* Gov. Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 1, GAO-18-480 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf.

42. Numerous 340B stakeholders objected that allowing covered entities to use an unlimited number of contract pharmacies would exacerbate the problems of diversion and duplicate discounts. The 2010 Guidance rejected these objections, asserting that "there are appropriate safeguards in place" to protect program integrity. 75 Fed. Reg. 10,274. Among other "Essential Covered Entity Compliance Elements," the guidance required covered entities to "maintain title to the drug and assume responsibility for establishing its price." *Id.* at 10,277. Ultimately, however, the 2010 Guidance emphasized that "responsibility" rests with "the covered entity to ensure against diversion and duplicate discounts." *Id.* at 10,274; *see id.* at 10,275. HRSA further rejected any suggestion that it should place reasonable limits on the number of contract pharmacies that a single covered entity could use, or that it should impose restrictions on the geographic location of contract pharmacies in relation to the covered entity they serve (such as preventing the use of pharmacies "over State lines"). *Id.* at 10,276.

43. As a result of its categorical stance, the 2010 Guidance purported to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States, even hundreds or thousands of miles away.

A Surge in Contract Pharmacy Arrangements Opens the Door to Profiteering and Undermines the Integrity of the 340B Program

44. HRSA's 2010 Guidance immediately triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 by 2017. 2018 GAO Report at 2. These numbers have continued to escalate. Today, more than 27,000 individual pharmacies participate in the 340B program, with a total of well over 100,000 individual contracts.[2] Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* 4 (Oct. 2020) (BRG Report), https://bit.ly/3owtUwa. The vast majority of these contract pharmacies (75% as of 2018) are national, for-profit retail pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

45. Make no mistake: The boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B discounted drugs. Under the so-called "replenishment model" that is now prevalent, the determination whether a medicine is eligible for the 340B discount is not made until *after* the medicine is dispensed to the patient and paid for at a non-

[2] The exact number of contract pharmacy arrangements currently in place is unknown because HRSA does not require a covered entity that has multiple sites to submit separate registrations for each of its sites. *See* 2018 GAO Report at 19-20. Thus, while HRSA's database includes well over 100,000 current contracts, *see* https://bit.ly/2HFB4gV, the real figure could be much higher than that. *See* 2018 GAO Report at 20.

discounted, commercial price by the patient and his or her health plan. In practice, pharmacies generally buy their inventory of drugs from wholesalers in commercial transactions. Pharmacies then dispense those medicines to any patient with a valid prescription. Those patients could have been treated at a 340B entity or a non-340B entity. Either way, the pharmacy dispenses product from its inventory to the patient consistent with the patient's insurance. Later, for medications determined to be dispensed to a patient of the 340B entity, the wholesaler processes a chargeback reflecting the difference between the pharmacy acquisition price and the 340B price. This means that a 340B discount is applied for the contract pharmacy sale even though it has *also* benefitted from the full insurance reimbursement. The pharmacy may well share some of its windfall with the covered entity or the covered entity's vendor, but the patient has still paid the full out-of-pocket amount designated under his or her insurance policy.

46. For example, in the Medicare Part B context, the Centers for Medicare & Medicaid Services (CMS)—an agency within HHS—found that prescription drugs dispensed to the patient of a covered entity typically cost between 20% and 50% less than the drugs' average sales price. *See, e.g.*, CMS, *Hospital Outpatient Prospective Payment System Proposed Rule Calendar Year 2021*, 85 Fed. Reg. 48,772, 48,886 (Aug. 12, 2020). Yet Medicare provides *full reimbursement* for dispensing the drugs to such a patient. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), https://www.gao.gov/assets/680/670676.pdf. The same goes for patients with private insurance or who pay out of pocket. Through this process, pharmacies and covered entities have been able to generate substantial profits from the difference between the low acquisition price mandated by Section 340B and the higher reimbursement value of the drug.

47. As Senator Chuck Grassley put it in a letter to HRSA, for profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Administrator, Health Resources and Servs. Admin. (March 27, 2013), https://bit.ly/3kFquVS (Grassley Letter). This has resulted in a significant business opportunity for Walgreens (and other for-profit national pharmacy chains). *See* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge* (Sept. 9, 2020) (Walgreens generated profits "in the hundreds of millions" through 340B contract pharmacy arrangements). Indeed, Walgreens' SEC filings report that any pricing changes "in connection with the federal 340B drug pricing program[] could significantly reduce our profitability." Walgreens Boots Alliance, Inc. Form 10-K (Oct. 15, 2020), https://bit.ly/2MoLX9d.

48. One study estimated that, due to the steep discounts mandated under Section 340B, "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines"—a margin more than triple that ordinarily available to independent pharmacies. BRG Report at 7. The study found that "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018, which represents over 25 percent of the total $48 billion in profits realized by all providers that dispensed or administered brand medicines in 2018." *Id.* Most of these profits are *not* going to federally qualified health centers or other federal grantees that provide services to underserved populations, such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance program. Instead, they are being captured by

340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. *Id.*

49. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id.* Likewise, the HHS Office of Inspector General has found that many contract pharmacies do not offer 340B discounted prices to uninsured patients at all. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." By contrast, the GAO noted that 17 of 23 of the surveyed covered entities that used *in-house* pharmacies reported offering discounts to their patients. *Id.*

50. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme that benefits national for-profit pharmacy chains and other for-profit intermediaries.

51. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts—the very risks that Congress sought to avoid when it enacted Section 340B. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more

sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients." Gov. Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28, GAO-11-836 (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

52. These structural problems have only intensified over time, as the use of multiple contract pharmacies has become rampant. In 2014, for instance, HHS's Office of the Inspector General conducted a study of contract pharmacy arrangements, which led to a finding that such arrangements "create complications" for efforts to prevent abuse of the 340B program. Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of the Inspector Gen., Dep't of Health and Human Servs., *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, at 1-2, OEI-05-13-00431 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. The Inspector General also determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." *Id.* at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45; *see id.* ("As the 340B Program continues to grow, it is essential that HRSA address these shortcomings.").

53. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.* at 44. And based on information from HRSA's website, over 25% of covered entities audited

since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

AstraZeneca Updates Its Contract Pharmacy Policy to Remedy Abuse of the 340B Program

54. Against this legal and factual backdrop, in August 2020 AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance. Moving forward as of October 1, AstraZeneca would "only . . . process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." Letter from Odalys Caprisecca dated Aug. 17, 2020 (Exhibit B).

55. From the outset, AstraZeneca was open and transparent with HRSA about this policy change. AstraZeneca first explained its new planned policy to HRSA in a letter dated July 24, 2020. *See* Letter from Christie Bloomquist to Krista Pedley dated July 24, 2020 (Exhibit C). In that letter, AstraZeneca explained that Section 340B refers only to outpatient drugs that are "***purchased by*** a covered entity," and provides that such drugs must be offered at the discounted price, but "does not mention 'contract pharmacies.'" *Id.* at 2. Its policy of recognizing one contract pharmacy per covered entity that does not maintain an on-site pharmacy thus "complies with operative 340B statutory provisions," AstraZeneca explained, because "AstraZeneca will make its products available to all covered entities at or below the applicable ceiling price." *Id.* AstraZeneca also cited to substantial evidence, drawn from HRSA's own audits, that the unlimited use of contract pharmacies had caused "significant increases in covered entity violations of the

statutory prohibitions against product diversion and duplicate discounting." *Id.* at 3. AstraZeneca closed its letter to HRSA by proposing to meet to discuss its policy change. *Id.*

56. After nearly a month had passed without any response from HRSA, AstraZeneca began informing its distributors directly of its new policy. *See* Ex. B. Then, on August 20, AstraZeneca provided HRSA with a notice for distribution to covered entities regarding the changed policy and requested that HRSA post it on HRSA's website. *See* Notice to Covered Entities Regarding 340B Pricing (Exhibit D). Consistent with AstraZeneca's prior letter to HRSA, the notice explained that, effective October 1, "AstraZeneca will recognize one Contract Pharmacy per Covered Entity for those Covered Entities that do not maintain an on-site dispensing pharmacy." *Id.* at 1. The notice emphasized that the new policy would not disrupt any covered entity's access to 340B drugs at 340B prices, explaining that "Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacy." *Id.* The notice also described the process by which covered entities could designate a contract pharmacy under the policy. *Id.* In its cover email to HRSA, AstraZeneca reiterated its offer to meet with HRSA to explain these changes in more detail.

57. HRSA did not respond to AstraZeneca's July letter and August email until September 2. *See* Letter from Krista Pedley to Christie Bloomquist dated Sept. 2, 2020 (Exhibit E). In its response, HRSA warned that it was "considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply," including "civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." *Id.* at 1. HRSA further asserted that it believed AstraZeneca's new policy "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the

Congressional intent behind enactment of the 340B statute." *Id.* at 1-2. HRSA neither responded to AstraZeneca's discussion of the text of Section 340B nor acknowledged AstraZeneca's citations to the agency's own reports as evidence that distribution to unlimited contract pharmacies has resulted in duplicate discounts and diversion. Instead, HRSA asked AstraZeneca to submit "evidence of specific duplicate discount and diversion violations, . . . including the alleged covered entities and drugs involved." *Id.* at 1.

58. AstraZeneca replied to HRSA's response letter on September 15. *See* Letter from Odalys Caprisecca to Krista Pedley dated Sept. 15, 2020 (Exhibit F). AstraZeneca expressed surprise that HRSA would threaten sanctions, such as civil monetary penalties, given that its policy was fully compliant with Section 340B as written and with guidance that HRSA itself had endorsed for fourteen years. AstraZeneca also expressed disappointment that HRSA chose to convey this threat by letter, rather than taking AstraZeneca up on its two separate offers to meet with HRSA to discuss its new policy. *Id.* at 1.

59. As to the merits, AstraZeneca reiterated that its "planned approach complies fully with the 340B statute" because "[u]nder [AstraZeneca's] new structure, each covered entity will be offered 340B drugs at the 340B price on non-discriminatory terms." *Id.* AstraZeneca further explained that its new policy in fact "will go beyond the statute's requirements by assuring access to 340B pricing through a contract pharmacy arrangement if a covered entity is unable to dispense 340B drugs from its own facilities." *Id.*

60. AstraZeneca's letter also rebutted HRSA's statement that the new policy could limit access to 340B drugs. "AstraZeneca's new approach to contract pharmacy recognition should not impact patient access," the letter explained, "as our medications will remain available to 340B entities at the 340B price." *Id.* Citing additional government data, AstraZeneca reaffirmed that

its new approach was intended to "bolster the integrity of the 340B program" by ensuring that patients—rather than contract pharmacies—actually reap the benefits of the 340B program, while also eliminating opportunities for diversion and duplicate discounting. *Id.* at 1-2.

61. AstraZeneca further requested that "HRSA confirm to us promptly in writing that it will not seek civil monetary penalties against AstraZeneca related to our impending change to contract pharmacy designation, which fully complies with applicable law." *Id.* Finally, AstraZeneca reiterated for a third time its offer to meet with HRSA "to discuss this critically important issue for 340B program integrity and to correct any misunderstandings that HRSA may have about our approach." *Id.* at 3.

62. In light of HRSA's failure to respond to its letters, AstraZeneca sent letters to approximately 8,000 covered entities individually informing them of the new policy. *See* Letter from Odalys Caprisecca, *Re: 340B Contract Pharmacy Pricing*, dated Sept. 14, 2020 (Exhibit G). Those letters explained that "AstraZeneca will continue to provide [its] products directly to all Covered Entities . . . at the required statutory ceiling price," and encouraged "any Covered Entity that does not have an outpatient, on-site dispensing pharmacy [to] contact AstraZeneca" by email "to identify a single Contract Pharmacy of its choice." *Id.*

63. On November 2, 2020, AstraZeneca sent another letter to HRSA. *See* Letter from Odalys Caprisecca to Krista Pedley dated Nov. 2, 2020 (Exhibit H). As in its previous correspondence, AstraZeneca emphasized that, under its new policy "all covered entities will continue to have access to AstraZeneca medicines at the 340B price," and that the policy "is fully compliant with the 340B statute." *Id.* at 2. AstraZeneca reaffirmed that "[t]he change that AstraZeneca has implemented makes its products available to covered entities either through their own in-house pharmacy or through a designated contract pharmacy." *Id.* at 2. AstraZeneca also

reiterated its request for a meeting with HRSA and asked the agency to advise whether it was "accepting or rejecting our formal meeting request." *Id.*

64. To this day, HRSA has not agreed to meet with AstraZeneca. Nor has HRSA corrected any of the erroneous public statements regarding AstraZeneca's approach to contract pharmacies. These failures have inhibited AstraZeneca's ability to fully implement its policy and have led to confusion by covered entities and delays in their designating a single contract pharmacy of their choosing under the policy. The result has caused harm to AstraZeneca and to covered entities.

The HHS General Counsel Issues an Advisory Opinion that Pharmaceutical Manufacturers Must Honor Unlimited Contract Pharmacy Arrangements

65. On December 30, 2020, Defendants issued *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*. The Advisory Opinion for the first time set out HHS's definitive response to the legal question of whether the 340B Statute requires manufacturers to provide 340B discounts for contract pharmacy sales. The Advisory Opinion "conclude[d]" that manufacturers' obligations to offer discounted drugs under the 340B Statute extend to contract pharmacy sales. Advisory Opinion 1. In the agency's view, "a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs" whenever a contract pharmacy acts as a covered entity's "agent." *Id.*; *see id.* at 8 ("[T]he Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients."); *see also* HHS, *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020),

https://bit.ly/38Qh0lB ("Through the new advisory opinion, HHS has clarified that drug manufacturers must provide 340B discounts when a contract pharmacy is acting as an agent of a covered entity, providing services on behalf of the covered entity.").

66. Although it purports to be grounded in "the plain text of the statute," Advisory Opinion 3, this Court has since explained that the Advisory Opinion "wrongly" made that determination and was therefore "legally flawed," D.I. 78 at 17. The Advisory Opinion nowhere explained how its reading of Section 340B complied with the plain statutory requirement that covered entities must "offer" discounted drugs to a "covered entity." 42 U.S.C. § 256b(a)(1). Nor did the opinion address the fact that Section 340B exhaustively lists fifteen types of non-profit healthcare providers that qualify as "covered entities," without mentioning contract pharmacies, *id.* § 256b(a)(4), or acknowledge that Section 340B carefully distinguishes in other respects between "covered entities" and agents—including "associations or organizations representing the interests of . . . covered entities," "wholesalers," and "distributors," *id.* § 256b(d)(1)(B)(v), (2)(B)(iii), (3)(B)(vi).

67. HHS issued the Advisory Opinion despite the fact that Congress did not grant Defendants general rulemaking power with respect to Section 340B(a). The U.S. District Court for the District of Columbia has *twice* held that Section 340B does not grant HHS "broad rulemaking authority." *Orphan Drug I*, 43 F. Supp. 3d at 42; *see PhRMA v. HHS* (*Orphan Drug II*), 138 F. Supp. 3d 31, 33 (D.D.C. 2015). Instead, "Congress has specifically delineated the scope of HHS's rulemaking authority" with respect to the 340B program. *Orphan Drug I*, 43 F. Supp. 3d at 42 (citing 42 U.S.C. § 256b(d)(3)). This focused grant of rulemaking authority does not empower the agency to "engag[e] in prophylactic non-adjudicatory rulemaking regarding the 340B program." *Id.* at 42-43.

68. Defendants' purported "withdrawal" of the Advisory Opinion, *see* D.I. 81, does not remedy the legal flaws in their position. The withdrawal notice makes clear that it "does not impact" Defendants' position that the statute requires drug manufacturers to provide discounts for unlimited contract pharmacy sales or their "ongoing efforts" to "enforce" that position. *Id.* And indeed, Defendants have sought to implement the very same position through the May 17 letter, and through the threat of ADR proceedings, the outcome of which is "preordained." D.I. 78 at 17.

HHS's Interpretation of Section 340B Is Contrary to the Statute's Plain Text, History, and Purpose

69. Notwithstanding the Advisory Opinion's claim that it engaged in "straightforward textual interpretation," Advisory Opinion 3, the opinion ignored the statute's key provision: Section 340B's must-offer provision requires a manufacturer solely to "offer" discounted drugs to a "covered entity." 42 U.S.C. § 256b(a)(1). Nothing in the statute supports that a manufacturer violates its obligation by declining to make discounts available for contract pharmacy sales.

70. As relevant here, the statute provides that a manufacturer must enter into an agreement with the HHS Secretary that "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Section 340B(a)(4), in turn, enumerates fifteen types of healthcare providers that qualify as "covered entities." *Id.* § 256b(a)(4). This exhaustive list does *not* include "contract pharmacies," a term that appears nowhere in Section 340B. As this Court noted, "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." D.I. 78 at 20.

71. Section 340B by its terms thus obliges a manufacturer to "offer" discounted drugs to a "covered entity." The word "offer" is not defined in the statute, but its ordinary meaning is to

"make available," or to present for acceptance or rejection. *See* Black's Law Dictionary (11th ed. 2019). Under AstraZeneca's current policy, discounted drugs have been "ma[d]e available" for purchase by every covered entity, and presented for their acceptance or rejection, because every covered entity has the opportunity to buy drugs from AstraZeneca at the statutory ceiling price. Merely qualifying for covered entity status is sufficient to make this purchase opportunity available. Indeed, AstraZeneca allows a covered entity that lacks an in-house pharmacy to purchase drugs through a contract pharmacy of its choosing.

72. Also significant is what Section 340B does *not* say. Congress could easily have written the statute to require a manufacturer to offer 340B discounted drugs to "each covered entity *or pharmacies operating under an agency relationship with a covered entity*," but Congress did not do so. Notably, from enactment through 2010, HRSA itself did not read the Section 340B to allow a covered entity to recognize multiple contract pharmacy relationships. Instead, the agency's position from 1996-2010 was that, in light of "gaps in the legislation," the agency could reasonably interpret Section 340B(a)(1) to allow a manufacturer to make drugs available either to the covered entity directly or to *one* contract pharmacy per covered entity that lacked an on-site dispensing pharmacy. 61 Fed. Reg. at 43,550.

73. Section 340B's history and purpose also demonstrate that Congress did not intend to guarantee access to deep 340B discounts for sales through an unlimited number of for-profit contract pharmacies. The Conference Report for the bill that eventually became Section 340B indicates that Congress intended "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). The report says nothing of creating an extensive system for the distribution of 340B drugs through contract pharmacies.

74. In fact, the legislative history shows the opposite—that despite its awareness that covered entities sometimes rely on contract pharmacies, Congress made a deliberate choice not to include contract pharmacy arrangements within Section 340B. Congress considered proposed statutory language in a prior version of the bill that would have expressly permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259 at 1-2. That language, however, did not make it into the final version of the bill that Congress passed and the President signed into law. The statute's failure to mention contract pharmacies (even on-site ones) thus was no mere oversight. As this Court explained in its recent Memorandum Opinion, "that omission suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." D.I. 78 at 20. And certainly nothing in the legislative history suggests that Congress intended, through silence, to create a vast system of *off-site* contract pharmacies for the distribution of drugs to patients of Section 340B covered entities. *See Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

75. As this Court recognized in its recent Memorandum Opinion:

> Other statutory provisions also cut against HHS's position. For example, another part of the VHCA (which established the 340B Program) refers specifically to "drugs procured by an agency of the Federal Government" that are "received[,] stored, and delivered" by "a commercial entity ***operating under contract*** with such agency." 38 U.S.C. § 8126(h)(3) (emphasis added). Likewise, a provision in a different health care statute explicitly covers "a person authorized to act as a purchasing ***agent*** for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(C) (emphasis added). Congress knows how to write statutes that cover agents and contractors, but it did not do so in the 340B statute."

D.I. 78 at 20-21 (alterations and emphases in original).

HHS's Advisory Opinion and the May 17 Letter Are Final Agency Action

76. The APA authorizes judicial review of any "final agency action for which there is no other adequate remedy in court." 5 U.S.C. § 704. An action is final if: (1) it "mark[s] the consummation of the agency's decision-making process," rather than being "of a merely tentative or interlocutory nature," and (2) it is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *see Sackett v. E.P.A.*, 566 U.S. 120, 126-27 (2012). The Advisory Opinion is final action under this test.

77. First, as this Court has held, the Advisory Opinion marked the "consummation" of the agency's decision-making process: HHS's analysis was not contingent, tentative, or interlocutory. The opinion conclusively announced the agency's legal interpretation of the statute; it did not contemplate any further deliberation or the need for further factual development. The Advisory Opinion determined (erroneously) that the plain text of Section 340B was unambiguous and thus "dispositive" of the legal question. Advisory Opinion 3. And the opinion's conclusion was unequivocal: "[T]he Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." *Id.* at 8.

78. Second, as this Court also found, the Advisory Opinion adopted an interpretation of Section 340B from which "rights or obligations have been determined or from which legal consequences will flow." *Bennett*, 520 U.S. at 177-78. Potential liability (including for

overcharges and claims for civil monetary penalties) would accrue every day that AstraZeneca does not submit to the agency's interpretation. *See Sackett*, 566 U.S. at 126-27.

79. This "finality" analysis applies with equal force to the May 17 letter. Like the Advisory Opinion, the May 17 letter represents the consummation of the agency's decision-making process and purports to impose legal obligations on AstraZeneca. The May 17 letter announces that "HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." Ex. A at 1. It also directs that AstraZeneca "*must* immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2 (emphasis added). The letter then warns that, under HRSA's interpretation of the statute, AstraZeneca may be liable for penalties of more than $5,000 per "overcharge." *Id.*

80. Through the May 17 letter, as with the Advisory Opinion, Defendants have put AstraZeneca to the "painful choice" of either complying with the incorrect "obligation[s]" that result from Defendants' erroneous interpretation of Section 340B or "risking the possibility of an enforcement action at an uncertain point in the future." *Orphan Drug II*, 138 F. Supp. 3d at 43 (quoting *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011)); *see Bauer v. J.B. Hunt Transp., Inc.*, 150 F.3d 759, 763 (7th Cir. 1998) (holding that a letter from the Department of Labor constituted final agency action because "[l]egal consequences flow from it, both with respect to [plaintiffs'] obligations to their employees and with respect to [their] vulnerability to penalties should they disregard [it]").

HRSA Promulgates ADR Procedures to Impose Liability on Manufacturers for Failing to Follow the Advisory Opinion's Approach to Contract Pharmacies

81. The harmful consequences of the agency's contract pharmacy position have become even more concrete in light of HRSA's publication of final ADR procedures for resolving claims related to overcharging, duplicate discounts, or diversion. *See* 85 Fed. Reg. 80,632 (Dec. 14, 2020) (ADR Rule). Rushed out in response to litigation in the waning months of the Trump Administration, the ADR Rule creates an unfair, legally faulty, and ultimately unconstitutional process.

82. In 2010, as part of Congress's amendments to the 340B statute in the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §7102(a), 124 Stat. 119 (2010), Congress required HHS, within 180 days of the law's enactment, to establish an ADR process for resolving "claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers … of violations of subsections (a)(5)(A) or (a)(5)(B)." *Id.*, 124 Stat. at 826-27 (codified at 42 U.S.C. § 256b(d)(3)). Congress directed that the agency, in establishing the ADR process, must "designate or establish a decision-making official or body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price … and claims by manufacturers that violations of [statutory prohibitions on conduct like diversion] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)).

83. HHS did not come close to meeting the 180-day deadline. Instead, approximately six years after the deadline passed, HHS issued a Notice of Proposed Rulemaking (NPRM) setting forth suggested ADR procedures. *See* 81 Fed. Reg. 53,381-01 (Aug. 12, 2016).

84. HHS proposed that claims would be resolved by three-member panels "chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of [HHS's Office of Pharmacy Affairs]." *Id.* at 53,382. Panel members would be "Federal employees (e.g., employees of [the Centers for Medicare & Medicaid Services, or CMS] or the U.S. Department of Veterans Affairs) with demonstrated expertise or familiarity with the 340B Program." *Id.* Panelists would be appointed by the HHS Secretary and could only be removed "for cause." *Id.*

85. The NPRM specified that panel decisions would "be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction. *Id.* at 53,383. It did not contemplate any appeal or other review within the agency of ADR Panel decisions.

86. The agency solicited comments on the NPRM. The Pharmaceutical Research and Manufacturers of America (PhRMA), of which AstraZeneca is a member, submitted comments proposing that the agency designate one or more HHS administrative law judges to decide ADR claims. PhRMA explained that use of administrative law judges—rather than regular agency officials, who might share the agency's predilections and biases—was necessary to ensure "that the ADR decision-makers both be independent and have expertise in the 340B program, so that they are well-positioned to make high-quality, impartial decisions." PhRMA Comments on 340B Drug Pricing Program Proposed Rule on Administrative Dispute Resolution, RIN 0906-AA90, at 8 (Oct. 11, 2016), https://bit.ly/36hlxNB.

87. After the notice-and-comment period ended on October 11, 2016, the NPRM was placed on the Unified Agenda of Federal Regulatory and Deregulatory Actions, a semiannual compilation of information about federal regulations under development. On August 1, 2017, however, the agency withdrew the NPRM from the Unified Agenda without explanation. *See*

Office of Mgmt. & Budget, *RIN: 0906-AA90: 340B Drug Pricing Program; Administrative Dispute Resolution Process*, https://bit.ly/363FZl5. And over the subsequent three years, the agency gave no indication that it had plans to resume or restart the ADR rulemaking.

88. Indeed, in March 2020—a full decade after enactment of the Affordable Care Act—HRSA made clear in public statements that it "*d[id] not plan* to create a binding dispute-resolution process for 340B 'until such time that HRSA receives regulatory authority for the issues that would be addressed.'" Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (emphasis added), https://340breport.substack.com/p/your-340b-report-for-thursday-march-eae. HRSA further stated that "many of the issues that would arise for dispute are only outlined in guidance," and that it "d[id] not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance." *Id.*

89. But that all quickly changed as the result of litigation. On October 9, 2020, Ryan White Clinics for 340B Access and two affiliated 340B-covered entities filed a complaint in federal court, seeking to compel HRSA to promulgate the ADR Rule. *See* Compl. ¶¶ 99-100, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Oct. 9, 2020), Dkt. 1. A complaint from the National Association of Community Health Centers (NACHC) followed less than two weeks later. *See* Compl. ¶¶ 87-101, *NACHC v. Azar*, No. 20-cv-3032 (D.D.C. Oct. 21, 2020). These complaints are premised on the same "legally flawed" conclusion that Section 340B requires manufacturers to deliver 340B-discounted products to an unlimited number of contract pharmacies. *See* Compl. ¶ 1, *Ryan White Clinics for 340B Access*, No. 20-cv-2906 ("Since 1996, the Secretary has expressly recognized that the 340B statute requires pharmaceutical manufacturers to provide 340B discounts when ordered by covered entities via contract

pharmacies."); Compl. ¶ 5, *NACHC*, No. 20-cv-3032 (describing AstraZeneca's policy as "a clear violation of 340B statutory requirements").

90. Only two months later—and nine months after HRSA's public statement that it did not intend to issue a regulation establishing an ADR process until after Congress amended the 340B statute to confer on it the necessary regulatory authority—HRSA reversed course to promulgate a final rule setting forth "the requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process." 85 Fed. Reg. 80,632 (Dec. 14, 2020).

91. HRSA had not issued a new NPRM in the interim; nor had it given the public any opportunity for notice and comment. Instead, HRSA claimed that it had "not formally withdraw[n] the [2016] NPRM, but rather had left it open as a viable option," citing a presidential memorandum freezing certain rulemaking implemented by the incoming Trump administration. 85 Fed. Reg. at 80,633. But the memorandum to which the agency referred explicitly *excluded* regulations, like the ADR Rule, that are "subject to statutory . . . deadlines." Reince Priebus, Asst. to the President and Chief of Staff, *Memorandum for the Heads of Executive Departments and Agencies* (Jan. 20, 2017), https://bit.ly/2KIutnM. And the agency's own conduct confirms the inapplicability of the memorandum: Notwithstanding the memorandum's order to remove pending regulations "immediately," *id.*, the agency waited *eight months* before removing the 2016 NPRM from the Unified Agenda. Moreover, although regulatory actions normally retain the same Regulatory Identification Number throughout the entire rulemaking process, the final ADR Rule was assigned a different RIN than the 2016 NPRM—further confirming that the NPRM had been withdrawn by the agency in contemplation of starting over. *Compare* 81 Fed. Reg. at 53,381 *with* 85 Fed. Reg. at 80,632.

92. Pointing to these procedural irregularities, PhRMA and several drug manufacturers have filed separate suits challenging the ADR Rule under the APA. In one such suit, a federal district court agreed that the promulgation of the ADR Rule had violated the APA:

> Considering these actions and circumstances together, the agency's message regarding the ongoing rulemaking related to the ADR Rule was ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA. Accordingly, we find that Plaintiffs have demonstrated a likelihood of establishing that a withdrawal of the NPRM was effected, thus requiring the agency to have engaged in notice-and-comment procedures before promulgating the final ADR Rule, which it failed to do.

Eli Lilly & Co. v. Cochran, No. 21-cv-81-SEB-MJD, --- F. Supp. 3d ----, 2021 WL 981350, at *10 (S.D. Ind. Mar. 16, 2021). The court accordingly granted a preliminary injunction prohibiting Defendants "from implementing or enforcing" the ADR Rule against the plaintiffs. *Id.* at *12.

93. The ADR Rule creates a 340B Administrative Dispute Resolution Board, which comprises "at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the HHS Office of the General Counsel (OGC)." 85 Fed. Reg. at 80,634. The Rule provides that disputes will be heard by three-member panels whose members are drawn from Administrative Dispute Resolution Board, with each panel composed of "one member from HRSA, CMS, and OGC with relevant expertise to review claims and make final agency decisions." *Id.*

94. The ADR Rule makes no provision for removal of any Board member. Instead, the Rule provides that individual panel members can be removed from a particular panel "for cause," but identifies "a conflict of interest" as the *only* ground for panel removal. *Id.*

95. Though the NPRM had been silent on the remedies available through the ADR process, the ADR Rule purports to authorize panels to resolve claims for "money damages," as well as other unspecified "equitable relief" sought by claimants. *Id.* at 80,633. And the ADR Rule

asserts that "[e]ach 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." *Id.* at 80,636.

96. Notably, the ADR Panelists also have authority to "make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers." *Id.* at 80,634; 42 C.F.R. § 10.20.

97. Despite the significant authority they wield, the ADR Panelists are not subject to supervision by any superior officer of the United States, nor are panel decisions subject to further review within the agency. Rather, the ADR Rule states that further oversight of panel decisions is not "necessary given that an aggrieved party has a right to seek judicial review." 85 Fed. Reg. at 80,641.

98. Promulgation of the ADR Rule places the contract pharmacy question front and center. Indeed, HRSA has already made clear that it intends to use the ADR process to impose liability on manufacturers for failure to follow the agency's approach to contract pharmacies. Although Section 340B vests HHS with limited authority to establish ADR procedures by which to resolve "claims," 42 U.S.C. § 256b(d)(3)(A)-(C), the ADR Rule aggrandizes power in the ADR Panel "to resolve related issues"—including purely *legal* questions "such as . . . whether a pharmacy is part of a 'covered entity,'" 85 Fed. Reg. at 80,633. It does so even though, just months earlier, HRSA reportedly asserted that it lacked authority to render such determinations. *See* Mirga, *supra*.

99. On June 24, 2021, HHS published a notice in the Federal Register announcing the appointment of the ADR Board members. 86 Fed. Reg. 33,317. The Board members are:

- Sean R. Keveney, Deputy General Counsel, the Office of the General Counsel, Department of Health and Human Services;
- Andy J. Miller, National Complex Litigation and Investigations Division Attorney, the Office of the General Counsel, Department of Health and Human Services;
- Glenn Clark, Public Health Advisor, HIV/AIDS Bureau, Health Resources and Services Administration, Department of Health and Human Services;
- CAPT Christina Meade, Area Regional Pharmacy Consultant, Office of Regional Operations, Health Resources and Services Administration, Department of Health and Human Services;
- CDR Timothy Lape, Division of Medicare Health Plans Operations, Medicare Branch, Centers for Medicare & Medicaid Services, Department of Health and Human Services;
- Adele Pietrantoni, Office of Program Operations and Local Engagement, Division of Drug and Health Plan Operations, Centers for Medicare & Medicaid Services, Department of Health and Human Services;
- Chantelle Britton, Senior Advisor, Office of Pharmacy Affairs, Health Resources and Services Administration, Department of Health and Human Services, as *ex-officio*, non-voting member; and
- Julie Zadecky, Pharmacist, Office of Pharmacy Affairs, Health Resources and Services Administration, Department of Health and Human Services, as *ex-officio*, non-voting member.

Id. The ADR process threatens to be a mechanism for the agency to enforce the erroneous legal positions asserted in its May 17 letter, and thus exacerbates the letter's harms.

The ADR Rule Has Accelerated and Magnified the Harm to AstraZeneca Resulting from the Agency's Contract Pharmacy Position

100. The ADR Rule needs to be considered in tandem with the Advisory Opinion and May 17 letter; combined, these unlawful agency actions have created several immediate and irreparable consequences for AstraZeneca, for several reasons.

101. ***First***, covered entities have *already* filed ADR complaints against AstraZeneca, threatening imminent legal sanctions based on the agency's enforcement of the Advisory Opinion and the May 17 letter.

102. Immediately after the ADR Rule went into effect on January 13, 2021, several covered entities filed ADR petitions against AstraZeneca, alleging that AstraZeneca is in violation of the 340B statute by failing to offer 340B-priced drugs to covered entities through their contract pharmacies. *See Open Door Community Health Centers v. AstraZeneca Pharms, LP*, No. 210112-1 (filed Jan. 13, 2021) (Exhibit I); *NACHC v. Eli Lilly & Co. et al.*, No. 210112-2 (filed Jan. 13, 2021) (Exhibit J); *Little Rivers Health Care, Inc. v. AstraZeneca Pharms., LP*, No. 210202-5 (filed Feb. 4, 2021) (Exhibit K).

103. The ADR petitioners call on the ADR Panel to impose a variety of legal sanctions against AstraZeneca: to order AstraZeneca to provide discounted pricing to drugs sold to contract pharmacies; to force AstraZeneca to refund purchases made through contract pharmacies at non-discounted prices; and to impose penalties against AstraZeneca for willfully violating its statutory obligations. *Open Door* Pet. ¶¶ 57-66, Relief Requested ¶¶ 1-4 (Ex. I at 19-22); *NACHC* Pet. ¶ 48, Request for Relief ¶¶ 1, 4-5 (Ex. J at 14-15); *Little Rivers* Pet. ¶¶ 61-70, Relief Requested ¶¶ 1-4 (Ex. K at 23).

104. In addition, the *NACHC* petition seeks a preliminary injunction, requesting that the ADR Panel "employ its equitable authority under 42 C.F.R. § 10.21(a)" to grant injunctive relief in its favor "pending the Panel's final resolution of this claim." *NACHC* Mot. for Prelim. Inj. at 1 (Exhibit L).

105. To justify subjecting AstraZeneca to the ADR Panel's jurisdiction, the ADR petitioners uniformly invoked the Advisory Opinion—and its "legally flawed" view, now shared

by the May 17 letter, that the "plain language" of the 340B statute "unambiguously requires" manufacturers to provide discounts for an unlimited number of contract pharmacy sales. *Open Door* Pet. ¶¶ 3, 47-52 (Ex. I at 2, 15-18); *see NACHC* Pet. ¶¶ 4, 16-19 (Ex. J at 3, 6-7); *Little Rivers* Pet. ¶¶ 3, 52-56 (Ex. K at 2, 16-19). Like the May 17 letter, the *Open Door* petition asserts that "[t]he 340B statute unambiguously requires [AstraZeneca] to sell covered outpatient drugs to Petitioner and places no limitation on the site of delivery." *Open Door* Pet. ¶ 3 (Ex. I at 2). Likewise, the *NACHC* petition asserts that "[Section 340B] is unambiguous in obligating drug manufacturers to sell covered outpatient drugs to covered entities at or below applicable ceiling prices regardless of whether the drugs are distributed through a covered entity's in-house or contract pharmacies. *NACHC* Pet. ¶ 16 (Ex. J at 6). And the *Little Rivers* petition asserts that "the plain language of the 340B statute requires manufacturers to offer drugs to covered entities at the ceiling prices regardless of whether the covered entity opts to use contract pharmacies to dispense those drugs." *Little Rivers* Pet. ¶ 53 (Ex. K at 17). Also like the May 17 letter, these petitioners assert that HRSA's position on the contract pharmacies has been consistent since 1996. *See Open Door* Pet. ¶¶ 2, 49, 59 (Ex. I at 2, 17, 19-20); *NACHC* Pet. ¶ 18 (Ex. J at 6); *Little Rivers* Pet. ¶¶ 2, 54, 63 (Ex. K at 2, 17, 20-21).

106. This Court has rejected these petitioners' reading of Section 340B and HRSA's guidance. *See* D.I. 78 at 17 ("Because the Opinion wrongly determines that *purportedly unambiguous statutory language* mandates its conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies, the Opinion is flawed.") (emphasis added); *id.* at 13 ("[T]he government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead materially shifted."). Nevertheless, Defendants persist in their erroneous view that they can enforce their "legally

flawed" (*id.*) reading of Section 340B, including through ADR proceedings: "HRSA does not consider the Court's Memorandum Opinion to prevent its enforcement actions under the 340B statute with respect to AstraZeneca, and those enforcement proceedings will continue." D.I. 82 at 8.

107. In any ADR proceeding, the ADR Panel's conclusion on the contract pharmacy question is preordained: The Advisory Opinion and May 17 letter have already conclusively announced HHS's legal position on the contract pharmacy issue, such that any attempt by a manufacturer to dispute that position in proceedings before an ADR Panel would be futile. Indeed, as this Court noted in its recent opinion, "If AstraZeneca (or another manufacturer) tries to raise the legal issue presented [in the Advisory Opinion] in ADR proceedings, the result is preordained." D.I. 78 at 17. As was true in *Orphan Drug II*, "[t]here is nothing to indicate that the administrative record produced during a specific enforcement proceeding would change HHS's legal interpretation." 138 F. Supp. 3d at 43-44; *see Bimini Superfast Operations LLC v. Winkowski*, 994 F. Supp. 2d 106, 117 (D.D.C. 2014) (holding that a Customs and Border Protection (CBP) letter detailing the agency's interpretation of the Immigration and Nationality Act constituted final agency action, where "[t]here is no indication that any such enforcement process would change CBP's legal position or require that an agency record be developed given the purely legal nature of CBP's position").

108. It is thus a foregone conclusion that the ADR Panel will issue a binding decision, which the agency will treat as precedential, holding that AstraZeneca must provide its products at the 340B discounted price to covered entities through any and all contract pharmacies designated by those entities. Such an ADR ruling is "imminent"—*i.e.*, it "will occur before a trial on the

merits can be had" in this Court—rather than "uncertain or speculative." *BP Chems. Ltd. v. Formosa Chem. & Fibre Corp.*, 263 F.3d 254, 263 (3d Cir. 2000).

109. ***Second***, administrative enforcement of the Advisory Opinion and May 17 letter will inflict severe harm that cannot be effectively remedied through litigation after the fact. An order directing AstraZeneca to rescind its contract pharmacy policy would force AstraZeneca to provide large subsidies to for-profit companies. Although the 340B program was intended to help patients, in practice, benefits that were designed to go to 340B patients and the covered entities that serve them are all too often going to contract pharmacies and other intermediaries.

110. Under the current system, if a health care provider (such as a major hospital system) qualifies as a 340B entity, then *any* "patient" of that entity may receive covered outpatient medicines purchased by the entity at the 340B price or better. If a patient treated at the 340B entity then fills their prescription through one of the covered entity's contract pharmacies—which are typically large national for-profit pharmacy chains such as CVS, Walgreens, Kroger, or Rite Aid—the pharmacy obtains reimbursement for that prescription from the patient's insurance company. That reimbursement is no different in amount or kind than if the patient filling the prescription had received their treatment at a non-340B hospital. But what is different is that, if the person filling the prescription received their treatment at a 340B hospital, then the for-profit pharmacy benefits from an *additional* (and significant) 340B discount on top of the insurance reimbursement amount

111. This double payment comes from AstraZeneca, which pays coverage rebates to payers based on utilization of AstraZeneca's medicines by the insurer's beneficiaries. While AstraZeneca attempts to carve out 340B utilization from its payer-rebate obligations, there is no mechanism to reliably do so because covered entities and contract pharmacies do not provide

AstraZeneca with information to identify when a reimbursement claims is for a 340B eligible patient.

112. AstraZeneca does not have access to the data to that would enable it to determine exactly when and where it is paying duplicate discounts. AstraZeneca would need contemporaneous claims data from covered entities or the contract pharmacies themselves, but neither discloses that information to AstraZeneca. In fact, Defendants have *forbidden* manufacturers from requiring covered entities to provide such information, and other manufacturers who have attempted to do so now face punishment.

113. The limited information available to AstraZeneca, however, does make clear that double payments are a significant problem that is causing substantial business losses. In some cases, the number of rebates submitted for AstraZeneca products (when 340B discounts are added to other types of rebates) actually exceeds the number of units sold. For example, in 2019 for one of AstraZeneca's Symbicort products, the company processed discounts on over 250,000 *more* units than the *total* number of units it sold. Likewise, the discounts processed for two Farxiga National Directory Codes (the FDA's identifier for drugs) exceeded actual sales by approximately 234,000 units. That AstraZeneca is receiving and processing more rebate requests than it is selling units shows that double discounts are being sought and obtained on 340B prescriptions.

114. The amount of harm is not measurable with precision, but it is significant. The 340B program requires manufacturers to offer discounts on covered drugs of at least 23.1%, plus an additional discount to offset price increases greater than inflation. Numerous 340B drugs cost just pennies after these discounts are applied. Payer rebates are often as large as, or larger than, 340B discounts. The number of duplicate discounts per year, multiplied by the substantial size of each discounts, results in losses of many millions of dollars annually.

115. Thus, even if AstraZeneca ultimately prevails on the merits in this Court, it will sustain substantial unrecoverable financial losses in the interim (*i.e.*, after the ADR Panel rules but before final judgment here). "[M]easuring these harms" would not only be "very difficult," but virtually impossible, and none of the harm "would be fully compensable" in litigation. *Res. Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 660 (D. Del. 2010) (Stark, M.J.).

116. The Advisory Opinion and May 17 letter are also already damaging AstraZeneca's business relationships with covered entities. They have caused covered entities to believe (incorrectly) that AstraZeneca is violating Section 340B and overcharging for covered medications. Covered entities have also relied on Defendants' guidance to reject participation in AstraZeneca's new contract pharmacy policy, potentially denying patients access to 340B covered medications. An ADR decision suspending AstraZeneca's policy will only prolong the uncertainty and exacerbate these harms.

117. ***Third,*** administrative enforcement through the ADR process inflicts two independent constitutional harms. The **first** is that the ADR Panel is unlawfully—and indeed unconstitutionally—composed. The Appointments Clause of the United States Constitution provides:

> [The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. Const. Art. II, § 2, cl. 2. The Clause provides for the appointment of "Officers of the United States," of which there are two types: "*Principal* officers must be appointed by the President with the advice and consent of the Senate, while *inferior* officers may be appointed by the President alone, the head of an executive department, or a court." *United States v. Arthrex, Inc.*, No. 19-1434, 2021 WL 2519433, at *5 (U.S. June 21, 2021); *see Assoc. of Am. R.R. v. U.S. Dep't of*

Transp., 821 F.3d 19, 38 (D.C. Cir. 2016) ("[T]he starting place for assessing the constitutionality of an officer's appointment is determining to which class the officer belongs.").

118. An "Officer of the United States" is an individual who has "continuing and permanent" duties and "exercis[es] significant authority pursuant to the laws of the United States." *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018).

119. The ADR Panelists are "Officers of the United States." The ADR Panelists' duties are "continuing and permanent," *Lucia*, 138 S. Ct. at 2051, because panel members serve for a fixed term of two years, rather than on an ad hoc basis. *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 112-13 (2007).

120. Panel members also exercise significant authority: They have "significant discretion" to "take testimony, conduct trials, [and] rule on the admissibility of evidence." *Lucia*, 138 S. Ct. at 2048; *see* 42 C.F.R. § 10.23 (permitting ADR Panel to "conduct an evidentiary hearing when there are material facts in dispute"); *id.* § 10.22(b)-(c) (permitting ADR Panel to "request additional information from either party" and sanction noncompliance); *see also* 85 Fed. Reg. 80,632, 80,641 (2020) (noting that the ADR Rule "allow[s] the 340B ADR Panel discretion in admitting evidence and testimony during the course of a proceeding"). And ADR Panels also issue "final agency decisions" that are "binding on the parties, and precedential." 85 Fed. Reg. at 80,642; *see* 42 C.F.R. § 10.24(d).

121. Moreover, the ADR Panelists are *principal* officers. "'Whether one is an "inferior" officer depends on whether he has a superior' other than the President." *Arthrex*, 2021 WL 2519433, at *6 (quoting *Edmond v. United States*, 520 U.S. 651, 662-63 (1997)). Thus, "'inferior officers' are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate," while principal

officers are not so supervised. *Edmond*, 520 U.S. at 662-63; *see Free Enterprise Fund v. Public Co. Accounting Oversight Board*, 561 U.S. 477. 486, 510 (2010) (finding Board members to be inferior officers because their actions are "subject to [SEC] approval and alteration"). In its recent *Arthrex* decision, the Supreme Court explained that constitutionally "adequate supervision entails review of decisions issued by inferior officers." *Arthrex*, 2021 WL 2519433, at *9. Agency officials' exercise of "unreviewable executive power" accordingly "is incompatible with their status as inferior officers." *Id.* In *Arthrex*, because Administrative Patent Judges (APJs) were authorized to rule on patent claims without further review by any superior executive official, the Supreme Court declared that APJs' exercise of such "unreviewable authority" was a "constitutional violation." *Id.* at *11.

122. The Supreme Court has further emphasized that officers who are subject to removal at will are inherently subject to greater control and supervision than officers who may only be removed for cause. *See Edmond*, 520 U.S. at 664 ("The power to remove officers . . . is a powerful tool for control."); *see also Arthrex*, 2021 WL 2519433, at *11 ("Here, however, Congress has assigned APJs 'significant authority' in adjudicating the public rights of private parties, while also insulating their decisions from review and their offices from removal.") (citation omitted); *Free Enterprise Fund*, 561 U.S. at 510 ("Given that the Commission is properly viewed . . . as possessing the power to remove Board members at will, and given the Commission's other oversight authority, we have no hesitation in concluding that under *Edmond* the Board members are inferior officers").

123. The ADR Panelists are principal officers. Like the APJs whose unreviewable authority the Supreme Court deemed unconstitutional in *Arthrex*, the decisions of ADR panels are not subject to further review by *any* superior executive official. Instead, the ADR Panelists are

empowered to "make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers." 42 C.F.R. § 10.20.

124. The ADR Panelists also are not removable at will. An ADR Panelist can be "[r]emove[d] . . . from a 340B ADR Panel" only "for cause," 42 C.F.R. § 10.20(a)(1)(ii), and the ADR Rule identifies a "conflict of interest" as the sole basis for panel removal, 85 Fed. Reg. at 80,634. In fact, it is even unclear whether members of the ADR Board can be removed from that body *at all*, as no provision of the ADR Rule governs such a removal.

125. The exercise of authority by a principal officer who was not appointed by the President with advice and consent of the Senate violates the Appointments Clause. *See Arthrex*, 2021 WL 2519433, at *11 ("Only an officer properly appointed to a principal office may issue a final decision binding the Executive Branch . . . ."). Despite being principal officers, all ADR Panelists are appointed by the Secretary of HHS, not by the President with the advice and consent of the Senate. *See* 85 Fed. Reg. at 80,634.

126. The harm to AstraZeneca that flows from the Appointments Clause violation is particularly severe with respect to ADR petitions that seek to have the ADR Panel implement and enforce the legal conclusions contained in the Advisory Opinion and May 17 letter. The ordinary ADR petition will simply seek reimbursement for specific overcharges, which are disputes that fall squarely within the decision-making authority conferred on the agency by Congress. But petitions such as those brought by Open Door (Ex. I), NACHC (Ex. J), and Little Rivers (Ex. K) ask the ADR Panel to resolve purely *legal* questions about the 340B statute's scope—questions that go to the heart of the Panel's *own* jurisdiction over AstraZeneca. Because panel decisions will be precedential, moreover, any ruling on the contract pharmacy issue will affect (and all but resolve) claims brought by or on behalf of potentially tens of thousands of contract pharmacies.

In these circumstances, the need for supervision by presidentially appointed, Senate-confirmed Executive Branch officials is most acute.

127. The **second** independent constitutional harm is that the resolution by ADR Panels of disputes between manufacturers and covered entities violates the Constitution's exclusive reservation of all judicial power to Article III courts. Article III, Section 1 of the United States Constitution provides: "The judicial power of the United States, shall be vested in one Supreme Court, and in such inferior courts as the Congress may from time to time ordain and establish." Article III, Section 2 provides: "The judicial power shall extend to *all cases*, in law and equity, arising under this Constitution[] [and] the laws of the United States." (Emphasis added).

128. As the Supreme Court has explained, this grant of exclusive judicial authority means that the other Branches of Government may not confer such power on non-Article III entities: "When a suit is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789, and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts." *Stern v. Marshall*, 564 U.S. 462, 484 (2011) (quoting *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 90 (1982) (Rehnquist, J., concurring in the judgment)). A statute or regulation thus violates the Constitution if it "confer[s] the Government's 'judicial Power' on entities outside Article III." *Id.*

129. Included among the cases that must be adjudicated by Article III courts are disputes over private property rights: "The legislative power . . . cannot directly reach the property or vested rights of the citizen, by providing for their forfeiture or transfer to another, without trial and judgment in the courts." *Newland v. Marsh*, 19 Ill. 376, 382 (1857). By contrast, Congress may

"assign adjudication of public rights to entities other than Article III courts." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018).

130. The ADR Rule violates Article III by empowering ADR Panels to issue final, precedential, self-executing judgments with respect to private rights—namely, financial disputes between private parties (manufacturers and covered entities) regarding the cost of commercial transactions. *See N. Pipeline*, 458 U.S. at 69-70 (private-party disputes involve "the liability of one individual to another under the law as defined") (quoting *Crowell v. Benson*, 285 U.S. 22, 51 (1932)).

131. The exercise of decision-making authority at issue here is particularly problematic. Even if a dispute arising *within* the 340B program could be considered a question of public rather than private rights, the contract pharmacy question does *not* arise within the 340B program: Contract pharmacies are not mentioned by the 340B statute, and sales through contract pharmacies are not covered by the must-offer requirement. By claiming authority to determine "whether a pharmacy is part of a 'covered entity,'" 85 Fed. Reg. at 80,633, the agency is attempting to use its adjudicatory authority to *expand* the 340B program to include private-party sales that are otherwise outside the program.

HRSA's Legally Flawed May 17 Letter Has Harmed AstraZeneca

132. On May 17, 2021, AstraZeneca received a letter from Defendant Diana Espinosa, the Acting Administrator of HRSA. *See* Ex. A. The May 17 letter informs AstraZeneca that HRSA has finished reviewing AstraZeneca's policy regarding contract pharmacy arrangements under the 340B Program, and that "HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." Ex. A at 1.

133. The May 17 letter then directs that "AstraZeneca must [1] 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," [2] "credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy," and [3] "work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements." *Id.* at 2. If AstraZeneca fails to comply with HRSA's demands, the May 17 letter threatens CMPs of up to $5,883 per instance of noncompliance. *Id.* at 2 & n.3; *see* 42 U.S.C. § 256b(d)(1)(vi) (authorizing the imposition of CMPs for each instance of knowing and intentional overcharging of a covered entity).

134. As noted, this Court has already found that the Advisory Opinion's conclusion—that Section 340B requires manufacturers to recognize sales made through an unlimited number of contract pharmacies—is "legally flawed." D.I. 78 at 17. Because the May 17 letter adopts the same "flawed" position, it is invalid for the same reason. Indeed, the May 17 letter features the same major procedural and substantive deficiencies of the Advisory Opinion, plus additional ones as well.

135. ***First***, the May 17 letter is yet another unacknowledged and unexplained change of agency position. As this has Court explained, the Advisory Opinion was the "first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." D.I. 78 at 12 (emphasis in original). Prior to that point, "the government's interpretation of manufacturers' obligations under the 340B program has not remained constant but has, instead, evolved over time." *Id.* at 12-13; *see id.* at 12 ("Strikingly, AstraZeneca's new policy . . . would not have run afoul of the 1996 Guidance—yet it directly

contradicts the Opinion."). Yet the Advisory Opinion "d[id] not acknowledge (much less explain) a change in approach from prior agency guidance." *Id.* at 13 n.11 (citation omitted).

136. The May 17 letter similarly fails to acknowledge or explain Defendants' change of position. Instead, the letter persists in the view 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." Ex. A at 1 (emphasis added). That is incorrect, as this Court's opinion made clear. And the agency's continued "failure to accept th[e] reality" of its position-change, D.I. 78 at 13, renders the May 17 letter invalid: Under the APA, an agency "must at least display awareness that it is changing position and show there are good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quotation marks omitted).

137. ***Second***, just like the Advisory Opinion, the May 17 letter is based on an erroneous interpretation of the 340B statute. The letter asserts that AstraZeneca's policy is "in direct violation of the 340B statute," and in particular the statute's must offer requirement. Ex. A at 1. The May 17 letter further declares that AstraZeneca's policy impermissibly "place[s] conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities," even though that "[n]othing in the 340B statute grants a manufacturer the right" to do so. *Id.*

138. But as this Court's opinion explained, "the government's interpretation [that] pharmaceutical manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies" is neither "contained in the statute" nor "compelled by it." D.I. 78 at 21-22. The must offer provision, on which the May 17 letter relies, "says nothing about the permissible role (if any) of contract pharmacies" and is "simply silent on this point." *Id.* at 18. Nor does any

other provision of the 340B statute impose a requirement to honor contract pharmacy sales. *See id.* at 19 (noting "[t]he statute's total omission of contract pharmacies").

139. Indeed, insofar as the 340B statute "offers any clues" about contract pharmacy sales, "they militate *against* the view" that manufacturers are required to provide discounts for such sales. *Id.* at 20 (emphasis added). The statute "enumerate[s] 15 types of covered entities with a high degree of precision," making it "hard to believe that Congress . . . intended to include contract pharmacies as a 16th option by implication." *Id.* "Other statutory provisions cut also against HHS's position," including provisions that specifically "cover agents and contractors." *Id.* at 20-21. The statute's "legislative history," too, "is of no greater assistance to the government," because it shows that Congress considered but "chose not to include pharmacy services in the version of the bill that it ultimately passed," evincing a *lack* of intent "to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* at 21.

140. In sum, the May 17 letter, like the Advisory Opinion, "is based on the 'unjustified assumption' that Congress imposed . . . a statutory requirement" for manufacturers to provide discounts for contract pharmacy sales. *Id.* at 23 (quoting *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)). Congress imposed no such requirement. Like the Advisory Opinion, therefore, the May 17 letter is "legally flawed." *Id.* at 17.

141. ***Third***, the May 17 letter incorrectly "determined that AstraZeneca's actions have resulted in overcharges" that can be collected in the (unconstitutional) ADR process. Ex. A at 1. But as this Court has recognized, the Advisory Opinion has already definitively announced the agency's position on the interpretation of the 340B statute—a position that it has *not* withdrawn—such that any proceeding before the ADR panel would be "preordained." *Id.* at 16. An adjudicative process in which the result is "preordained" is invalid under the APA. *See Kelly v. United States*,

34 F. Supp. 2d 8, 12 (D.D.C. 1998) ("Where the outcome is preordained, [an agency] hearing operates as little more than an empty, irrational process rather than a substantive inquiry.").

142. ***Fourth***, the May 17 letter is in excess of Defendants' authority. Unlike an "interpretative rule," which "is not binding on anyone" and "does not contain new substance" beyond statutory requirements, *Nat'l Latino Media Coal. v. FCC*, 816 F.2d 785, 787-88 (D.C. Cir. 1987), the May 17 letter is a legislative rule because it seeks to impose duties and obligations not contained in the language of the 340B statute. By commanding compliance with requirements that the statute itself does not impose, the letter "creates duties, rights and obligations" and thus is "substantive." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1811-12 (2019).

143. Yet Defendants have no authority to issue legislative edicts that "gap-fill" congressional silences or to expand the substantive scope of the 340B program. Instead, "Congress specifically authorized" the agency to engage in substantive rulemaking with respect to the 340B program only "in three places": (1) the establishment of an administrative dispute resolution process; (2) the issuance of precisely defined standards of methodology for calculation of ceiling prices; and (3) the imposition of monetary civil sanctions. *Orphan Drug I*, 43 F. Supp. 3d at 41; *see id.* at 42 ("The rulemaking authority granted HHS by Congress under the 340B program has thus been specifically limited, and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program."). Because Congress has "specifically delineated the scope of HHS's rulemaking authority" in those three areas, Congress "did not delegate" authority for the agency to promulgate substantive rules on other issues. *Id.* at 42-43.

144. Accordingly, because no requirement to recognize contract pharmacy sales is "contained in the statute," D.I. 78 at 21, HRSA may not impose such a requirement through agency guidance. Any attempt to do so—whether through the Advisory Opinion, the May 17 letter, or the

ADR process—necessarily exceeds its "specifically limited" rulemaking authority. *Orphan Drug I*, 43 F. Supp. 3d at 42. As the Court's opinion explained, "Congress may very well want pharmaceutical manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies as a condition for manufacturers' participation in the Medicare Part B and Medicaid programs. But that kind of policymaking is for Congress, not this Court." D.I. 78 at 25. Without statutory authorization, that kind of policymaking is not for HRSA, either.

145. ***Fifth***, the legally flawed May 17 letter has *already* caused serious harm to AstraZeneca, and threatens further harm. HRSA's threat to impose CMPs could amount to hundreds of millions of dollars in fines each month. *See* Declaration of Odalys Caprisecca ¶¶ 8-10 (Exhibit M). Moreover, this threat, which was publicly posted on HRSA's website, is also causing AstraZeneca immediate and direct reputational harms, including among AstraZeneca's customers, covered entities, and investors. *Id.* ¶¶ 11-14. These reputational harms, including lost goodwill, cannot practically be remedied even if AstraZeneca is eventually successful in challenging HRSA's interpretation of Section 340B and overturning any CMPs imposed in the interim. *Id.* ¶ 14. To the extent that Defendants seek to enforce through the ADR process the position asserted in the May 17 letter, moreover, that would also cause harm to AstraZeneca in view of that process's major procedural flaws and constitutional defects. Such ADR proceedings would also be futile, and AstraZeneca cannot lawfully be required to defend its position in a preordained, procedurally invalid, and constitutionally defective administrative proceeding.

Civil Monetary Penalties Are Unlawful After This Court's Opinion

146. In addition to the many errors of the May 17 letter just identified, the letter's threat of CMPs invokes still more legal defects: Even if HRSA's reading of the statute were correct—and it is not—the agency's threat to impose CMPs would still be legally flawed, on multiple levels.

147. ***First,*** the 340B statute only authorizes imposition of CMPs for knowing and intentional "overcharges"—*i.e.*, where the manufacturer "charges a covered entity a price for purchase of a drug that exceeds the maximum applicable [statutory] price," 42 U.S.C. § 256b(d)(1)(B)(vi)(III). Yet there have been no "overcharges" under AstraZeneca's policy, let alone knowing and intentional overcharges. The agency's CMP regulations define an "instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price . . . for that covered outpatient drug." 42 C.F.R. § 10.11(b); *see 340B Program Ceiling Price and Civil Monetary Penalties Final Rule*, 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017) (*CMP Final Rule*). But AstraZeneca's policy *never* results in a covered entity paying more than the 340B price. *See CMP Final Rule*, 82 Fed. Reg. at 1224 ("[I]t is the actual sale of the covered outpatient drug above the 340B ceiling price by the manufacturers to the covered entity that is the subject of the overcharge per the statute."). Indeed, under the prevailing contract pharmacy model, AstraZeneca does not "charge" covered entities at all. Instead, AstraZeneca sells its medicines mostly through wholesalers, who then sell those medicines to end customers, including to pharmacies.

148. ***Second***, HHS's CMP regulations make clear that there can be no overcharge if "a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible ***at the time of purchase***." *CMP Final Rule*, 82 Fed. Reg. at 1221 (emphasis added). In fact, the CMP Final Rule acknowledges that a failure to identify the purchase as 340B-eligible at the outset is a "particular circumstance[] under which an instance of overcharging did not occur." *Id.* And under the replenishment model, covered entities do not identify purchases as 340B eligible at the time that drugs are sold.

149. HRSA's May 17 letter ignores these requirements entirely, instead citing to the CMP Final Rule as justification for HRSA's position that "a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute." Ex. A at 1. But the Rule says no such thing. To the contrary, it cautions that *manufacturers* should not circumvent their 340B pricing obligations by using wholesalers or other distribution systems. 82 Fed. Reg. at 1224-25. It says nothing about whether *covered entities* may alter manufacturers' obligations by creating a web of third-party administrators, contract pharmacy arrangements, and replenishment systems that work to deny AstraZeneca access to 340B eligibility information at the point of sale.

150. ***Third***, and in any event, the 340B statute only allows imposition of CMPs where a manufacturer "*knowingly and intentionally* charges a covered entity" more than the ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi)(III) (emphasis added). Given the statute's "total omission" of any requirement to honor contract pharmacy sales, D.I. 78 at 19, AstraZeneca cannot have knowingly and intentionally violated its statutory obligations. Indeed, this Court's decision recognized that "[i]f the statute offers any clues on the issue, they militate *against* the view" that AstraZeneca's policy is unlawful, *id.* at 20 (emphasis added), which means that any violation (even if one existed) *a fortiori* cannot have been "knowing and intentional." The fact that the "government's interpretation of manufacturers' obligations under the 340B Program has not remained constant but has, instead, evolved over time," *id.* at 13, further supports this conclusion—especially since that AstraZeneca's policy aligns fully with HRSA's *own position* from 1996 through 2010.

151. Finally, this Court's conclusion that "AstraZeneca's view of its obligations under the 340B statute" is "permissible," *id.* at 23, is in itself sufficient to render inappropriate the threat of CMPs in the May 17 letter. The fact that AstraZeneca has adopted a permissible interpretation

of Section 340B forecloses any finding that the company has engaged in a knowing and intentional violation of the statute. *See Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69 (2007).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

[DENIED WITHOUT PREJUDICE. MEM. ORDER ¶ 3 (D.I. 82 at 3).]

(Declaratory/Injunctive Relief – In Promulgating and Enforcing the Advisory Opinion, Defendants Failed to Observe Notice and Comment Procedure Required by Law Under 5 U.S.C. § 706(2)(D))

152. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

153. The APA provides that courts must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

154. The APA requires agencies to publish notice of all "proposed rulemaking" in the Federal Register, *id.* § 553(b), and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). Likewise, the Social Security Act requires the HHS Secretary, before issuing the relevant types of regulations "in final form," to "provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

155. The APA also generally requires "publication . . . of a substantive rule [to] be made not less than 30 days before its effective date." 5 U.S.C. § 553(d). Similarly, the Social Security Act requires that relevant regulations "not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be," the regulation. 42 U.S.C. § 1395hh(e)(1)(B)(i).

156. The Advisory Opinion constitutes "final agency action[s] for which there is no other adequate remedy." 5 U.S.C. § 704.

157. Because the Advisory Opinion definitively "concludes" that manufacturers must provide contract pharmacies with 340B prices, it constitutes an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." 5 U.S.C. § 551(4). It is thus a "rule" under the APA. The Advisory Opinion is not exempt from the APA notice-and-comment requirement under 5 U.S.C. § 553(b)(A) because, despite its label, it is not an "interpretive rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." Instead, it is a legislative rule that creates rights and imposes obligations on drug manufacturers with which they must comply, on pain of potential civil monetary penalties and other potential monetary and administrative penalties. *See Pennsylvania Dep't of Human Servs. v. United States*, 897 F.3d 497, 505 (3d Cir. 2018) ("Legislative rules, which have the force of law, 'impose new duties upon the regulated party.'") (quoting *Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003)).

158. The Advisory Opinion was not adopted through required notice-and-comment procedures, nor did it provide for the required 30-day delay in effective date. There is no "good cause" that waives either requirement. The Advisory Opinion was therefore promulgated "without observance of procedure required by law" and must be set aside under 5 U.S.C. § 706(2)(D).

SECOND CLAIM FOR RELIEF

[DENIED WITHOUT PREJUDICE. MEM. ORDER ¶ 3 (D.I. 82 at 3).]

(Declaratory/Injunctive Relief – Defendants' Advisory Opinion Exceeds Defendants' Statutory Authority Under 42 U.S.C. § 256b)

159. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

160. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

161. Independent of the APA, courts have a duty to set aside agency action that is *ultra vires*. *See Shalom Pentecostal Church v. Acting Sec'y U.S. Dep't of Homeland Sec.*, 783 F.3d 156, 167 (3d Cir. 2015); *see also Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003).

162. Section 340B does not grant Defendants general rulemaking authority or authority to promulgate regulations with respect to Section 340B(a). *See Orphan Drug I*, 43 F. Supp. 3d at 45; *Orphan Drug II*, 138 F. Supp. 3d at 32. Rather, HRSA possesses limited rulemaking authority in only three areas: (1) the establishment of an administrative dispute resolution process; (2) the issuance of precisely defined standards of methodology for calculation of ceiling prices; and (3) the imposition of monetary civil sanctions. *See Orphan Drug I*, 43 F. Supp. 3d at 45.

163. Section 340B does not empower Defendants to require drug manufacturers, on pain of potential civil monetary penalties and other sanctions, to provide discounted drugs under Section 340B to contract pharmacies because contract pharmacies are not covered entities as defined by Section 340B and the statute does not authorize Defendants to require manufacturers to offer discounts to any other type of entity. *See Orphan Drug I*, 43 F. Supp. 3d at 45; *Orphan*

Drug II, 138 F. Supp. 3d at 32. Defendants likewise have no authority to broaden the scope of the 340B Statute to expand the statutory term "covered entities" to include contract pharmacies, as they have now purported to do in the Advisory Opinion.

164. The Advisory Opinion is not entitled to deference under *Chevron USA, Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984), because Congress has not delegated authority to the agency to resolve the status of contract pharmacy sales under the 340B statute, and because the text of the statute is unambiguous. And, for the same reasons, as well as the agency's failure to acknowledge its change of position, the Advisory Opinion fails to persuade under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

165. The Advisory Opinion is therefore "not in accordance with law," it is "in excess of statutory jurisdiction, authority, or limitations," and it must be set aside under 5 U.S.C. § 706(2)(A), (C). For the same reasons, the Advisory Opinion is also *ultra vires*.

THIRD CLAIM FOR RELIEF

[JUDGMENT GRANTED FOR ASTRAZENECA. MEM. ORDER ¶ 2 (D.I. 82 at 2-3).]

(Declaratory/Injunctive Relief – The Advisory Opinion Is Arbitrary and Capricious Under 5 U.S.C. § 706(2)(A))

166. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

167. The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

168. 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 of U.S., Inc. 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.*

169. Any change to an agency's policy must also be adequately explained. The agency must "display awareness that it is changing position," "show that there are good reasons for the new policy," and be aware that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). "[A]n unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars*, 136 S. Ct. at 2126 (citation and alterations omitted).

170. The Advisory Opinion is arbitrary and capricious because Defendants did not consider the relevant factors. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008). Indeed, Defendants entirely failed to give adequate consideration to Section 340B's text, which limits the 340B program to the fifteen classes of covered entities Congress specifically enumerated.

171. The Advisory Opinion is also arbitrary and capricious because Defendants gave no apparent consideration to the abuses contract pharmacy arrangements have facilitated—abuses which the Section 340B was designed to avoid. Defendants' application of their legally incorrect reading of Section 340B to mandate that manufacturers offer 340B discounts for contract pharmacy transactions enables the very diversion by covered entities that the 340B statute

expressly prohibits. *See* 42 U.S.C. § 256b(a)(5)(B). Contract pharmacy transactions result in covered entities selling or otherwise transferring covered outpatient drugs to entities that are not "patients" of the covered entity. The use of contract pharmacies as authorized in the Advisory Opinion necessarily involves a prohibited "transfer" of 340B discounted products to a non-340B covered entity, the contract pharmacy.

172. Finally, the Advisory Opinion is arbitrary and capricious because Defendants did not even attempt to reconcile the "obligation" enshrined in it with their earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices for contract pharmacy sales. The Advisory Opinion thus arbitrarily and capriciously fails to explain the Defendants' change in policy.

173. The Advisory Opinion is thus "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and must be set aside under 5 U.S.C. § 706(2)(A).

FOURTH CLAIM FOR RELIEF [NEW]

(Declaratory/Injunctive Relief – In Issuing and Enforcing the May 17 Letter, Defendants Failed to Observe Notice and Comment Procedure Required by Law Under 5 U.S.C. § 706(2)(D))

174. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

175. The APA provides that courts must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

176. The APA requires agencies to publish notice of all "proposed rulemaking" in the Federal Register, *id.* § 553(b), and to "give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments," *id.* § 553(c). Likewise, the Social Security Act requires the HHS Secretary, before issuing the relevant types of regulations

"in final form," to "provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

177. The APA also generally requires "publication . . . of a substantive rule [to] be made not less than 30 days before its effective date." 5 U.S.C. § 553(d). Similarly, the Social Security Act requires that relevant regulations "not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be," the regulation. 42 U.S.C. § 1395hh(e)(1)(B)(i).

178. The May 17 letter constitutes "final agency action[s] for which there is no other adequate remedy." 5 U.S.C. § 704.

179. Because the May 17 letter definitively "concludes" that manufacturers must provide contract pharmacies with 340B prices, it constitutes an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." 5 U.S.C. § 551(4). It is thus a "rule" under the APA. The May 17 letter is not exempt from the APA notice-and-comment requirement under 5 U.S.C. § 553(b)(A) because it is not an "interpretive rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." Instead, it is a legislative rule that creates rights and imposes obligations on drug manufacturers with which they must comply, on pain of potential civil monetary penalties and other potential monetary and administrative penalties. *See Pennsylvania Dep't of Human Servs.*, 897 F.3d at 505 ("Legislative rules, which have the force of law, 'impose new duties upon the regulated party.'") (quoting *Chao*, 327 F.3d at 227).

180. The May 17 letter was not adopted through required notice-and-comment procedures, nor did it provide for the required 30-day delay in effective date. There is no "good cause" that waives either requirement. The May 17 letter was therefore promulgated "without

observance of procedure required by law" and must be set aside under 5 U.S.C. § 706(2)(D). Defendants thus should not be permitted to implement or enforce the May 17 letter, including through the imposition of civil monetary penalties or through ADR proceedings.

FIFTH CLAIM FOR RELIEF [NEW]

(Declaratory/Injunctive Relief – Defendants' May 17 Letter Exceeds Defendants' Statutory Authority Under 42 U.S.C. § 256b)

181. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

182. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

183. Independent of the APA, courts have a duty to set aside agency action that is *ultra vires*. *See Shalom Pentecostal Church*, 783 F.3d at 167; *see also Aid Ass'n for Lutherans*, 321 F.3d at 1173.

184. Section 340B not does require drug manufacturers—on pain of potential civil monetary penalties, ADR proceedings, or any other sanctions—to provide discounts under Section 340B for contract pharmacy sales. D.I. 78 at 17. Defendants likewise lack authority to broaden the scope of manufacturers' obligations under the 340B Statute to encompass contract pharmacy sales, as they have purported to do in the May 17 letter, nor can Defendants do so through ADR proceedings. *See Orphan Drug I*, 43 F. Supp. 3d at 45; *Orphan Drug II*, 138 F. Supp. 3d at 32.

185. The May 17 letter is not entitled to *Chevron* deference because the 340B statute itself does not require discounts for contract pharmacy sales, and because Congress has not delegated authority to the agency to issue substantive, gap-filling regulations. And, for the same

reasons, as well as the agency's failure to acknowledge its change of position, the May 17 letter fails to persuade under *Skidmore*.

186. The May 17 letter is therefore "not in accordance with law," is "in excess of statutory jurisdiction, authority, or limitations," and must be set aside under 5 U.S.C. § 706(2)(A), (C). For the same reasons, the is also *ultra vires*. Defendants thus should not be permitted to implement or enforce the May 17 letter, including through the imposition of civil monetary penalties or through ADR proceedings.

SIXTH CLAIM FOR RELIEF [NEW]

(Declaratory/Injunctive Relief – The May 17 Letter Is Arbitrary and Capricious Under 5 U.S.C. § 706(2)(A))

187. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

188. The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

189. 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." *State Farm*, 463 U.S. at 43. "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.*

190. Any change to an agency's policy must also be adequately explained. The agency must "display awareness that it is changing position," "show that there are good reasons for the

new policy," and take account of the fact that longstanding policies may have "engendered serious reliance interests that must be taken into account." *Fox Television*, 556 U.S. at 515. "[A]n unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars*, 136 S. Ct. at 2126 (citation and alterations omitted).

191. The May 17 letter is arbitrary and capricious because Defendants did not consider the relevant factors. *See Citizens to Preserve Overton Park*, 401 U.S. at 416; *Am. Radio Relay League*, 524 F.3d at 241. Indeed, Defendants entirely failed to give adequate consideration to Section 340B's text, instead adopting the same "legally flawed" reading that this Court previously rejected. D.I. 78 at 17.

192. The May 17 letter is also arbitrary and capricious because Defendants did not even attempt to reconcile the position it takes with their earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices for unlimited contract pharmacy sales. Instead, the May 17 letter asserts 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." Ex. A at 1. This Court has rejected that view, concluding that "the government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead materially shifted." D.I. 78 at 13. The May 17 letter thus arbitrarily and capriciously fails to explain Defendants' change in policy.

193. The May 17 letter is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and must be set aside under 5 U.S.C. § 706(2)(A). Defendants should not

be permitted to implement or enforce the May 17 letter, including through the imposition of civil monetary penalties or through ADR proceedings.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff requests a judgment in their favor against Defendants as follows:

A. Declare that the Advisory Opinion is not in accordance with law, is without observance of procedure required by law, and is invalid [ALREADY ORDERED];

B. Set aside and vacate the Advisory Opinion [ALREADY ORDERED];

C. Declare that the May 17 letter is not in accordance with law, is without observance of procedure required by law, and is invalid;

D. Set aside and vacate the May 17 letter;

E. Declare that AstraZeneca is not required to offer 340B discounts for contract pharmacy sales;

F. Declare that AstraZeneca's approach of either selling direct to covered entities that have their own in-house pharmacy or, if the covered entity lacks an in-house pharmacy, allowing the covered entity to designate a single contract pharmacy through which to purchase AstraZeneca medicines at the 340B price, complies with Section 340B;

G. Issue preliminary and permanent injunctive relief preventing Defendants from implementing or enforcing the Advisory Opinion and the May 17 letter, through ADR proceedings or otherwise;

H. Issue preliminary and permanent injunctive relief preventing Defendants from imposing civil monetary penalties against AstraZeneca based on the Advisory Opinion and the May 17 letter;

I. Issue preliminary and permanent injunctive relief preventing Defendants from undertaking any action or issuing any final decision, judgment, order, or relief against AstraZeneca based on the Advisory Opinion and the May 17 letter;

J. Award Plaintiff reasonable attorneys' fees and costs, plus interest accruing thereon, under the Equal Access to Justice Act, 28 U.S.C. § 2412; and

K. Grant such other and further relief as the Court may deem appropriate.

Dated: July 9, 2021

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Ms. Odalys Caprisecca
Executive Director, US Strategic Price & Operations
AstraZeneca Pharmaceuticals, LP
1800 Concord Pike
Wilmington, DE 19803

Dear Ms. Caprisecca:

The Health Resources and Services Administration (HRSA) has completed its review of AstraZeneca Pharmaceuticals, LP's (AstraZeneca) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing 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. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. AstraZeneca is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. 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.

AstraZeneca purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, AstraZeneca must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. AstraZeneca must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy. AstraZeneca must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on AstraZeneca's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that AstraZeneca provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

Exhibit B

AstraZeneca

Date: August 17, 2020

Re: 340B Contract Pharmacy Pricing

Dear Valued Partner,

AstraZeneca to date has processed chargebacks associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.

To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity. To initiate this process, please contact Membership@AstraZeneca.com.

340B Pricing for Contract Pharmacies will be honored on all invoices, consistent with AstraZeneca's historic approach, through September 30, 2020. For additional information or questions, please contact your AstraZeneca Account Director.

Sincerely,

DocuSigned by:
0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

Exhibit C

July 24, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Office of Pharmacy Affairs
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Re: AstraZeneca: 340B Contract Pharmacies

Dear Rear Admiral Pedley:

I am writing on behalf of AstraZeneca Pharmaceuticals, LP ("AstraZeneca" or the "Company") to address upcoming changes to the Company's approach to "contract pharmacy" arrangements in the 340B Program. AstraZeneca to date has honored chargebacks associated with contract pharmacy arrangements consistent with the Health Resources and Services Administration's ("HRSA") 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed in the Attachment to this letter and any future products, such that AstraZeneca will recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy.

AstraZeneca is deeply committed to the 340B Program and to ensuring that any patient prescribed an AstraZeneca product has access to that medicine. Our new approach to recognizing contract pharmacies will be fully consistent with HRSA's original 1996 guidance regarding the use of contract pharmacies and will continue to ensure that eligible covered entities are offered the 340B ceiling pricing consistent with the 340B statute. At the same time, we hope this new approach will help to mitigate the significant compliance issues that exist -- and that AstraZeneca has experienced -- with covered entity contract pharmacy arrangements. We explain the basis for our revised approach below and we would be pleased to discuss with HRSA at the agency's convenience.

Contract Pharmacy Background and HRSA Guidance

The 340B statute requires manufacturers that have signed a Pharmaceutical Pricing Agreement to make the statutory ceiling pricing available for covered outpatient drugs that are

"***purchased by*** a covered entity[.]"[1] The statute thus focuses exclusively on purchases by covered entities. It does not mention "contract pharmacies." The 340B statute requires manufacturers to provide discounted drug purchases for dispensing to eligible outpatients ***at a provider site*** -- not through contracted pharmacies.

HRSA first published guidelines regarding contract pharmacy arrangements in 1996. Shortly after the inception of the 340B Program, HRSA recognized that some covered entities lacked on-site pharmacies and therefore had no vehicle for dispensing outpatient drugs to their patients. To remedy this concern, HRSA allowed those covered entities who lacked their own in-house pharmacy to retain a contract pharmacy "to facilitate program participation for those eligible covered entities that do not have access to appropriate 'in house' pharmacy services."[2] HRSA limited covered entities to ***one contract pharmacy***: "The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple sites, ***as long as only one site is used for the contracted services***."[3]

But, in 2010, HRSA replaced its 1996 guidelines with new guidance that enabled covered entities to use multiple contract pharmacies per covered entity site without regard to geographic considerations or whether the covered entity itself maintained an in-house pharmacy.[4] This guidance has spurred dramatic growth in the use of contract pharmacies and has caused many implementation challenges. While many covered entities, including hospitals, maintain their own dispensing capabilities, they also have entered myriad contract pharmacy arrangements. In fact, a recent independent analysis identified over 25,000 contract pharmacy locations.[5] This number contrasts starkly with the fewer than 3,000 contract pharmacies that existed in 2010.[6] AstraZeneca also has determined that, as of the first quarter of 2018, 415 covered entities within California alone maintained 1,245 contract pharmacy arrangements, several of those contract pharmacies are located in states not contiguous with California. AstraZeneca does not believe that this overly-expansive use of contract pharmacies supports the mission and the central goals of the 340B Program.

When HRSA issued the 2010 contract pharmacy guidelines, it asserted that the Program had "appropriate safeguards in place" to combat covered entity statutory violations that could arise in connection with contract pharmacy arrangements.[7] But, since that time, the 340B Program has

[1] 42 U.S.C. § 256b(a)(1) (emphasis added).
[2] 61 Fed. Reg. 43549, 43555 (Aug. 23, 1996).
[3] 61 Fed. Reg. at 43555.
[4] *See* Final Notice Regarding 340B Drug Pricing Program - Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).
[5] *See* https://www.drugchannels.net/2019/07/walgreens-cvs-and-walmart-lead-25000.html.
[6] *See* https://www.drugchannels.net/2017/07/the-booming-340b-contract-pharmacy.html.
[7] 75 Fed. Reg. at 10274.

seen significant increases in covered entity violations of the statutory prohibitions against product diversion and duplicate discounting.

HRSA's audits of covered entities have identified considerable concerns with contract pharmacies. For example, based on information on the HRSA website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. AstraZeneca itself has received numerous covered entity refund disclosures associated with contract pharmacy violations. Additionally, HRSA itself has raised concerns that contract pharmacy arrangements are correlated with product diversion. HRSA has reported, for example, that it is "aware of a resolution practice" utilized by contract pharmacies for instances of product diversion.[8] Where product dispensed at 340B pricing later is identified not to meet program criteria, contract pharmacies may issue "repayment to the manufacturer(s) for transactions the contract pharmacy/TPA no longer considers 340B-eligible." HRSA observed that covered entities may have no "prior knowledge or engagement" as to this practice. In HRSA's view, these arrangements do not comply with 340B Program rules and each "covered entity [must] retain responsibility for ensuring full compliance and integrity of its use of the 340B Program."

AstraZeneca's Contract Pharmacy Approach Beginning October 1, 2020

AstraZeneca fully supports the mission of the 340B Program to provide a healthcare safety net for the most vulnerable patients in our country. But the Company does not believe that today's contract pharmacy framework is necessary to further that mission. We also are cognizant of the statutory "must offer" provision, and we are committed to ensuring that our products remain available to patients of covered entities consistent with that provision. Accordingly, and balancing these considerations, AstraZeneca will change its approach to working with contract pharmacies going forward. For those products listed in the Attachment to this letter, beginning October 1, 2020, AstraZeneca will recognize one contract pharmacy arrangement per covered entity site in the event that the covered entity does not maintain its own, on-site pharmacy. This change is fully consistent with the guidelines that HRSA put in place in 1996 and that remained through 2010. This approach also complies with operative 340B statutory provisions because AstraZeneca will make its products available to all covered entities at or below the applicable ceiling price.

AstraZeneca plans to communicate this change in operations to its supply chain partners and customers by August 10, 2020. AstraZeneca also will ensure that Company personnel are well versed in this change in operations so that they will be able to field inquiries from any customers.

[8] *See* "Best Practices for Covered Entities: Resolving Contract Pharmacy Related Non-Compliance" *available at* https://www.hrsa.gov/opa/updates/2018/june.html.

* * *

AstraZeneca thanks HRSA for its attention to this important matter, and the Company looks forward to its continued participation in the 340B Program. As noted above, AstraZeneca will plan to communicate this change in approach to wholesalers and other stakeholders by August 10, 2020 and to implement this change effective October 1, 2020. We would be happy to discuss this change with the agency in more detail if helpful. Please note that the information contained in this letter is confidential and not subject to disclosure under Exemption 4 to the Freedom of Information Act, 5 U.S.C. § 552(b)(4), the Trade Secrets Act, 18 U.S.C. § 1905, and the Medicaid Drug Rebate Act, 42 U.S.C. §1396r-8(b)(3)(D).

Sincerely,

Christie Bloomquist

Vice President Corporate Affairs, North America

AstraZeneca

ATTACHMENT

Product Name		NDC
BEVESPI AEROSPHERE®		
	9/4.8 MCG 120 ACT INHALATION	00310-4600-12
	9/4.8 MCG 28 ACT INHALATION	00310-4600-39
BRILINTA®		
	TAB 90MG UD	00186-0777-39
	TAB 90MG	00186-0777-60
	TAB 60MG	00186-0776-60
BYDUREON®		
	PEN 2MG	00310-6530-04
	BCISE AUTOINJECTOR	00310-6540-04
BYETTA®		
	PEN 250MCG/ML	00310-6512-01
	PEN 250MCG/ML	00310-6524-01
CALQUENCE™		
	CAP 100MG	00310-0512-60
CRESTOR®		
	TAB 5MG	00310-0755-90
	TAB 10 MG	00310-0751-90
	TAB 20 MG	00310-0752-90

	TAB 40 MG	00310-0754-30
DALIRESP®		
	TAB 250MCG	00310-0088-28
	TAB 250MCG	00310-0088-39
	TAB 500MCG	00310-0095-30
	TAB 500MCG	00310-0095-90
FARXIGA®		
	TAB 5MG	00310-6205-30
	TAB 10MG	00310-6210-30
FASENRA®		
	SOLUTION 30MG/ML	00310-1730-30
FASLODEX®		
	INJ 250 MG/5 ML	00310-0720-10
KOMBIGLYZE® XR		
	TAB 5MG/500MG	00310-6135-30
	TAB 2.5MG/1000MG	00310-6125-60
	TAB 5MG/1000MG	00310-6145-30
LOKELMA™		
	ORAL SUSPENSION 5G	00310-1105-30
	ORAL SUSPENSION 5G	00310-1105-39
	ORAL SUSPENSION 10G	00310-1110-30
	ORAL SUSPENSION 10G	00310-1110-39
LUMOXITI™		
	POWDER 1MG	00310-4700-01
	IVSS FOR LUMOXITI	00310-4715-11
LYNPARZA®		
	TAB 100MG	00310-0668-12

	TAB 100MG	00310-0668-60
	TAB 150MG	00310-0679-12
	TAB 150MG	00310-0679-60
MOVANTIK®		
	TAB 12.5MG	00310-1969-30
	TAB 25MG	00310-1970-30
	TAB 25MG	00310-1970-39
NEXIUM®		
	CAPS 20MG	00186-5020-31
	CAPS 20MG	00186-5020-54
	CAPS 40MG	00186-5040-31
	CAPS 40MG	00186-5040-54
	CAPS 40MG	00186-5040-82
	IV INJ 40MG/5mL	00186-6040-01
	ORAL SUSPENSION 2.5MG	00186-4025-01
	ORAL SUSPENSION 5MG	00186-4050-01
	ORAL SUSPENSION 10MG	00186-4010-01
	ORAL SUSPENSION 20MG	00186-4020-01
	ORAL SUSPENSION 40MG	00186-4040-01
ONGLYZA®		
	TAB 2.5MG	00310-6100-30
	TAB 2.5MG	00310-6100-90
	TAB 5MG	00310-6105-30
	TAB 5MG	00310-6105-90
PULMICORT®		
	FLEXHALER 90-MCG	00186-0917-06
	FLEXHALER 180-MCG	00186-0916-12
	RESPULES .25 mg/2 ml	00186-1988-04

	RESPULES .5 mg/2 ml	00186-1989-04
	RESPULES 1 mg/2 ml	00186-1990-04
QTERN®		
	TAB 5MG/5MG	00310-6770-30
	TAB 10MG/5MG	00310-6780-30
SEROQUEL®		
	TAB 100MG	00310-0271-10
	TAB 200MG	00310-0272-10
	TAB 25MG	00310-0275-10
	TAB 300 MG	00310-0274-60
	TAB 50 MG	00310-0278-10
	TAB 400 MG	00310-0279-10
SEROQUEL XR®		
	TAB 50 MG	00310-0280-60
	TAB 150 MG	00310-0281-60
	TAB 200 MG	00310-0282-60
	TAB 300 MG	00310-0283-60
	TAB 400 MG	00310-0284-60
SYMBICORT®		
	80/4.5MCG	00186-0372-20
	160/4.5MCG	00186-0370-20
	80/4.5MCG Inst. Pack	00186-0372-28
	160/4.5MCG Inst. Pack	00186-0370-28
SYMLIN®		
	60-PEN 1000mcg/ml	00310-6615-02
	120-PEN 1000mcg/ml	00310-6627-02
SYNAGIS®		
	100 MG/ML VIAL	60574-4113-01
	50MG/0.5 ML VIAL	60574-4114-01

TAGRISSO®		
	TAB 40MG	00310-1349-30
	TAB 80MG	00310-1350-30
[redacted]		
TUDORZA® PRESSAIR®		
	INHALER 400MCG	00310-0800-39
	INHALER 400MCG	00310-0800-60
XIGDUO® XR		
	TAB 2.5MG/1000MG	00310-6225-60
	TAB 5MG/500MG	00310-6250-30
	TAB 5MG/1000MG	00310-6260-60
	TAB 10MG/500MG	00310-6270-30
	TAB 10MG/1000MG	00310-6280-30

Exhibit D

Notice to Covered Entities Regarding 340B Pricing Eligibility

August 2020

AstraZeneca to date has provided 340B pricing to pharmacies associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed on the enclosed attachment, such that AstraZeneca will recognize one Contract Pharmacy per Covered Entity for those Covered Entities that do not maintain an on-site dispensing pharmacy. AstraZeneca will continue to provide our products directly to all Covered Entities at the required statutory ceiling price. Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacy.

To implement this process, any Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca at the email below to identify a single Contract Pharmacy of its choice that would be eligible to receive 340B pricing on behalf of the Covered Entity. AstraZeneca deeply values its participation in the 340B program and with Covered Entities and is committed to complying with all applicable requirements of the program. Please contact us at Membership@AstraZeneca.com with any questions or to initiate the process of selecting a single Contract Pharmacy to receive 340B pricing on behalf of your Covered Entity.

NDCs

AstraZeneca

Product Name	NDC	Pkg Qty	Each Size/Description
BEVESPI AEROSPHERE®			
9/4.8 MCG 120 ACT INHALATION	00310-4600-12	1	1 INHALER
9/4.8 MCG 28 ACT INHALATION	00310-4600-39	1	1 INHALER
BRILINTA®			
TAB 90MG UD	00186-0777-39	1	100 COUNT BOX
TAB 90MG	00186-0777-60	1	60 COUNT BOTTLE
TAB 60MG	00186-0776-60	1	60 COUNT BOTTLE
BYDUREON®			
PEN 2MG	00310-6530-04	4	4 X 2MG Pen
BCISE AUTOINJECTOR	00310-6540-04	4	4 X 2MG AUTOINJECTOR
BYETTA®			
PEN 250MCG/ML	00310-6512-01	1	1 PEN X 1.2ML
PEN 250MCG/ML	00310-6524-01	1	1 PEN X 2.4ML
CRESTOR®			
TAB 5MG	00310-0755-90	1	90 COUNT BOTTLE
TAB 10 MG	00310-0751-90	1	90 COUNT BOTTLE
TAB 20 MG	00310-0752-90	1	90 COUNT BOTTLE
TAB 40 MG	00310-0754-30	1	30 COUNT BOTTLE
DALIRESP®			
TAB 250MCG	00310-0088-28	1	28 COUNT BLISTER
TAB 250MCG	00310-0088-39	1	2X10 HUD BLISTER PACK
TAB 500MCG	00310-0095-30	1	30 COUNT BOTTLE
TAB 500MCG	00310-0095-90	1	90 COUNT BOTTLE
FARXIGA®			
TAB 5MG	00310-6205-30	1	30 COUNT BOTTLE
TAB 10MG	00310-6210-30	1	30 COUNT BOTTLE
KOMBIGLYZE® XR			
TAB 5MG/500MG	00310-6135-30	1	30 COUNT BOTTLE
TAB 2.5MG/1000MG	00310-6125-60	1	60 COUNT BOTTLE
TAB 5MG/1000MG	00310-6145-30	1	30 COUNT BOTTLE
LOKELMA™			
ORAL SUSPENSION 5G	00310-1105-30	30	30 PACKETS
ORAL SUSPENSION 5G	00310-1105-39	11	11 PACKETS
ORAL SUSPENSION 10G	00310-1110-30	30	30 PACKETS
ORAL SUSPENSION 10G	00310-1110-39	11	11 PACKETS
NEXIUM®			
CAPS 20MG	00186-5020-31	1	30 COUNT BOTTLE
CAPS 20MG	00186-5020-54	1	90 COUNT BOTTLE
CAPS 40MG	00186-5040-31	1	30 COUNT BOTTLE
CAPS 40MG	00186-5040-54	1	90 COUNT BOTTLE

	IV INJ 40MG/5mL	00186-6040-01	10	10 x 5.0mL VIAL
	ORAL SUSPENSION 2.5MG	00186-4025-01	30	30 PACKETS
	ORAL SUSPENSION 5MG	00186-4050-01	30	30 PACKETS
	ORAL SUSPENSION 10MG	00186-4010-01	30	30 PACKETS
	ORAL SUSPENSION 20MG	00186-4020-01	30	30 PACKETS
	ORAL SUSPENSION 40MG	00186-4040-01	30	30 PACKETS
ONGLYZA®				
	TAB 2.5MG	00310-6100-30	1	30 COUNT BOTTLE
	TAB 2.5MG	00310-6100-90	1	90 COUNT BOTTLE
	TAB 5MG	00310-6105-30	1	30 COUNT BOTTLE
	TAB 5MG	00310-6105-90	1	90 COUNT BOTTLE
PULMICORT®				
	FLEXHALER 90-MCG	00186-0917-06	1	1 INHALER
	FLEXHALER 180-MCG	00186-0916-12	1	1 INHALER
	RESPULES .25 mg/2 ml	00186-1988-04	30	30 RESPULE BOX
	RESPULES .5 mg/2 ml	00186-1989-04	30	30 RESPULE BOX
	RESPULES 1 mg/2 ml	00186-1990-04	30	30 RESPULE BOX
QTERN®				
	TAB 5MG/5MG	00310-6770-30	30	30 COUNT BOTTLE
	TAB 10MG/5MG	00310-6780-30	30	30 COUNT BOTTLE
SEROQUEL®				
	TAB 100MG	00310-0271-10	1	100 COUNT BOTTLE
	TAB 200MG	00310-0272-10	1	100 COUNT BOTTLE
	TAB 25MG	00310-0275-10	1	100 COUNT BOTTLE
	TAB 300 MG	00310-0274-60	1	60 COUNT BOTTLE
	TAB 50 MG	00310-0278-10	1	100 COUNT BOTTLE
	TAB 400 MG	00310-0279-10	1	100 COUNT BOTTLE
SEROQUEL XR®				
	TAB 50 MG	00310-0280-60	1	60 COUNT BOTTLE
	TAB 150 MG	00310-0281-60	1	60 COUNT BOTTLE
	TAB 200 MG	00310-0282-60	1	60 COUNT BOTTLE
	TAB 300 MG	00310-0283-60	1	60 COUNT BOTTLE
	TAB 400 MG	00310-0284-60	1	60 COUNT BOTTLE
SYMBICORT®				
	80/4.5MCG	00186-0372-20	1	1 INHALER
	160/4.5MCG	00186-0370-20	1	1 INHALER
	80/4.5MCG Inst. Pack	00186-0372-28	1	1 INHALER
	160/4.5MCG Inst. Pack	00186-0370-28	1	1 INHALER
SYMLIN®				
	60-PEN 1000mcg/ml	00310-6615-02	2	2 PEN X 1.5ml
	120-PEN 1000mcg/ml	00310-6627-02	2	2 PEN X 2.7ml
XIGDUO® XR				
	TAB 2.5MG/1000MG	00310-6225-60	1	60 COUNT BOTTLE
	TAB 5MG/500MG	00310-6250-30	1	30 COUNT BOTTLE
	TAB 5MG/1000MG	00310-6260-60	1	60 COUNT BOTTLE
	TAB 10MG/500MG	00310-6270-30	1	30 COUNT BOTTLE
	TAB 10MG/1000MG	00310-6280-30	1	30 COUNT BOTTLE

Exhibit E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration
Office of Pharmacy Affairs

Rockville, MD 20857

September 2, 2020

Christie Bloomquist
Vice President Corporate Affairs, North America
AstraZeneca Pharmaceuticals, LP
701 Pennsylvania Avenue NW #500
Washington, DC 20004

Dear Ms. Bloomquist:

This in response to your July 24, 2020 correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Your letter states that beginning October 1, 2020, AstraZeneca Pharmaceuticals, LP (AstraZeneca) will recognize only one contract pharmacy arrangement per covered entity site for covered entities that do not maintain an on-site pharmacy for certain drug products.

Under 42 U.S.C. §256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices. HRSA is considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the Public Health Service Act.

We understand that AstraZeneca's rationale is its concern that distribution to contract pharmacies can lead to duplicate discounts and diversion. To the extent that AstraZeneca has any evidence of specific duplicate discount and diversion violations, please share that evidence, including the alleged covered entities and drugs involved.

Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Many health centers, and other safety net organizations receiving HRSA grants are able to participate in the 340B Program only through a contract pharmacy, and having multiple contract pharmacy arrangements allows them to reach to the patients they serve. In addition, certain covered entities serve communities where patients must travel great distances for health care services. In order to encourage medication adherence, these covered entities often contract with pharmacies that are closer to where their patients reside. AstraZeneca's policy could have the effect of severely limiting access for underserved and vulnerable populations served by these covered entities' access to 340B discounted drugs. This result would undermine

the 340B Program and the Congressional intent behind enactment of the 340B statute.[1] Even for those covered entities with in-house pharmacies, AstraZeneca's position to limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions.

AstraZeneca's limitation of the number of contract pharmacies a covered entity can use to obtain 340B discounts would significantly harm the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic and maintain general public health, often in limited in-person settings.

AstraZeneca indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential or proprietary information in the letter. If AstraZeneca believes that portions of its correspondence are confidential or proprietary, please respond by September 30 with an explanation and reference to the specific portions of the letter that AstraZeneca believes are confidential and proprietary.

As HRSA continues to evaluate this issue, it will not be posting AstraZeneca's "Notice to Covered Entities Regarding 340B Pricing" until this matter is resolved. If you have any further questions, please feel free to contact me. Thank you for your interest in the 340B Program.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs

[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report)).

Exhibit F

September 15, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Re: AstraZeneca: 340B Contract Pharmacies

Dear Rear Admiral Pedley:

I write in response to your letter of September 2, 2020 regarding the AstraZeneca Pharmaceuticals, LP ("AstraZeneca" or the "Company") plan to recognize one contract pharmacy per 340B covered entity for those covered entities that do not have an on-site dispensing pharmacy. We were surprised by your letter's warning that the Health Resources and Services Administration ("HRSA") "is considering whether" our plan may "constitute[] a violation of the 340B statute" and whether sanctions such as civil money penalties would apply. We are also disappointed that HRSA chose to convey this threat by letter rather than taking AstraZeneca up on our two separate offers to meet with HRSA to discuss our new approach.

As to the merits of the issues raised in your letter, our planned approach complies fully with the 340B statute. As we outlined in our July 24, 2020 letter, the must offer provision requires that manufacturers with a signed pharmaceutical pricing agreement must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." Under our new structure, each covered entity will be offered 340B drugs at the 340B price on non-discriminatory terms. Thus, the approach fully satisfies the must offer provision and all other operative 340B requirements. AstraZeneca will go beyond the statute's requirements by assuring access to 340B pricing through a contract pharmacy arrangement if a covered entity is unable to dispense 340B drugs from its own facilities. Indeed, our approach simply conforms to the contract pharmacy guidance that HRSA itself applied from 1996 through 2010.

Moreover, AstraZeneca's new approach to contract pharmacy recognition should not impact patient access, as our medicines will remain available to 340B entities at the 340B price. Our new approach is instead intended to bolster the integrity of the 340B program. For example,

according to the Government Accountability Office ("GAO"), patients -- even the low-income uninsured -- often receive no discount on drugs dispensed by contract pharmacies.[1] 340B in-house pharmacies, by contrast, are significantly more likely to offer discounts to patients.[2] The GAO also has expressed concern that the financial conflicts for covered entities created by the 340B program have distorted prescribing decisions, increased patient out-of-pocket costs, and jeopardized patient care.[3] HRSA's audits of covered entities have identified widespread contract pharmacy non-compliance. According to the HRSA website, over 25% of covered entities audited by HRSA since 2017 have had at least one finding related to contract pharmacy non-compliance. Our new approach responds to these systemic problems and seeks to restore balance to the 340B program.

HRSA's refusal to post our notice to covered entities is causing very real and tangible harm, as it is denying covered entities access to vital information on how to register their designated pharmacy. We fully recognize that AstraZeneca's change in contract pharmacy approach will require covered entities to make adjustments to their internal processes. Accordingly, we intended to give covered entities a 45-day advance notice in which they could work with our team to designate and enroll, if necessary, a contract pharmacy to dispense AstraZeneca medicines to the entity's 340B patients. We have a team of AstraZeneca personnel prepared to help covered entities navigate this process. HRSA's delay in posting our notice is depriving covered entities of the information they need to designate their contract pharmacy.

We request, therefore, that HRSA immediately post our notice on its website so that covered entities can learn how they may enroll and designate their pharmacy to receive AstraZeneca medicines. We also request that HRSA confirm to us promptly in writing that it will not seek civil monetary penalties against AstraZeneca related to our impending change to contract pharmacy designation, which fully complies with applicable law. As HRSA is aware, AstraZeneca has informed stakeholders that it intends to transition to its new approach by October 1, 2020. We accordingly request HRSA's written confirmation by October 1, 2020. Failure to post AstraZeneca's notice or to respond by that date could cause substantial confusion and disruption, interfering with AstraZeneca's ability to work with covered entities to implement its new approach.

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[1] See GAO, Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 30 (June 2018).

[2] See id. at n.46.

[3] See GAO, Medicare Part B Drugs, Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, "Highlights" page (June 2015) ("[Medicare] beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. . . . The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status. . . . Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. In addition, this raises potential concerns about the appropriateness of the health care provided to these beneficiaries."). Although the government has taken steps to curb these incentives and risks for physician-administered drugs provided to Medicare patients, they remain unabated, for example, with respect to retail pharmacy drugs and drugs covered under commercial insurance.

As to the issue of confidentiality associated with AstraZeneca's communication to HRSA, AstraZeneca appreciates that these issues are subject to public awareness, however our intention was to work closely with HRSA during this transition process in an effort to receive the agency's direct feedback in a collaborative fashion. Once again, we would be very pleased to meet with HRSA at your earliest convenience to discuss this critically important issue for 340B program integrity and to correct any misunderstandings that HRSA may have about our approach. Thank you for your attention to this important matter.

Sincerely,

DocuSigned by:

0781790EE5034A7...

Odalys Caprisecca
Executive Director
US Strategic Pricing & Operations

Exhibit G

AstraZeneca

Date: September 14, 2020

Re: 340B Contract Pharmacy Pricing

AstraZeneca to date has provided 340B pricing to pharmacies associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed on the enclosed attachment, such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy. AstraZeneca will continue to provide our products directly to all Covered Entities at the required statutory ceiling price. Covered Entities will continue to be able to purchase our products at the statutory ceiling price from either their designated single Contract Pharmacy or the Covered Entity's on-site dispensing pharmacies.

To implement this process, any Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca at the email below to identify a single Contract Pharmacy of its choice that would be eligible to receive 340B pricing on behalf of the Covered Entity. AstraZeneca deeply values its participation in the 340B program and with Covered Entities and is committed to complying with all applicable requirements of the program. Please contact us at Membership@AstraZeneca.com with any questions or to initiate the process of selecting a single Contract Pharmacy to receive 340B pricing on behalf of your Covered Entity.

Sincerely,

DocuSigned by:

0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

NDCs

AstraZeneca

Product Name	NDC	Pkg Qty	Each Size/Description
BEVESPI AEROSPHERE®			
9/4.8 MCG 120 ACT INHALATION	00310-4600-12	1	1 INHALER
9/4.8 MCG 28 ACT INHALATION	00310-4600-39	1	1 INHALER
BRILINTA®			
TAB 90MG UD	00186-0777-39	1	100 COUNT BOX
TAB 90MG	00186-0777-60	1	60 COUNT BOTTLE
TAB 60MG	00186-0776-60	1	60 COUNT BOTTLE
BYDUREON®			
PEN 2MG	00310-6530-04	4	4 X 2MG Pen
BCISE AUTOINJECTOR	00310-6540-04	4	4 X 2MG AUTOINJECTOR
BYETTA®			
PEN 250MCG/ML	00310-6512-01	1	1 PEN X 1.2ML
PEN 250MCG/ML	00310-6524-01	1	1 PEN X 2.4ML
CRESTOR®			
TAB 5MG	00310-0755-90	1	90 COUNT BOTTLE
TAB 10 MG	00310-0751-90	1	90 COUNT BOTTLE
TAB 20 MG	00310-0752-90	1	90 COUNT BOTTLE
TAB 40 MG	00310-0754-30	1	30 COUNT BOTTLE
DALIRESP®			
TAB 250MCG	00310-0088-28	1	28 COUNT BLISTER
TAB 250MCG	00310-0088-39	1	2X10 HUD BLISTER PACK
TAB 500MCG	00310-0095-30	1	30 COUNT BOTTLE
TAB 500MCG	00310-0095-90	1	90 COUNT BOTTLE
FARXIGA®			
TAB 5MG	00310-6205-30	1	30 COUNT BOTTLE
TAB 10MG	00310-6210-30	1	30 COUNT BOTTLE
KOMBIGLYZE® XR			
TAB 5MG/500MG	00310-6135-30	1	30 COUNT BOTTLE
TAB 2.5MG/1000MG	00310-6125-60	1	60 COUNT BOTTLE
TAB 5MG/1000MG	00310-6145-30	1	30 COUNT BOTTLE
LOKELMA™			
ORAL SUSPENSION 5G	00310-1105-30	30	30 PACKETS
ORAL SUSPENSION 5G	00310-1105-39	11	11 PACKETS
ORAL SUSPENSION 10G	00310-1110-30	30	30 PACKETS
ORAL SUSPENSION 10G	00310-1110-39	11	11 PACKETS
NEXIUM®			
CAPS 20MG	00186-5020-31	1	30 COUNT BOTTLE
CAPS 20MG	00186-5020-54	1	90 COUNT BOTTLE
CAPS 40MG	00186-5040-31	1	30 COUNT BOTTLE
CAPS 40MG	00186-5040-54	1	90 COUNT BOTTLE

	IV INJ 40MG/5mL	00186-6040-01	10	10 x 5.0mL VIAL
	ORAL SUSPENSION 2.5MG	00186-4025-01	30	30 PACKETS
	ORAL SUSPENSION 5MG	00186-4050-01	30	30 PACKETS
	ORAL SUSPENSION 10MG	00186-4010-01	30	30 PACKETS
	ORAL SUSPENSION 20MG	00186-4020-01	30	30 PACKETS
	ORAL SUSPENSION 40MG	00186-4040-01	30	30 PACKETS
ONGLYZA®				
	TAB 2.5MG	00310-6100-30	1	30 COUNT BOTTLE
	TAB 2.5MG	00310-6100-90	1	90 COUNT BOTTLE
	TAB 5MG	00310-6105-30	1	30 COUNT BOTTLE
	TAB 5MG	00310-6105-90	1	90 COUNT BOTTLE
PULMICORT®				
	FLEXHALER 90-MCG	00186-0917-06	1	1 INHALER
	FLEXHALER 180-MCG	00186-0916-12	1	1 INHALER
	RESPULES .25 mg/2 ml	00186-1988-04	30	30 RESPULE BOX
	RESPULES .5 mg/2 ml	00186-1989-04	30	30 RESPULE BOX
	RESPULES 1 mg/2 ml	00186-1990-04	30	30 RESPULE BOX
QTERN®				
	TAB 5MG/5MG	00310-6770-30	30	30 COUNT BOTTLE
	TAB 10MG/5MG	00310-6780-30	30	30 COUNT BOTTLE
SEROQUEL®				
	TAB 100MG	00310-0271-10	1	100 COUNT BOTTLE
	TAB 200MG	00310-0272-10	1	100 COUNT BOTTLE
	TAB 25MG	00310-0275-10	1	100 COUNT BOTTLE
	TAB 300 MG	00310-0274-60	1	60 COUNT BOTTLE
	TAB 50 MG	00310-0278-10	1	100 COUNT BOTTLE
	TAB 400 MG	00310-0279-10	1	100 COUNT BOTTLE
SEROQUEL XR®				
	TAB 50 MG	00310-0280-60	1	60 COUNT BOTTLE
	TAB 150 MG	00310-0281-60	1	60 COUNT BOTTLE
	TAB 200 MG	00310-0282-60	1	60 COUNT BOTTLE
	TAB 300 MG	00310-0283-60	1	60 COUNT BOTTLE
	TAB 400 MG	00310-0284-60	1	60 COUNT BOTTLE
SYMBICORT®				
	80/4.5MCG	00186-0372-20	1	1 INHALER
	160/4.5MCG	00186-0370-20	1	1 INHALER
	80/4.5MCG Inst. Pack	00186-0372-28	1	1 INHALER
	160/4.5MCG Inst. Pack	00186-0370-28	1	1 INHALER
SYMLIN®				
	60-PEN 1000mcg/ml	00310-6615-02	2	2 PEN X 1.5ml
	120-PEN 1000mcg/ml	00310-6627-02	2	2 PEN X 2.7ml
XIGDUO® XR				
	TAB 2.5MG/1000MG	00310-6225-60	1	60 COUNT BOTTLE
	TAB 5MG/500MG	00310-6250-30	1	30 COUNT BOTTLE
	TAB 5MG/1000MG	00310-6260-60	1	60 COUNT BOTTLE
	TAB 10MG/500MG	00310-6270-30	1	30 COUNT BOTTLE
	TAB 10MG/1000MG	00310-6280-30	1	30 COUNT BOTTLE

Exhibit H

1800 Concord Pike
Legal
PO Box 15437
Wilmington, DE 19850-5437

November 02, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Office of Pharmacy Affairs
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Dear Rear Admiral Pedley:

I write on behalf of AstraZeneca following up on our July 24 and September 15, 2020 letters concerning our approach under 340B to contract pharmacies, particularly in the wake of a lawsuit, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C.), recently filed by a 340B trade association and two covered entities against HHS, HRSA, Secretary Azar, and Administrator Engels. The lawsuit relates to the decision by AstraZeneca, and apparent decisions by other drug manufacturers, to change their approach to contract pharmacies.

Neither AstraZeneca nor any other manufacturers were named as defendants in this lawsuit. But plaintiffs seek relief that would significantly affect AstraZeneca's rights. For example, plaintiffs seek a declaration that they are entitled to purchase and dispense covered outpatient drugs through contract pharmacies at 340B discounts, as well as a variety of orders directing the government to seek various forms of penalties from AstraZeneca.[*] As the basis for these claims, plaintiffs allege that AstraZeneca "ha[s] flouted the 340B statute and regulation by openly refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements." Compl. ¶ 2; *see id.* ¶¶ 52–64. The complaint excerpts selectively from a letter that AstraZeneca sent to 340B covered entities and claims that these excerpts demonstrate that AstraZeneca "ceased offering 340B pricing on drugs dispensed at contract pharmacies on October 1, 2020." *Id.* ¶ 62. The complaint further asserts that AstraZeneca has "denied 340B discounts to the Plaintiff Covered

[*] Plaintiffs also seek an order directing the Secretary to promulgate administrative dispute resolution (ADR) regulations within 60 days of the court's order.

Entities," *id.* ¶ 2, and that "[s]ince October 1, 2020," one of the named plaintiffs "has not been able to purchase 340B discounted drugs from AstraZeneca," *id.* ¶ 78.

As you know from our prior correspondence with HRSA, these allegations are not correct. As explained previously, under our approach, all covered entities will continue to have access to AstraZeneca medicines at the 340B price. The change that AstraZeneca has implemented makes its products available to covered entities either through their own in-house pharmacy or through a designated contract pharmacy. It is intended to mitigate program integrity risks associated with contract pharmacy transactions and, for the reasons articulated in our prior letters, is fully compliant with the 340B statute. We also note that, based on our investigations to date, none of the named plaintiffs has purchased AstraZeneca products through a contract pharmacy within the last 12 months; and all of the named plaintiffs continue to access our medicines at the statutory ceiling price through their on-site pharmacies.

Our prior correspondence requested meetings with HRSA to discuss our approach, with the first such request having been made in July 2020. HRSA unfortunately has not responded to any of our prior meeting requests. We continue to believe that such a meeting could resolve any misperceptions that may exist about AstraZeneca's contract pharmacy model. We therefore hereby formally request again to meet with HRSA to discuss this matter. Please advise us at your earliest convenience if the agency is accepting or rejecting our formal meeting request.

Sincerely,

DocuSigned by:

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Odalys Caprisecca
Executive Director
US Strategic Pricing & Operations

Exhibit I

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
340B ADMINISTRATIVE DISPUTE RESOLUTION PANEL

OPEN DOOR COMMUNITY HEALTH CENTERS
1275 8TH STREET
ARCATA, CA 95521

Petitioner,

vs.

ASTRAZENECA PHARMACEUTICALS, LP
1800 CONCORD PIKE
WILMINGTON, DE 19803

Respondent.

ADR ID: 210112-1

PETITION FOR DAMAGES AND EQUITABLE RELIEF FROM RESPONDENT'S REFUSAL TO OFFER THE 340B CEILING PRICE FOR COVERED OUTPATIENT DRUGS DISTRIBUTED THROUGH PETITIONER'S CONTRACT PHARMACIES

INTRODUCTION

1. Open Door Community Health Centers ("Petitioner") submits this Petition to the Administrative Dispute Resolution Panel, established at 42 C.F.R. § 10.3 ("340B ADR Panel"), to seek an order stating that AstraZeneca Pharmaceuticals, LP ("Respondent") has violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements; to order Respondent to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order Respondent to pay Petitioner an amount equal to the 340B discounts that Respondent has failed to provide to Petitioner since October 1, 2020.

2. The 340B Program, established at 42 U.S.C. § 256b ("340B Program"), requires pharmaceutical manufacturers to sell discounted drugs to certain statutorily defined health care providers, known as "covered entities," as a condition of the manufacturers participating in the

Medicaid and Medicare Part B insurance programs. Petitioner is a covered entity that qualifies for and participates in the 340B Program. Petitioner purchases discounted drugs through the 340B Program, but because it does not own and operate a pharmacy, it relies exclusively on third-party pharmacies, referred to as "contract pharmacies," to dispense its drugs. Under these arrangements, Petitioner places orders for 340B discounted drugs that are billed to the covered entity and shipped to the contract pharmacy to be dispensed to the Petitioner's patients. Since 1996, the Secretary of Health and Human Services ("Secretary") has expressly recognized that the 340B statute requires pharmaceutical manufacturers to provide 340B discounts on covered outpatient drugs when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also* Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

3. In an Advisory Opinion dated December 30, 2020, the Department of Health and Human Services, Office of General Counsel ("HHS OGC") affirmed that all drug manufacturers that participate in the 340B Program are required to offer drugs at 340B discounted prices to covered entities when drugs are shipped to contract pharmacies. Robert P. Charrow, HHS OGC, Advisory Op. 20-06, Contract Pharmacies under the 340B Program (Dec. 30, 2020) ("HHS OGC Advisory Op."), Exhibit 1.

4. Beginning October 1, 2020, Respondent adopted a policy to deny 340B discounts to the Petitioner by refusing to sell Respondent's drugs through the 340B wholesaler accounts associated with contract pharmacies.

5. Respondent's actions are unlawful. The 340B statute unambiguously requires Respondent to sell covered outpatient drugs to Petitioner and places no limitation on the site of delivery. 42 U.S.C. § 256b. A 340B regulation expressly defines a manufacturer overcharge to

include an order placed through an "agent," such as a contract pharmacy. 42 C.F.R. § 10.11(b)(1). Accordingly, the 340B ADR Panel should order Respondent to sell covered outpatient drugs to Petitioner at 340B prices regardless of the delivery location and repay 340B discounts that Respondent has denied Petitioner.

JURISDICTION

6. The 340B ADR Panel has jurisdiction over the subject matter of this action under 42 U.S.C. § 256b(d)(3), which authorizes the Secretary of the Department of Health and Human Services ("HHS") to "implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section . . . including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B)."

7. The 340B ADR Panel has jurisdiction over this petition because it presents "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21(c)(1).

8. The damages sought in this Petition exceed $25,000. *Id.* § 10.21(b). Exhibit 2. The damages at Exhibit 2 were incurred by the Petitioner from October 1, 2020, to January 5, 2021. Petitioner will continue to incur damages as long as Respondent does not offer 340B pricing at Petitioner's contract pharmacies. The first two spreadsheets at Exhibit 2 are a calculation of the amounts that Petitioner was forced to forgo as the result of Respondent's actions at certain of its contract pharmacies. The third spreadsheet at Exhibit 2 is a calculation of the amounts that Petitioner had to pay to certain of its contract pharmacies that dispensed drugs at 340B prices that were purchased at above the 340B price and could not be replenished before

October 1, 2020. These amounts include damages associated with Respondent's contract pharmacy arrangements with pharmacies other than Walgreen's. Thus, Petitioner's damages are even higher than reflected in Exhibit 2. Petitioner submits the documentation at Exhibit 2 in order to establish that the ADR Panel has jurisdiction because the Petitioner has met the requirements for the minimum amount in controversy and reserves the right to submit documentation of additional damages to the ADR Panel. Exhibit 2 does not include protected health information, but Petitioner can furnish additional information if necessary to prove its damages, subject to protecting patient information as required by law.

PARTIES

9. Petitioner's corporate address is 1275 8th Street, Arcata, CA 95521. Petitioner is a Federally-qualified health center ("FQHC") as a result of receiving grant funding under Section 330 of the Public Health Service Act. Petitioner has participated in the 340B Program as an FQHC since 1996. HRSA, *Office of Pharmacy Affairs Information System*, https://340bopais.hrsa.gov/SearchLanding (last updated Jan. 11, 2021).

10. Petitioner operates at numerous sites and provides services though three mobile vans. The Petitioner's sites and their 340B IDs are as follows:

Humboldt Open Door Clinic, CH091540: 770 10th St., Arcata, CA 95521

Eureka Community Health Center, CH09154A: 2200 Tydd St., Eureka, CA 95501

Del Norte Community Health Center, CH09154B: 550 E. Washington Blvd., Suite 100, Crescent City, CA 95531

North Country Clinic, CH09154D: 785 18th Street, Arcata, CA 95521

McKinleyville Community Health Center, CH09154F: 1644 Central Avenue, Suite F, McKinleyville, CA 95519

Willow Creek Community Health Center, CH09154H: 38883 Highway 299, Willow Creek, CA 95573

Burre Dental Center, CH09154I: 959 Myrtle Avenue, Eureka, CA 95501

Perinatal Services of Northcountry Clinic, CH09154J: 3800 Janes Rd., Suite 101, Arcata, CA 95521

Mobile Health Services/Telehealth & Visiting Specialist Center, CH09154K: 2426 Buhne St., Eureka, CA 95501

Ferndale Community Health Center, CH09154L: 638 Main Street, Ferndale, CA 95536

Fortuna Community Health and Wellness Center, CH09154M: 3750 Rohnerville Rd., Fortuna, CA 95540

Mobile Health Services Van #1, CH09154Q: 2412 Buhne St., Eureka, CA 95501

Redwood Community Health Center, CH09154R: 2350 Buhne Street A, Eureka, CA 95501

Open Door Women's Health, CH09154S: 3798 Janes Rd Ste. 5, Arcata, CA 95521

Harding Street Clinic, CH09154T: 833 W Washington Blvd., Crescent City, CA 95531

Burre Mobile Dental, CH09154U: 959 Myrtle Ave., Eureka, CA 95501

Open Door Downtown, CH09154V: 622 H St., Eureka, CA 95501

11. The mission of Open Door Community Health Centers is as follows: "Open Door Community Health Centers provides quality medical, dental, and mental health care and health education to all regardless of financial, geographic, or social barriers." Open Door Community Health Centers, *About*, https://opendoorhealth.com/about/ (last visited Jan. 11, 2021).

12. Open Door does not operate an in-house pharmacy. It stocks a small number of commonly needed medications at its facilities that it includes in the visit cost for patients whose income is under 200% of the Federal Poverty Level (FPL). Open Door does not have the space or the pharmacy staff to house the range of all medications its patients require.

13. Through its contract pharmacies, Petitioner provides covered outpatient drugs at reduced costs to its patients who are uninsured, underinsured, or otherwise unable to afford the cost of their drugs. For these patients, Petitioner provides the drug to its patients at the 340B cost, plus the dispensing fee charged by the pharmacy and a minor administrative fee. Exhibit 3.

14. In 2019, Petitioner served more than 60,000 patients, 16,898 of which had income at or below 200% of FPL, and 10,380 of which had income at or below 100% of the FPL. HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Jan. 11, 2021). Of these patients, approximately 20% were racial and/or ethnic minorities. *Id.* More than 46% of patients were Medicaid recipients, and more than 7% of patients were uninsured. *Id.* Petitioner serves patients across two counties in Northern California, Del Norte and Humboldt, an area that spans 5,282 square miles and is larger than the state of Connecticut. *Id.*

15. Respondent is a manufacturer of covered outpatient drugs that participates in the 340B Program. As a manufacturer participating in the 340B Program, Respondent is required to sign a pharmaceutical pricing agreement ("PPA") and addendum. 42 U.S.C. § 256b(a)(1). The PPA and addendum require Respondent to offer covered outpatient drugs to covered entities at no more than the 340B ceiling price. *Id.*

BACKGROUND

I. The 340B Program

16. Congress established the 340B Program in 1992 by enacting Section 602 of the Veterans Health Care Act of 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b. Section 340B—in conjunction with certain related provisions in Section 1927 of the Social Security Act—requires the Secretary to execute

PPAs with manufacturers of certain outpatient drugs covered by the Medicaid program as a condition of the manufacturers' participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1).

17. The 340B Program is administered by the Office of Pharmacy Affairs ("OPA"), a part of Health Resources & Services Administration ("HRSA"), which is a unit of HHS.

18. The PPAs "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1). The "ceiling price" is "equal to the average manufacturer price for the drug under title XIX of the Social Security Act [Medicaid] in the preceding calendar quarter," reduced by a rebate percentage calculated under Medicaid. *Id.* § 256b(a)(1)-(2).

19. Congress intended the 340B Program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also Cares Cmty Health v. U.S. Dep't of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings "help safety-net providers fund the uncompensated care they supply and expand the services they offer."). 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest individuals, regardless of ability to pay. The 340B Program is a vital and indispensable tool for 340B covered entities that qualify for the program based on receiving federal grants. The 340B Program helps them offset the costs of uncompensated or under-compensated care, enabling covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B Program, many covered entities would be forced to restrict access

significantly or, in some cases, cease operations. For these reasons, ensuring access to 340B drugs and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

20. The 340B statute enumerates several types of health care providers that may qualify as "covered entities" eligible to participate in and purchase discounted drugs under the 340B Program. 42 U.S.C. § 256b(a)(4).

21. One category of covered entity under the 340B statute is "[a] Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)," 42 U.S.C. § 1396d(l)(2)(B). 42 U.S.C. § 256b(a)(4)(A). An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last updated May 2018). FQHCs must provide "care on a sliding fee scale based on ability to pay." *Id.*

II. 340B Program Integrity Requirements

22. The Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") amended the 340B statute to include "improvements in program integrity," including "manufacturer compliance." ACA, Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (codified at 42 U.S.C. § 256b(d)(1)).

23. The 340B statute requires the Secretary to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers." 42 U.S.C. § 256b(d)(1)(B)(ii).

24. The statute also mandates 340B ADR regulations:

> Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered

> entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.

42 U.S.C. § 256b(d)(3). The ACA was enacted on March 23, 2010.

25. On December 14, 2020, the Secretary issued a final ADR rule to implement the ADR process, effective January 13, 2020. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020).

26. The ACA also required the imposition of civil monetary penalties ("CMPs") upon pharmaceutical manufacturers that "knowingly and intentionally" overcharge 340B covered entities. 42 U.S.C. § 256b(d)(1)(B)(vi). Congress directed that "each instance of overcharging" would be subject to a penalty not to exceed $5,000. *Id* § 256b(d)(1)(B)(vi)(II); *see also* 42 C.F.R. § 10.11(a).

27. The Secretary issued a CMP regulation on January 5, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) ("CMP Final Rule") (codified at 42 C.F.R. § 10.11). The regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC [national drug code], which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." *Id.* § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.*

28. When finalizing the CMP rule, the Secretary stated, "Failure to ensure the covered entities are receiving the 340B ceiling prices through a third party may be grounds for the assessment of CMPs under this final rule." CMP Final Rule, 82 Fed. Reg. at 1,224. The

Secretary also stated, "All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system." *Id.* at 1,225.

III. 340B Contract Pharmacies

29. Many covered entities choose not "to expend precious resources to develop their own in-house pharmacies" because the requirements to obtain a pharmacy license are complex, and operating a pharmacy can be expensive. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

30. Thus, from the beginning of the 340B Program, HRSA recognized that the program could only function if certain covered entities could dispense their 340B discounted drugs through third-party pharmacy contractors:

> During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

Id.

31. In 1995, HRSA published in the Federal Register proposed guidelines for contract pharmacy services under the 340B Program. Notice Regarding Section 602 of the Veterans

Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (proposed Nov. 1, 1995).

32. In 1996, after considering comments submitted in response to its November 1, 1995 notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute. Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

33. "Contract pharmacy services," as HRSA's August 23, 1996, notice described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id.* at 43,550. Under such an arrangement, a covered entity purchases 340B drugs from a manufacturer and directs the manufacturer to ship the 340B drugs to an address other than the address listed in HRSA's database for the covered entity.

34. In its August 23, 1996, guidance, HRSA noted that "many covered entities … do not operate their own licensed pharmacies." *Id.* at 43,549. HRSA explained why the 340B Program is essential for these covered entities:

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Id. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id.* at 43,555.

35. HRSA's August 23, 1996, guidance was clear that the 340B statute requires pharmaceutical manufacturers to sell 340B discounted drugs to covered entities through contract pharmacy arrangements:

> Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS [Public Health Service] Act and results in an unauthorized expansion of the program.
>
> Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is 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.
>
> It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

Id. at 43,549-50.

36. Responding to a separate comment regarding the requirements of notice and comment rulemaking under the Administrative Procedure Act ("APA"), the agency stated:

> The guidelines explain how the Department intends to administer the 340B [program], further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties.

Id. at 43,550.

37. HRSA was also clear that covered entity arrangements with contract pharmacies are agency relationships:

> Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B

> drugs. By issuing guidelines in this area, ODP [Office of Drug Pricing] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.
>
> Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Id.

38. Although HRSA indicated that its August 23, 1996, contract pharmacy guidance was "designed to facilitate program participation for those eligible covered entities that do not have access to an [sic] appropriate 'in-house' pharmacy services," it clarified that "this is not a bar to the use of the mechanism by any covered entity," and "[t]he statute does not limit the covered entities' access to [various] avenues of drug purchasing." *Id.* at 43,551.

39. In 2007, HRSA again published proposed guidelines for contract pharmacies in the Federal Register. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1,540 (proposed Jan. 12, 2007). Subsequently, HRSA published a final notice regarding contract pharmacies on March 5, 2010. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

40. HRSA's March 5, 2010, guidance permits covered entities to contract with multiple contract pharmacies. HRSA responded to a comment regarding its action as follows:

> Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.
>
> Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA.

Id. at 10,273.

41. Contract pharmacy arrangements are not unique to the 340B Program. The Federal Trade Commission has recognized the right of non-profit organizations to contract with community pharmacies for purposes of dispensing drugs subject to discounts negotiated and used within the parameters of the Robinson-Patman Act and the Non-Profit Institutions Act. Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).

IV. AstraZeneca's About-Face Rejection of Contract Pharmacy Arrangements

42. Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, Respondent announced its intention no longer to do so, effective October 1, 2020.

43. By letter dated July 24, 2020, Respondent informed HRSA of its plan to cease offering 340B discounts on drugs purchased by covered entities and distributed by contract pharmacies. Exhibit 4. HRSA responded by letter dated September 2, 2020, stating that the 340B statute requires manufacturers to offer covered outpatient drugs at the ceiling price and that HRSA was considering whether Respondent's actions violate the 340B statute. Exhibit 5. In response to HRSA's letter, Respondent sent a letter dated September 15, 2020, to HRSA informing it again of its plans. Exhibit 6.

44. On or around August 17, 2020, Respondent issued a letter to approximately 6,800 covered entities, stating that Respondent would no longer honor most 340B contact pharmacy arrangements effective October 1, 2020:

> Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.

> To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020.[1] Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity.

Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf. Exhibit 7.

45. In response to the notice from Respondent, Petitioner's drug wholesaler blocked drugs manufactured by Respondent from being available for purchase through Petitioner's 340B accounts at contract pharmacies.

46. Petitioner notified HRSA that it was unable to purchase covered outpatient drugs manufactured by Respondent for distribution by its contract pharmacies through a form provided by HRSA's prime vendor. Exhibit 8.

V. HHS Response to Manufacturer Actions

47. On December 30, 2020, the HHS OGC issued an Advisory Opinion in response to numerous requests by both drug manufacturers and covered entities to address whether manufacturers may refuse to provide covered outpatient drugs to covered entities at the 340B ceiling price when those drugs are distributed through contract pharmacies. HHS OGC Advisory Opinion 1, Exhibit 1. The HHS OGC Advisory Opinion states unequivocally that drug manufacturers must offer covered outpatient drugs to covered entities at or below the 340B

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[1] A "chargeback" describes the method by which drug wholesalers request reimbursement from manufacturers for 340B discounts provided to entities for 340B covered outpatient drugs. Wholesalers purchase drugs from the manufacturer at a non-340B price and sell to 340B entities at the contracted 340B price, which is typically significantly lower than the non-340B price. The wholesaler submits a chargeback request to the manufacturer to account for the difference. *See* Apexus 340B Glossary of Terms, https://docs.340bpvp.com/documents/public/resourcecenter/340b-glossary-of-terms.pdf. HRSA has contracted with Apexus as its "prime vendor" to provide technical assistance to covered entities and manufacturers and to secure sub-340B discounts on covered outpatient drugs.

ceiling price regardless of how the covered entity distributes those drugs. As the HHS OIG succinctly stated, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." HHS OGC Advisory Op. 3, Exhibit 1 .

48. The HHS OGC Advisory Opinion makes three principal points. First, the HHS OGC Advisory Opinion recognizes that the plain language of the 340B statute requires manufacturers to offer drugs to covered entities at the ceiling price regardless of whether the covered entity opts to use contract pharmacies to dispense those drugs. HHS OGC Advisory Op. 4, Exhibit 1. The 340B statute requires drug manufacturers to enter into a PPA with HHS, under which the manufacturer agrees to offer any covered outpatient drugs "purchased by a covered entity" at the 340B ceiling price. The PPA also obligates the manufacturer to offer covered outpatient drugs at the ceiling price if those drugs are made available to any other purchaser at any price. HHS OGC Advisory Op. 2, Exhibit 1. The HHS OIG Advisory Opinion states as follows:

> Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.

HHS OGC Advisory Op. 2, Exhibit 1.

49. Second, the HHS OGC Advisory Opinion states that the purpose and history of the 340B Program reflect the plain meaning of the statute as it relates to contract pharmacy arrangements. The HHS OGC Advisory Opinion notes that the purpose of the 340B Program is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." HHS OGC Advisory Op. 3, Exhibit 1 (quoting H.R. Rept. No. 102–384(II), at 12 (1992)). It also states that many covered entities are only able to participate in the 340B Program by using contract pharmacies, as

reflected by only 5% of covered entities operating in-house pharmacies at the beginning of the program. HHS OGC Advisory Op. 4, Exhibit 1. In addition, the HHS OGC Advisory Opinion states that HHS has interpreted the 340B statute for the last 24 years to require manufacturers to offer 340B discounted drugs through contract pharmacies and that manufacturers have been honoring contract pharmacy arrangements for 24 years. HHS OGC Advisory Op. 4, Exhibit 1. The HHS OGC Advisory Opinion correctly notes that courts, when interpreting statutes, typically defer to the expertise of an agency that oversees a complex administrative program and may look to the actions of regulated parties. HHS OGC Advisory Op. 4, Exhibit 1.

50. Third, the HHS OGC Advisory Opinion repudiates the purported reasoning that certain manufacturers, including Respondent, offered as the basis for their unilateral decisions to stop offering 340B discounted drugs through contract pharmacy arrangements. Manufacturers have asserted that they are not distributing 340B drugs to contract pharmacies to obviate the alleged risk of diversion and duplicate discounts. HHS OGC Advisory Op. 5, Exhibit 1. The HHS OGC Advisory Opinion states that manufacturers are attempting "to circumvent 340B's procedures for resolving disputes between manufacturers and covered entities." HHS OGC Advisory Op. 5, Exhibit 1.

51. Moreover, the HHS OGC Advisory Opinion refutes the argument made by certain manufacturers that contract pharmacy arrangements constitute diversion through transfer of 340B drugs to pharmacies, which are not covered entities, and use of an inventory replenishment model. The HHS OGC Advisory Opinion states that "[t]he notion that the legitimate transfer of drugs to contract pharmacies constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct but function as principal-agent." HHS OGC Advisory Op. 6, Exhibit 1. It also states that the use of "complex" inventory

models does not, by itself, constitute diversion. Lastly, the HHS OGC Advisory Opinion states that the manufacturers' argument ignores the reality that a covered entity's purchase of outpatient drugs often occurs through an agent, such as a wholesaler. HHS OGC Advisory Op. 7, Exhibit 1.

52. According to media reports, Respondent has no plans to resume offering 340B discounts to covered entities for drugs distributed at contract pharmacies despite the strongly worded HHS OGC Advisory Opinion that Respondent is acting unlawfully. A spokesperson for AstraZeneca told Modern Healthcare the following:

> We changed our approach to help mitigate the significant compliance issues that have been well documented in audits performed by GAO [the U.S. Government Accountability Office] regarding contract pharmacy arrangements. AstraZeneca's approach to contract pharmacy arrangements fully complies with all operative requirements and continues to support the mission of the program to provide a healthcare safety net for the most vulnerable patients in our country.

Rachel Cohrs, *Some Drugmakers May Not Comply with HHS' 340B Opinion on Contract Pharmacies*, Modern Healthcare (Jan. 4, 2021), https://www.modernhealthcare.com/supply-chain/some-drugmakers-may-not-comply-hhs-340b-opinion-contract-pharmacies. For this reason, Petitioner contends that any good faith attempt to resolve this issue with Respondent would not have been fruitful. Indeed, on January 12, 2021, Respondent filed suit in the U.S. District of Delaware seeking to invalidate the HHS OGC Advisory Opinion. *AstraZeneca Pharmaceuticals LP v. Azar*, No. 1:21-cv-00027 (D. Del. filed Jan. 12, 2021).

VI. Facts Related to Petitioner's Contract Pharmacy Arrangements

53. Petitioner has contract pharmacy arrangements registered with HRSA. HRSA, *340B Office of Pharmacy Affairs Information System*, https://340bopais.hrsa.gov/ContractPharmacySearch (Last updated Jan. 11, 2021).

54. Petitioner serves a very large service area and has made arrangements with pharmacies across its service area to serve as contract pharmacies. By having contract pharmacy arrangements across its service area, Petitioner is able to provide covered outpatient drugs to patients that qualify for its community benefits program at the patient's local pharmacy.

55. Petitioner has also entered into arrangements with specialty pharmacies to obtain drugs that are only available through those pharmacies and are not available through community pharmacies.

COUNT I
VIOLATION OF THE 340B STATUTE

56. Petitioner reallege and incorporates by reference paragraphs 1–55 as if fully set forth below.

57. Respondent has violated the clear mandate of the 340B statute. In pertinent part, the 340B statute states that manufacturers of covered outpatient drugs must enter into a PPA under which the manufacturer agrees to sell covered outpatient drugs to covered entities at or below the 340B ceiling price:

> the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs … purchased by a covered entity…. does not exceed an amount equal to the [340B ceiling price].

42 U.S.C. § 256b(a)(1).

58. The 340B statute also states that the PPA must include a provision to "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*

59. Indeed, since 1996, the Secretary has expressly interpreted the 340B statute to require pharmaceutical manufacturers to provide 340B discounts when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550

(Aug. 23, 1996). In 2010, the Secretary reconfirmed the agency's longstanding interpretation that covered entities are entitled to 340B discounts on drugs shipped to contract pharmacies. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

60. Just last month, the HHS OGC reaffirmed that the plain language of the 340B statute entitles covered entities "to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." HHS OGC Advisory Op. 8, Exhibit 1. The HHS OGC affirmed that "the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." HHS OGC Advisory Op. 2, Exhibit 1.

61. Therefore, the 340B statute unambiguously requires Respondent to offer covered outpatient drugs at the 340B ceiling price to Petitioner and does not place any limitation on the site for the delivery of those drugs. The ADR Panel must give effect to the unambiguous text to the statute. *See Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). Accordingly, Respondent has violated the 340B statute by refusing to provide covered outpatient drugs to Petitioner at its contract pharmacies since October 1, 2020.

COUNT II
VIOLATION OF 340B REGULATIONS

62. Petitioner reallege and incorporates by reference paragraphs 1–55 as if fully set forth below.

63. Respondent has violated a 340B regulation by refusing to offer 340B pricing for drugs shipped to Respondent's contract pharmacies. A 340B regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." 42 CFR § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.* The Secretary explained that an instance of overcharging includes an order placed "through a third party" and "regardless of the distribution system." CMP Final Rule, 82 Fed. Reg. at 1,224, 1,225.

64. The HHS OGC affirmed that "the covered entity and contract pharmacy are not distinct, but function as principal-agent." HHS OGC Advisory Op. 6, Exhibit 1.

65. HRSA has confirmed that contract pharmacies function as agents of covered entities. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550.

66. Accordingly, Respondent has overcharged Petitioner for each instance in which Respondent did not offer the 340B ceiling price on an "order placed . . . through . . . [an] agent" contract pharmacy. 42 C.F.R. § 10.11(b)(1).

RELIEF REQUESTED

WHEREFORE, Petitioner respectfully requests relief as follows:

1. A declaration that Respondent is in violation of the 340B statute and HRSA's contract pharmacy guidelines by refusing to provide covered outpatient drugs at the 340B ceiling price through contract pharmacy arrangements.

2. An order directing Respondent to resume offering covered outpatient drugs to Petitioner at the 340B ceiling price through contract pharmacy agreements.

3. An order directing Respondent to pay to Petitioner any 340B discounts that Respondent has withheld from Petitioner for covered outpatient drugs distributed through contract pharmacies since October 1, 2020.

4. An order directing HRSA to take any other "appropriate action regarding refunds, penalties, removal or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e).

Respectfully submitted,

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Attorneys for Petitioner

Dated: January 13, 2021

Exhibit J

BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave Suite 1100W
Bethesda, MD 20814,

Petitioner,

v.

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

and

ASTRAZENECA PLC
AstraZeneca
1800 Concord Pike
Wilmington, DE 19803,

Respondents.

Petition No: 210112-2

PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

Petitioner, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally-qualified health center ("FQHC") members, brings this action for equitable relief under Section 340B of the Public Health Service ("PHS") Act, 42 U.S.C. § 256b, pursuant to and in compliance with the procedures set forth in 42

C.F.R. § 10.21, and alleges as follows:

NATURE OF ACTION

1. Petitioner seeks equitable relief to remedy ongoing and unlawful overcharging activity by drug manufacturers Eli Lilly and Company, Sanofi-Aventis U.S. LLC, and AstraZeneca PLC—collectively, "the drug manufacturers"—each of which, as described more fully below, recently restricted FQHC covered entity access to covered outpatient drugs at federal 340B drug discount program ("340B" or "340B Program") pricing by refusing to offer covered outpatient drugs for FQHC covered entity purchase at or below the applicable ceiling price whenever the FQHC covered entity will dispense the drugs to its patients through contract pharmacy arrangements.

2. The drug manufacturers' actions constitute unlawful overcharging and a clear violation of both the 340B statute and the binding pharmaceutical pricing agreements ("PPAs") between manufacturers and the United States Department of the Health and Human Services ("HHS") that statute requires. The 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The drug manufacturers cannot impose their own unilateral conditions or restrictions on this unequivocal statutory requirement.

3. FQHC covered entities are statutorily required to provide "pharmaceutical services as may be appropriate for particular centers" and authorized to provide those services either through their own staff, through "contracts or cooperative arrangements" with other entities, or through a combination of the two approaches. 42 U.S.C. § 254b(a)(1), (b)(1)(A)(i)(V).

4. HHS has long recognized that FQHCs are statutorily afforded the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy owned by the health center. Indeed, in response to the recent, unilateral drug manufacturer actions underlying this claim, HHS—through its Office of General Counsel (OGC)—issued an advisory opinion which forcefully reiterates and reinforces the agency's longstanding position.

5. The drug manufacturers have acted strikingly similarly, if not in concert, to limit the FQHC covered entities' ability to purchase drugs at 340B pricing when those drugs will be dispensed to eligible FQHC patients via contracted pharmacies. The drug manufacturers' actions, taken close in time, form part of the same series of transactions or occurrences, and the ADR panel's resolution of Petitioner's joint claims against each manufacturer will involve common issues of law and fact—namely whether prohibited overcharging in violation of the 340B statute results from the drug manufacturers' refusal to provide covered outpatient drugs at the 340B ceiling price to FQHC covered entities for drugs dispensed to such entities' patients via contract pharmacies. Accordingly, joinder of the drug manufacturers in this single action is appropriate under Rule 20(a)(2) of the Federal Rules of Civil Procedure and the 340B statute, which provides that claims "shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii); 42 C.F.R. § 10.21(e)(4).

PARTIES

6. Petitioner is a national, nonprofit corporation whose primary objective is to further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. The FQHCs represented herein play a vital role in our nation's health care safety-net by providing primary and other health care and related services—including pharmaceutical services—to

medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services. FQHCs have been recognized as 340B Program covered entities since the 340B Program's 1992 inception.

7. Petitioner brings this joint claim, as defined in 42 C.F.R. § 10.3 and authorized under 42 C.F.R. § 10.21(e), on behalf of its FQHC covered entity members listed in Exhibit A. Each FQHC covered entity so listed could, on its own, bring claims against one or more of the drug manufacturers for the equitable relief sought, has authorized NACHC to bring this joint claim on its behalf, and otherwise meets applicable regulatory requirements for bringing this joint claim.

8. Eli Lilly and Company ("Lilly") is a publicly traded pharmaceutical manufacturer and participant in the 340B Program. Lilly is organized under the laws of the State of Indiana and headquartered in Indianapolis, Indiana.

9. Sanofi-Aventis U.S. LLC ("Sanofi") is a pharmaceutical manufacturer and participant in the 340B Program. Sanofi is headquartered in Bridgewater Township, New Jersey.

10. AstraZeneca PLC ("AstraZeneca") is a limited partnership biopharmaceutical manufacturer and participant in the 340B Program. AstraZeneca is organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware.

JURISDICTION

11. This panel has jurisdiction over Petitioner's claims because, in accordance with the requirements of 42 C.F.R. §§ 10.3 and 10.21: (1) the claims are based on the drug manufacturers' unlawful overcharging activity, in particular their efforts to limit FQHC covered entities' ability to purchase covered outpatient drugs at or below 340B ceiling prices, and (2) the equitable relief sought will likely have a value of more than $25,000 for each joint claimant FQHC covered entity

member of NACHC during the twelve-month period after the 340B ADR Panel's final agency decision.

ALLEGATIONS

I. The 340B Program

12. The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). Under the 340B Program, drug manufacturers who wish to have their products covered by Medicare and Medicaid must provide covered outpatient drugs at a discount to covered entities.

13. Such covered entities, defined at 42 U.S.C. § 256b(a)(4), include, at subsection (a)(4)(1), "Federally-qualified health center[s] (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)])."

14. For more than 20 years—from 1996 until mid-2020 when the prohibited overcharging activity leading to this Petition began—drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' contract pharmacies, i.e. third-party pharmacies with which FQHCs contract to dispense drugs to FQHC patients. All but a handful of the hundreds of manufacturers participating in the 340B Program under PPAs continue to do so.

15. Section 340B, at 42 U.S.C. § 256b(a)(1), requires HHS to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." Per that same statutory subsection, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or

below the applicable ceiling price if such drug is made available to any other purchaser at any price." That agreement is the PPA.

16. As HHS recently made clear through its Office of General Counsel ("OGC"), the statute HHS is authorized to implement is unambiguous in obligating drug manufacturers to sell covered outpatient drugs to covered entities at or below applicable ceiling prices regardless of whether the drugs are distributed through a covered entity's in-house or contract pharmacies:

> [T]he core requirement of the 340B statute, as also reflected in the PPA and [PPA] Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. . . . It is difficult to envision a less ambiguous phrase [than "purchased by"] and no amount of linguistic gymnastics can ordain otherwise. . . . The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant.

HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* at 2 (Dec. 30, 2020). This Advisory Opinion is attached as Exhibit B.

17. The December 30, 2020 OGC Advisory Opinion was written in response to the unlawful overcharging activity underlying this Petition.

18. The view espoused in that Advisory Opinion is not novel; it reiterates the longstanding and well-settled concept that covered entities, including FQHCs, have the common law right to contract with third-parties to provide services on their behalf, as HHS recognized in 1996, reiterated in 2010, and reaffirmed in the 2020 Advisory Opinion.

19. HHS has repeatedly made clear that contract pharmacy arrangements are a consistent and necessary outgrowth of the FQHC program's authorizing statute, Section 330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq.*, which requires FQHCs to provide pharmacy services and which permits the provision of such services through "contracts or cooperative

arrangements" with other entities. As HHS OGC noted in its 2020 Advisory Opinion: "the [340B] Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. . . . These are the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4.

20. HHS is not alone in interpreting the plain language of a plainly written statue to obligate the drug manufacturers to offer covered entities drugs at 340B pricing regardless of whether those drugs are dispensed in-house or through a contract pharmacy arrangement. On September 14, 2020, numerous Members of Congress, weighing in on the drug manufacturer's "series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities"—i.e. the actions underlying this Petition—wrote:

> the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." *There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.*

Letter from Members of Congress to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1, Exhibit C (Sept. 14, 2020) (emphasis added). The letter, directed to the HHS Secretary, strongly condemned the unlawful overcharging activity at issue here, noting that "[t]he recent actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B." *Id.* at 1.

II. FQHC Participation in the 340B Program

21. The FQHC covered entities on whose behalf Petitioner brings this action, as indicated in Exhibit A, purchase covered outpatient drugs from some or all of the drug manufacturers

named in this Petition. Certain of the covered entities regular purchases—where applicable provider and patient eligibility elements are satisfied—qualify for 340B discount pricing.

22. The FQHC covered entities represented herein utilize contract pharmacy arrangements to fulfill some or all of their patients' pharmaceutical dispensing needs, including the dispensing of drugs eligible for 340B discount pricing.

23. Under their agreements with contract pharmacies, the covered entities (either directly or through a third-party administrator) order and pay for the 340B drugs and direct the shipment of those drugs from the manufacturer (or wholesaler) to the contract pharmacy.

24. As Congress intended, the FQHC covered entities' participation in the 340B Program generates both savings and revenue at no cost to taxpayers: savings are realized when an FQHC covered entity pays the ceiling price for a particular drug provided to an uninsured or underinsured patient; revenue is generated on the spread between the ceiling price and any reimbursement at or above that price from third-party payers including the Medicare Program, Medicaid managed care organizations, or patients' private insurance carriers.

25. Section 330 of the PHS Act obligates the FQHC covered entities to use any non-grant or program income—e.g. revenue generated through public or private reimbursement for services—in furtherance of their health care safety-net mission. See 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-grant funds be used to further center's project objectives).

III. The Drug Manufacturers' Unlawful Overcharging

A. Lilly

26. Beginning in or around the second half of 2020, the drug manufacturers threatened—and then imposed—significant limitations on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable 340B ceiling prices. The prohibited overcharging actions of each of the three named drug manufacturers are as follows:

27. On or about July 1, 2020, Lilly posted a notice on HHS's designated 340B Program webpage informing 340B covered entities that, effective immediately, it would no longer fulfill covered entities' purchases for multiple formulations of the drug Cialis at 340B pricing for dispensing through the covered entities' contract pharmacies. *See* Limited Distribution Plan Notice for Cialis, Exhibit D.

On or about September 2, 2020, Lilly disseminated another notice (which HHS declined to post on its webpage) informing the covered entities that, effective the day prior, it would no longer fulfill covered entities' purchases for *any* of its covered outpatient drugs at 340B pricing to be dispensed to FQHC patients through any contract pharmacies of a covered entity. Lilly's notice indicated it would provide an exception for certain insulin products. *See* Limited Distribution Plan Notice for Eli Lilly & Co. Prods., Exhibit F; *see also* Letter from Robert P. Charrow, General Counsel, U.S. Dep't of Health & Human Servs., to Anat Hakim, Senior Vice President and General Counsel, Eli Lilly & Co. (Sept. 21, 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf, Exhibit E (expressing grave concern and refusing to endorse Lilly's actions). The limited insulin exception has proved infeasible.

28. Lilly's near total restriction on the FQHC covered entities' ability to purchase Lilly drugs at 340B pricing is an overcharge as defined in 42 C.F.R. § 10.21(c)(1), i.e. a "limit[ation on]

the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." It is also exactly the sort of "knowing and intentional" overcharging HHS called out in its civil monetary penalty regulations at 42 CFR § 10.11(b).

29. A list of NDCs impacted by Lilly's overcharging is attached as Exhibit I.

B. Sanofi

30. On or around July, 2020 Sanofi announced that, effective October 1, 2020, Sanofi would no longer permit covered entities to purchase covered outpatient drugs at or below 340B ceiling prices for dispensing through the entities' contract pharmacies unless the covered entities submit claims data to Sanofi through third-party software vendor Second Sight Solutions. *See* Sanofi Letter Re: 340B Program Integrity Initiative, Exhibit H.

31. Sanofi claims publicly that it needs this data to identify and prevent duplicate discounts, but has no legal right to demand this information or condition its statutory obligation to offer covered outpatient drugs to covered entities at or below 340B ceiling prices on compliance with its demands. HHS has long made clear that the 340B statute does not permit manufacturers to impose any conditions on covered entities, including by, for example, conditioning the offer of 340B discounts on a covered entity's assurance of compliance with 340B Program requirements. *See, e.g.*, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110 (May 13, 1994); HRSA, 340B Drug Pricing Program, Manufacturer Resources, https://www.hrsa.gov/opa/manufacturers/indExhibithtml (*last accessed* Jan. 13, 2021); HRSA, 340B Drug Pricing Program Notice No. 2011-1.1 (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.

32. Sanofi's conditioning of the FQHC covered entities' ability to purchase its drugs at 340B pricing on participation in unsanctioned data sharing is an unlawful overcharge—i.e. a limitation on the covered entities' ability to purchase Sanofi drugs at or below applicable ceiling prices—as defined in 42 C.F.R. § 10.21(c)(1). Like Lilly's conduct, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

33. A list of NDCs impacted by Sanofi's overcharging is attached as Exhibit K.

C. AstraZeneca

34. In or around August 2020, AstraZeneca informed the covered entities that, effective October 1, 2020, it would no longer ship covered entities' purchases of 340B discounted drugs to the entities' contract pharmacies. AstraZeneca followed through on its threat, with a limited exception for covered entities that lack any other pharmacy outlet to designate one single contract pharmacy per covered entity. *See* AstraZeneca Letter Re: 340B Contract Pharmacy Pricing (Aug. 17, 2020), Exhibit G.

35. AstraZeneca's "exception" concedes that it is refusing to make its covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices based on its unilateral decision as to whether a covered entity's use of contract pharmacies is permissible under the 340B Program. This documented action meets the definition of an overcharge included in 42 C.F.R. § 10.21(c)(1)—it is a "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." Like the other manufacturers' actions, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

36. A list of NDCs impacted by AstraZeneca's overcharging is attached as Exhibit J.

IV. Harm to the FQHC Covered Entities

37. The drug manufacturers' ongoing and unlawful overcharging activities have caused and will continue to cause significant financial and other harms to the FQHC covered entities—and their patients—so long as the manufacturers' limitations on the entities' purchases continue.

38. The differential between the non-discounted "wholesale acquisition cost" ("WAC") and 340B ceiling price for affected drugs can be enormous, even for commonly prescribed drugs such as insulin, osteoporosis treatments, and asthma inhalers.

39. As just one example of the magnitude of the manufacturer's overcharging, the WAC for the Lilly osteoporosis treatment Forteo is approximately $3,663.39 per unit, while the 340B price is $0.02, resulting in an approximate overcharge of $3,663.37 for each unit of Forteo that Lilly refuses to offer the FQHC covered entities at 340B pricing. A sample of WAC/340B price comparisons is attached as Exhibit L to further illustrate the value of the drug manufacturers' sweeping restrictions on covered entity purchasing.

40. The cumulative financial harm to the FQHC covered entities caused by each drug manufacturer, taken separately, will far surpass the *de minimus* regulatory threshold for equitable relief—namely, an impact on the covered entity with an estimated value of $25,000 or more in the twelve months following the 340B ADR Panel's resolution of the claim.

41. Indeed, several of the FQHC covered entities on whose behalf Petitioner brings this joint claim anticipate that the equitable relief sought—i.e. the restoration of the covered entities' access to Lilly, Sanofi, and AstraZeneca drugs at applicable 340B pricing for dispensing to their patients at contract pharmacies—will have a far greater value than the estimated prospective threshold in 42 C.F.R. § 10.21(b).

42. Covered entity patients also stand to be harmed by cuts to non-reimbursable services that FQHCs currently support with funds generated through 340B Program participation.

These services—which may be drastically reduced or eliminated entirely due the drug manufacturers' refusal to offer their drugs at 340B pricing—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE: LILLY

43. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

44. By refusing to allow the FQHC covered entities to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Lilly has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

COUNT TWO: SANOFI

45. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

46. By placing restrictions and conditions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Sanofi has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS,

it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

COUNT THREE: ASTRAZENECA

47. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

48. By restricting the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, AstraZeneca has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

REQUEST FOR RELIEF

Petitioner respectfully requests equitable relief as follows:

1. Declare that each FQHC covered entity is entitled to purchase the drug manufacturers' covered outpatient drugs at 340B pricing to be dispensed to eligible patients through each covered entity's contract pharmacies.

2. Declare that Lilly, by restricting the FQHC covered entities' ability to purchase Lilly drugs at or below applicable ceiling prices, as described in paragraphs 27–28 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

3. Declare that Sanofi, by restricting the covered entities' ability to purchase Sanofi drugs at or below 340B ceiling prices unless the covered entities' submit claims data to Sanofi

through a third-party vendor, as described in paragraphs 31–32 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

4. Declare that AstraZeneca, by restricting the FQHC covered entities' ability to purchase Lilly drugs at or below applicable ceiling prices, as described in paragraphs 35–36 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

5. Order the drug manufacturers to comply with 42 U.S.C. § 256b(a)(1) and the terms of their PPAs by removing all manufacturer-imposed qualifications, limitations, conditions, or restrictions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices.

6. Order such other equitable relief as the Panel deems just and proper.

Dated: January 13, 2021

Respectfully submitted,

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Exhibit K

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
340B ADMINISTRATIVE DISPUTE RESOLUTION PANEL

LITTLE RIVERS HEALTH CARE, INC.
65 MAIN STREET N.
WELLS RIVER, VT 05081
Petitioner,

vs.

ASTRAZENECA PHARMACEUTICALS, LP
1800 CONCORD PIKE
WILMINGTON, DE 19803
Respondent.

ADR ID: 210202-5

PETITION FOR DAMAGES AND EQUITABLE RELIEF FROM RESPONDENT'S REFUSAL TO OFFER THE 340B CEILING PRICE FOR COVERED OUTPATIENT DRUGS DISTRIBUTED THROUGH PETITIONER'S CONTRACT PHARMACIES

INTRODUCTION

1. Little Rivers Health Care, Inc. ("Petitioner") submits this Petition to the Administrative Dispute Resolution Panel, established at 42 C.F.R. § 10.3 ("340B ADR Panel"), to seek an order stating that AstraZeneca Pharmaceuticals, LP ("Respondent") has violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements; to order Respondent to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order Respondent to pay Petitioner an amount equal to the 340B discounts that Respondent has failed to provide to Petitioner since October 1, 2020.

2. The 340B Program, established at 42 U.S.C. § 256b ("340B Program"), requires pharmaceutical manufacturers to sell discounted drugs to certain statutorily defined health care providers, known as "covered entities," as a condition of the manufacturers participating in the Medicaid and Medicare Part B insurance programs. Petitioner is a covered entity that qualifies

for and participates in the 340B Program. Petitioner purchases discounted drugs through the 340B Program, but because it does not own and operate a pharmacy, it relies exclusively on third-party pharmacies, referred to as "contract pharmacies," to dispense its drugs. Under these arrangements, Petitioner places orders for 340B discounted drugs that are billed to the covered entity and shipped to the contract pharmacy to be dispensed to the Petitioner's patients. Since 1996, the Secretary of Health and Human Services ("Secretary") has expressly recognized that the 340B statute requires pharmaceutical manufacturers to provide 340B discounts on covered outpatient drugs when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also* Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

3. In an Advisory Opinion dated December 30, 2020, the Department of Health and Human Services, Office of General Counsel ("HHS OGC") affirmed that all drug manufacturers that participate in the 340B Program are required to offer drugs at 340B discounted prices to covered entities when drugs are shipped to contract pharmacies. Robert P. Charrow, HHS OGC, Advisory Op. 20-06, Contract Pharmacies under the 340B Program (Dec. 30, 2020) ("HHS OGC Advisory Op."), Exhibit 1.

4. Beginning October 1, 2020, Respondent adopted a policy to deny 340B discounts to the Petitioner by refusing to sell Respondent's drugs through the 340B wholesaler accounts associated with contract pharmacies.

5. Respondent's actions are unlawful. The 340B statute unambiguously requires Respondent to sell covered outpatient drugs to Petitioner and places no limitation on the site of delivery. 42 U.S.C. § 256b. A 340B regulation expressly defines a manufacturer overcharge to include an order placed through an "agent," such as a contract pharmacy. 42 C.F.R. §

10.11(b)(1). Accordingly, the 340B ADR Panel should order Respondent to sell covered outpatient drugs to Petitioner at 340B prices regardless of the delivery location and repay 340B discounts that Respondent has denied Petitioner.

JURISDICTION

6. The 340B ADR Panel has jurisdiction over the subject matter of this action under 42 U.S.C. § 256b(d)(3), which authorizes the Secretary of the Department of Health and Human Services ("HHS") to "implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section . . . including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B)."

7. The 340B ADR Panel has jurisdiction over this petition because it presents "[c]laims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. § 10.21(c)(1).

8. The damages sought in this Petition exceed $25,000. *Id.* § 10.21(b). Little Rivers Preliminary Damages Calculation to Establish Jurisdiction, Exhibit 2. The damages at Exhibit 2 were incurred by the Petitioner from October 1, 2020, to January 31, 2021. Petitioner will continue to incur damages as long as Respondent does not offer 340B pricing at Petitioner's contract pharmacies. The spreadsheet at Exhibit 2 is a calculation of the amounts that Petitioner was forced to forgo as the result of Respondent's actions at its contract pharmacies. Petitioner submits the documentation at Exhibit 2 in order to establish that the 340B ADR Panel has jurisdiction because the Petitioner has met the requirements for the minimum amount in controversy and reserves the right to submit documentation of additional damages to the 340B

ADR Panel. Exhibit 2 does not include protected health information, but Petitioner can furnish additional information if necessary to prove its damages, subject to protecting patient information as required by law.

PARTIES

9. Petitioner's corporate address is 65 Main Street N, Wells River, VT 05081. Petitioner is a Federally-qualified health center ("FQHC") as a result of receiving grant funding under Section 330 of the Public Health Service Act. Petitioner has participated in the 340B Program as an FQHC since 2006. HRSA, *Office of Pharmacy Affairs Information System*, https://340bopais.hrsa.gov/SearchLanding (last updated Feb. 2, 2021).

10. Petitioner operates outpatient health care facilities in Wells River, Bradford, and East Corinth, Vermont. The Petitioner's sites and their 340B IDs are as follows:

- Wells River Office, CH0112220: 65 Main Street N, Wells River, VT 05081
- Bradford Office, CH011222A: 437 S Main Street, Bradford, VT 05033
- East Corinth Office, CH011222B: 720 Village Road, East Corinth, VT 05040

11. Petitioner provides family medicine, pediatrics, obstetrics, behavioral health, and oral health care. Petitioners' mission is to provide respectful, comprehensive primary health care for all residents in its region, regardless of their ability to pay. Little Rivers Health Care, *About*, https://www.littlerivers.org/about (last visited Feb. 2, 2021).

12. In 2019, Petitioner served more than 5,500 patients, 1,555 of which had income at or below 200% of FPL, and 495 of which had income at or below 100% of the FPL. HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Feb. 2, 2021). More than 25% of patients were Medicaid recipients, and approximately 5% of patients were uninsured. *Id.* Approximately

15.46% of Petitioner's patients were under the age of 18 and 25.68% were 65 years of age or older. *Id.* In 2019, Petition provided health care services to 93 agricultural workers and families, 46 homeless individuals, 265 veterans, 261 uninsured patients, and 37 prenatal patients. *Id.* It also provided mental health services to 519 patients, 4,304 behavioral health visits, and dental services to 475 children. *Id.*

13. Petitioner does not operate an in-house pharmacy. Affidavit of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Inc. ("Auclair Aff.") ¶ 19, Exhibit 3. It relies exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients. Auclair Aff. ¶ 19, Exhibit 3.

14. Petitioner relies on contract pharmacy arrangements to fund the following services that are not funded, or are only partially funded, through grants and private insurance:

- a chronic care management program to assist patients with chronic diseases;
- working with Willing Hands, a non-profit, charitable organization, to distribute fresh produce and dairy to Petitioner's clinics for care coordinators to deliver to patients in need;
- behavioral health services at local public schools that include counseling for students and families; and
- a Medication Assisted Treatment ("MAT") program that provides services to individuals who are on a drug regimen to treat addiction.

Auclair Aff. ¶ 12-15, Exhibit 3.

15. Petitioner also employs six care coordinators, including at least one care coordinator who specializes in behavioral health issues and works with patients to improve their overall social-emotional wellbeing. Auclair Aff. ¶ 16, Exhibit 3. Care coordinators provide assistance with transportation, insurance enrollment, sliding fee discount eligibility, linkage to affordable housing, food access, and patient care advocacy. Auclair Aff. ¶ 16, Exhibit 3. Petitioner relies on contract pharmacy arrangements to cover costs associated with these care coordination services. Auclair Aff. ¶ 16, Exhibit 3.

16. Petitioner offers a sliding fee scale to patients whose incomes are under 200% of the Federal Poverty Level. Auclair Aff. ¶ 18, Exhibit 3. This discount includes access to prescription drugs through the 340B program when they receive a prescription as the result of health care services provided by Petitioner. Auclair Aff. ¶ 18, Exhibit 3. If a patient's income is at or below 100% of the federal poverty level, and the patient does not have insurance coverage for retail prescription drugs, Petitioner pays 100% of that patient's drug costs. Auclair Aff. ¶ 18, Exhibit 3. For patients whose income is between 100% and 200% of the federal poverty level, Petitioner pays a percentage of the cost of the drug (25%, 50% or 75%, depending on the patient's income level). Most of Petitioner's patients in the sliding fee program qualify for the 100% discount. Auclair Aff. ¶ 18, Exhibit 3.

17. Annual financial statements prepared by certified public accountants show that Little Rivers Petitioner operated at a loss in 2018 and 2019. Little Rivers 2019 Annual Report, https://irp-cdn.multiscreensite.com/cca16267/files/uploaded/FY2019%20Annual%20Report_gx0WPXrQb2KqTNIv6OIZ.pdf (last visited Feb. 4, 2021), Exhibit 4. In 2019, Petitioner's expenses exceeded its revenues by $188,451. *Id.* In 2018, Petitioner's expenses exceeded its revenues by $289,380. *Id.*

18. Petitioner is a plaintiff in a lawsuit against HHS requesting that HHS take action against Respondent and other drug manufacturers for failing to provide 340B discounts at contract pharmacies. Amended Complaint, *RWC-340B v Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020). As of the date this Petition was filed, Petitioner's lawsuit against HHS is stayed. Joint Motion for Stay, *RWC-340B v Azar*, No. 1:20-cv-02906 (D.D.C. Jan. 13, 2021).

19. Respondent is a manufacturer of covered outpatient drugs that participates in the 340B Program. As a manufacturer participating in the 340B Program, Respondent is required to sign a pharmaceutical pricing agreement ("PPA") and PPA Addendum. 42 U.S.C. § 256b(a)(1).

The PPA and PPA Addendum require Respondent to offer covered outpatient drugs to covered entities at no more than the 340B ceiling price. *Id.*

BACKGROUND

I. The 340B Program

20. Congress established the 340B Program in 1992 by enacting Section 602 of the Veterans Health Care Act of 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b. Section 340B—in conjunction with certain related provisions in Section 1927 of the Social Security Act—requires the Secretary to execute PPAs with manufacturers of certain outpatient drugs covered by the Medicaid program as a condition of the manufacturers' participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1).

21. The 340B Program is administered by the Office of Pharmacy Affairs ("OPA"), a part of Health Resources & Services Administration ("HRSA"), which is a unit of HHS.

22. The PPAs "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1). The "ceiling price" is "equal to the average manufacturer price for the drug under title XIX of the Social Security Act [Medicaid] in the preceding calendar quarter," reduced by a rebate percentage calculated under Medicaid. *Id.* § 256b(a)(1)-(2).

23. Congress intended the 340B Program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also Cares Cmty Health v. U.S. Dep't of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings

"help safety-net providers fund the uncompensated care they supply and expand the services they offer."). 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest individuals, regardless of ability to pay. The 340B Program is a vital and indispensable tool for 340B covered entities that qualify for the program based on receiving federal grants. The 340B Program helps them offset the costs of uncompensated or under-compensated care, enabling covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B Program, many covered entities would be forced to restrict access significantly or, in some cases, cease operations. For these reasons, ensuring access to 340B drugs and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

24. The 340B statute enumerates several types of health care providers that may qualify as "covered entities" eligible to participate in and purchase discounted drugs under the 340B Program. 42 U.S.C. § 256b(a)(4).

25. One category of covered entity under the 340B statute is "[a] Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)," 42 U.S.C. § 1396d(l)(2)(B). 42 U.S.C. § 256b(a)(4)(A). An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last updated May 2018). FQHCs must provide "care on a sliding fee scale based on ability to pay." *Id.*

II. 340B Program Integrity Requirements

26. The Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") amended the 340B statute to include "improvements in program integrity," including

"manufacturer compliance." ACA, Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (codified at 42 U.S.C. § 256b(d)(1)).

27. The 340B statute requires the Secretary to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers." 42 U.S.C. § 256b(d)(1)(B)(ii).

28. The statute also mandates 340B ADR regulations:

> Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.

42 U.S.C. § 256b(d)(3). The ACA was enacted on March 23, 2010.

29. On December 14, 2020, the Secretary issued a final ADR rule to implement the ADR process, effective January 13, 2020. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020).

30. The ACA also required the imposition of civil monetary penalties ("CMPs") upon pharmaceutical manufacturers that "knowingly and intentionally" overcharge 340B covered entities. 42 U.S.C. § 256b(d)(1)(B)(vi). Congress directed that "each instance of overcharging" would be subject to a penalty not to exceed $5,000. *Id* § 256b(d)(1)(B)(vi)(II); *see also* 42 C.F.R. § 10.11(a).

31. The Secretary issued a CMP regulation on January 5, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) ("CMP Final Rule") (codified at 42 C.F.R. § 10.11). The regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC [national

drug code], which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." *Id.* § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.*

32. When finalizing the CMP rule, the Secretary stated, "Failure to ensure the covered entities are receiving the 340B ceiling prices through a third party may be grounds for the assessment of CMPs under this final rule." CMP Final Rule, 82 Fed. Reg. at 1,224. The Secretary also stated, "All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system." *Id.* at 1,225.

III. 340B Contract Pharmacies

33. Many covered entities choose not "to expend precious resources to develop their own in-house pharmacies" because the requirements to obtain a pharmacy license are complex, and operating a pharmacy can be expensive. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. at 43,550.

34. Thus, from the beginning of the 340B Program, HRSA recognized that the program could only function if certain covered entities could dispense their 340B discounted drugs through third-party pharmacy contractors:

> During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program.

> Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

Id.

35. In 1995, HRSA published in the Federal Register proposed guidelines for contract pharmacy services under the 340B Program. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55,586 (proposed Nov. 1, 1995).

36. In 1996, after considering comments submitted in response to its November 1, 1995 notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute. Contract Pharmacy Services, 61 Fed. Reg. at 43,549.

37. "Contract pharmacy services," as HRSA's August 23, 1996, notice described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id.* at 43,550. Under such an arrangement, a covered entity purchases 340B drugs from a manufacturer and directs the manufacturer to ship the 340B drugs to an address other than the address listed in HRSA's database for the covered entity.

38. In its August 23, 1996, guidance, HRSA noted that "many covered entities … do not operate their own licensed pharmacies." *Id.* at 43,549. HRSA explained why the 340B Program is essential for these covered entities:

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Id. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id.* at 43,555.

39. HRSA's August 23, 1996, guidance was clear that the 340B statute requires pharmaceutical manufacturers to sell 340B discounted drugs to covered entities through contract pharmacy arrangements:

> Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS [Public Health Service] Act and results in an unauthorized expansion of the program.
>
> Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is 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.
>
> It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

Id. at 43,549-50.

40. Responding to a separate comment regarding the requirements of notice and comment rulemaking under the Administrative Procedure Act ("APA"), the agency stated:

> The guidelines explain how the Department intends to administer the 340B [program], further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties.

Id. at 43,550.

41. HRSA was also clear that covered entity arrangements with contract pharmacies are agency relationships:

> Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs. By issuing guidelines in this area, ODP [Office of Drug Pricing] is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.
>
> Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Id.

42. Although HRSA indicated that its August 23, 1996, contract pharmacy guidance was "designed to facilitate program participation for those eligible covered entities that do not have access to an [sic] appropriate 'in-house' pharmacy services," it clarified that "this is not a bar to the use of the mechanism by any covered entity," and "[t]he statute does not limit the covered entities' access to [various] avenues of drug purchasing." *Id.* at 43,551.

43. In 2007, HRSA again published proposed guidelines for contract pharmacies in the Federal Register. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1,540 (proposed Jan. 12, 2007). Subsequently, HRSA published a final notice regarding contract pharmacies on March 5, 2010. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272.

44. HRSA's March 5, 2010, guidance permits covered entities to contract with multiple contract pharmacies. HRSA responded to a comment regarding its action as follows:

> Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.
>
> Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA.

Id. at 10,273.

45. Contract pharmacy arrangements are not unique to the 340B Program. The Federal Trade Commission has recognized the right of non-profit organizations to contract with community pharmacies for purposes of dispensing drugs subject to discounts negotiated and used within the parameters of the Robinson-Patman Act and the Non-Profit Institutions Act. Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).

IV. AstraZeneca's About-Face Rejection of Contract Pharmacy Arrangements

46. Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, Respondent announced its intention no longer to do so, effective October 1, 2020.

47. By letter dated July 24, 2020, Respondent informed HRSA of its plan to cease offering 340B discounts on drugs purchased by covered entities and distributed by contract pharmacies. Letter from Christie Bloomquist, VP Corporate Affairs, AstraZeneca PLC to Admiral Krista Pedley, Director, Office of Pharmacy Affairs (July 24, 2020), Exhibit 5. HRSA responded by letter dated September 2, 2020, stating that the 340B statute requires manufacturers to offer covered outpatient drugs at the ceiling price and that HRSA was considering whether Respondent's actions violate the 340B statute. Letter from Admiral Krista Pedley, Director,

Office of Pharmacy Affairs to Christie Bloomquist, VP Corporate Affairs, AstraZeneca PLC (Sept. 2, 2020), Exhibit 6. In response to HRSA's letter, Respondent sent a letter dated September 15, 2020, to HRSA informing it again of its plans. Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC to Admiral Krista Pedley, Director, Office of Pharmacy Affairs (Sept. 15, 2020), Exhibit 7.

48. On or around August 17, 2020, Respondent issued a letter to approximately 6,800 covered entities, stating that Respondent would no longer honor most 340B contact pharmacy arrangements effective October 1, 2020:

> Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.
>
> To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all 340B Contract Pharmacy arrangements effective October 1, 2020.[1] Any 340B Covered Entity that does not have an outpatient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity.

Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020), Exhibit 8.

49. In response to the notice from Respondent, Petitioner's drug wholesaler blocked drugs manufactured by Respondent from being available for purchase through Petitioner's 340B accounts at contract pharmacies.

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[1] A "chargeback" describes the method by which drug wholesalers request reimbursement from manufacturers for 340B discounts provided to entities for 340B covered outpatient drugs. Wholesalers purchase drugs from the manufacturer at a non-340B price and sell to 340B entities at the contracted 340B price, which is typically significantly lower than the non-340B price. The wholesaler submits a chargeback request to the manufacturer to account for the difference. *See* Apexus 340B Glossary of Terms, https://docs.340bpvp.com/documents/public/resourcecenter/340b-glossary-of-terms.pdf. HRSA has contracted with Apexus as its "prime vendor" to provide technical assistance to covered entities and manufacturers and to secure sub-340B discounts on covered outpatient drugs.

50. Attorneys for Petitioner, Powers Law Firm, contacted Rich Buckley, Vice President of Global Corporate Affairs at Respondent in the summer of 2020 to discuss Respondent's policy to no longer offer covered outpatient drugs at the 340B ceiling price to covered entities if those drugs were to be delivered to a contract pharmacy (with some limited exceptions). On September 17, 2020, Mr. Buckley responded via text to a Powers attorney that Respondent would contact Powers to set up a teleconference. Message from Rich Buckley, Vice President of Global Corporate Affairs at AstraZeneca PLC to Peggy Tighe, Principal, Powers Pyles Sutter & Verville (Sept. 17, 2020), Exhibit 9. To date, Respondent has not sent any follow-up communication.

51. Petitioner notified HRSA that it was unable to purchase covered outpatient drugs manufactured by Respondent for distribution by its contract pharmacies through a form provided by HRSA's prime vendor. Little Rivers 340B Ceiling Price Unavailable Notice to HRSA, Exhibit 10.

V. HHS Response to Manufacturer Actions

52. On December 30, 2020, the HHS OGC issued an Advisory Opinion in response to numerous requests by both drug manufacturers and covered entities to address whether manufacturers may refuse to provide covered outpatient drugs to covered entities at the 340B ceiling price when those drugs are distributed through contract pharmacies. HHS OGC Advisory Opinion 1, Exhibit 1. The HHS OGC Advisory Opinion states unequivocally that drug manufacturers must offer covered outpatient drugs to covered entities at or below the 340B ceiling price regardless of how the covered entity distributes those drugs. As the HHS OIG succinctly stated, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." HHS OGC Advisory Op. 3, Exhibit 1.

53. The HHS OGC Advisory Opinion makes three principal points. First, the HHS OGC Advisory Opinion recognizes that the plain language of the 340B statute requires manufacturers to offer drugs to covered entities at the ceiling price regardless of whether the covered entity opts to use contract pharmacies to dispense those drugs. HHS OGC Advisory Op. 4, Exhibit 1. The 340B statute requires drug manufacturers to enter into a PPA with HHS, under which the manufacturer agrees to offer any covered outpatient drugs "purchased by a covered entity" at the 340B ceiling price. The PPA also obligates the manufacturer to offer covered outpatient drugs at the ceiling price if those drugs are made available to any other purchaser at any price. HHS OGC Advisory Op. 2, Exhibit 1. The HHS OIG Advisory Opinion states as follows:

> Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.

HHS OGC Advisory Op. 2, Exhibit 1.

54. Second, the HHS OGC Advisory Opinion states that the purpose and history of the 340B Program reflect the plain meaning of the statute as it relates to contract pharmacy arrangements. The HHS OGC Advisory Opinion notes that the purpose of the 340B Program is to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." HHS OGC Advisory Op. 3, Exhibit 1 (quoting H.R. Rept. No. 102–384(II), at 12 (1992)). It also states that many covered entities are only able to participate in the 340B Program by using contract pharmacies, as reflected by only 5% of covered entities operating in-house pharmacies at the beginning of the program. HHS OGC Advisory Op. 4, Exhibit 1. In addition, the HHS OGC Advisory Opinion states that HHS has interpreted the 340B statute for the last 24 years to require manufacturers to

offer 340B discounted drugs through contract pharmacies and that manufacturers have been honoring contract pharmacy arrangements for 24 years. HHS OGC Advisory Op. 4, Exhibit 1. The HHS OGC Advisory Opinion correctly notes that courts, when interpreting statutes, typically defer to the expertise of an agency that oversees a complex administrative program and may look to the actions of regulated parties. HHS OGC Advisory Op. 4, Exhibit 1.

55. Third, the HHS OGC Advisory Opinion repudiates the purported reasoning that certain manufacturers, including Respondent, offered as the basis for their unilateral decisions to stop offering 340B discounted drugs through contract pharmacy arrangements. Manufacturers have asserted that they are not distributing 340B drugs to contract pharmacies to obviate the alleged risk of diversion and duplicate discounts. HHS OGC Advisory Op. 5, Exhibit 1. The HHS OGC Advisory Opinion states that manufacturers are attempting "to circumvent 340B's procedures for resolving disputes between manufacturers and covered entities." HHS OGC Advisory Op. 5, Exhibit 1.

56. Moreover, the HHS OGC Advisory Opinion refutes the argument made by certain manufacturers that contract pharmacy arrangements constitute diversion through transfer of 340B drugs to pharmacies, which are not covered entities, and use of an inventory replenishment model. The HHS OGC Advisory Opinion states that "[t]he notion that the legitimate transfer of drugs to contract pharmacies constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct but function as principal-agent." HHS OGC Advisory Op. 6, Exhibit 1. It also states that the use of "complex" inventory models does not, by itself, constitute diversion. Lastly, the HHS OGC Advisory Opinion states that the manufacturers' argument ignores the reality that a covered entity's purchase of

outpatient drugs often occurs through an agent, such as a wholesaler. HHS OGC Advisory Op. 7, Exhibit 1.

57. According to media reports, Respondent has no plans to resume offering 340B discounts to covered entities for drugs distributed at contract pharmacies despite the strongly worded HHS OGC Advisory Opinion that Respondent is acting unlawfully. A spokesperson for AstraZeneca told Modern Healthcare the following:

> We changed our approach to help mitigate the significant compliance issues that have been well documented in audits performed by GAO [the U.S. Government Accountability Office] regarding contract pharmacy arrangements. AstraZeneca's approach to contract pharmacy arrangements fully complies with all operative requirements and continues to support the mission of the program to provide a healthcare safety net for the most vulnerable patients in our country.

Rachel Cohrs, *Some Drugmakers May Not Comply with HHS' 340B Opinion on Contract Pharmacies*, Modern Healthcare (Jan. 4, 2021), https://www.modernhealthcare.com/supply-chain/some-drugmakers-may-not-comply-hhs-340b-opinion-contract-pharmacies. For this reason, Petitioner contends that any good faith attempt to resolve this issue with Respondent would not have been fruitful. Indeed, on January 12, 2021, Respondent filed suit in the U.S. District of Delaware seeking to invalidate the HHS OGC Advisory Opinion. *AstraZeneca Pharmaceuticals LP v. Azar*, No. 1:21-cv-00027 (D. Del. filed Jan. 12, 2021).

VI. Facts Related to Petitioner's Contract Pharmacy Arrangements

58. Petitioner has four contract pharmacy arrangements registered with HRSA. HRSA, *340B Office of Pharmacy Affairs Information System*, https://340bopais.hrsa.gov/ContractPharmacySearch (Last updated Feb. 2, 2021). Two of those locations are for repackaging drugs for sale at retail pharmacies. Stated differently, only two of the contract pharmacies registered by Petitioner on the HRSA database dispense 340B drugs directly, in-person, to Petitioner's patients.

59. The savings from Petitioner's contract pharmacy arrangements allow it to: 1) pay for drugs needed by its patients who cannot afford to pay for the drugs; and 2) pay for support services for its patients that are not covered by insurance or paid for through grant funding. Auclair Aff. ¶ 21, Exhibit 3.

COUNT I
VIOLATION OF THE 340B STATUTE

60. Petitioner realleges and incorporates by reference paragraphs 1–55 as if fully set forth below.

61. Respondent has violated the clear mandate of the 340B statute. In pertinent part, the 340B statute states that manufacturers of covered outpatient drugs must enter into a PPA under which the manufacturer agrees to sell covered outpatient drugs to covered entities at or below the 340B ceiling price:

> the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs … purchased by a covered entity…. does not exceed an amount equal to the [340B ceiling price].

42 U.S.C. § 256b(a)(1).

62. The 340B statute also states that the PPA must include a provision to "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*

63. Indeed, since 1996, the Secretary has expressly interpreted the 340B statute to require pharmaceutical manufacturers to provide 340B discounts when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. at 43,550. In 2010, the Secretary reconfirmed the agency's longstanding interpretation that covered entities are

entitled to 340B discounts on drugs shipped to contract pharmacies. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272.

64. Late last year, the HHS OGC reaffirmed that the plain language of the 340B statute entitles covered entities "to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." HHS OGC Advisory Op. 8. The HHS OGC affirmed that,

> the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs.

HHS OGC Advisory Op. 2.

65. Therefore, the 340B statute unambiguously requires Respondent to offer covered outpatient drugs at the 340B ceiling price to Petitioner and does not place any limitation on the site for the delivery of those drugs. The ADR Panel must give effect to the unambiguous text to the statute. *See Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). Accordingly, Respondent has violated the 340B statute by refusing to provide covered outpatient drugs to Petitioner at its contract pharmacies since October 1, 2020.

COUNT II
VIOLATION OF 340B REGULATIONS

66. Petitioner realleges and incorporates by reference paragraphs 1–55 as if fully set forth below.

67. Respondent has violated a 340B regulation by refusing to offer 340B pricing for drugs shipped to Respondent's contract pharmacies. A 340B regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." 42 CFR § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.* The Secretary explained that an instance of overcharging includes an order placed "through a third party" and "regardless of the distribution system." CMP Final Rule, 82 Fed. Reg. at 1,224-1,225.

68. The HHS OGC affirmed that "the covered entity and contract pharmacy are not distinct, but function as principal-agent." HHS OGC Advisory Op. 6, Exhibit 1.

69. HRSA has confirmed that contract pharmacies function as agents of covered entities. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550.

70. Accordingly, Respondent has overcharged Petitioner for each instance in which Respondent did not offer the 340B ceiling price on an "order placed . . . through . . . [an] agent" contract pharmacy. 42 C.F.R. § 10.11(b)(1).

RELIEF REQUESTED

WHEREFORE, Petitioner respectfully requests relief as follows:

1. A declaration that Respondent is in violation of the 340B statute and HRSA's contract pharmacy guidelines by refusing to provide covered outpatient drugs at the 340B ceiling price through contract pharmacy arrangements.

2. An order directing Respondent to resume offering covered outpatient drugs to Petitioner at the 340B ceiling price through contract pharmacy agreements.

3. An order directing Respondent to pay to Petitioner any 340B discounts that Respondent has withheld from Petitioner for covered outpatient drugs distributed through contract pharmacies since October 1, 2020.

4. An order directing HRSA to take any other "appropriate action regarding refunds, penalties, removal or referral to appropriate Federal authorities." 42 C.F.R. § 10.24(e).

Respectfully submitted,

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Dated: February 4, 2021

Exhibit L

BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS *Petitioner,* v. ELI LILLY AND COMPANY and SANOFI-AVENTIS U.S. LLC and ASTRAZENECA PLC *Respondents.*	Petition No: 210112-2

PETITIONER'S MOTION FOR PRELIMINARY INJUNCTION

Petitioner National Association of Community Health Centers ("NACHC"), on behalf of its joint claimant Federally-qualified health center ("FQHC") covered entity members, hereby moves the Administrative Dispute Resolution Panel ("Panel") to employ its equitable authority under 42 C.F.R. § 10.21(a) to compel drug manufacturers Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), and AstraZeneca PLLC ("AstraZeneca") (collectively, the "drug manufacturers") to immediately make their covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices when shipped to a contract pharmacy, pending the Panel's final resolution of this claim.

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

The joint claimants—FQHC covered entities who are required by statute to care for some of the country's most vulnerable and medically underserved patients—participate in the 340B Program as Congress intended. NACHC Pet. ¶¶ 6, 24 (Jan. 13, 2021).

In recent months, pharmaceutical manufacturers Lilly, Sanofi, and AstraZeneca (the "drug manufacturers" or "manufacturers") have unlawfully restricted the joint claimants' ability to purchase covered outpatient drugs at 340B discount pricing by ceasing such sales to covered entities where the drugs at issue will be dispensed to covered entity patients via contract pharmacies. *See* Pet.. ¶¶ 1, 26–28, 30–32, 34–35. As alleged in the joint claimants' Petition, such limitations on access are unlawful overcharges in violation of 42 U.S.C. § 256b(a)(1) and 42 C.F.R. § 10.21(c)(1).

The factual record is clear and no material facts are in dispute. In addition to the public notices and correspondence the joint claimants cite in their Petition, several federal district court filings document and describe the drug manufacturers' unlawful actions in the manufacturers' own words. *See, e.g.,* Mem. in Supp. of Eli Lilly and Co's Mot. to Intervene, ECF No. 12-1 at 19–21, *Ryan White Clinics for 340B Access v. Azar*, Case No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020); Mem. in Supp. Of Sanofi-Aventis U.S. LLC's Mot. to Intervene, ECF No. 13-1 at 3, *Ryan White Clinics v. Azar*, Case No. 1:20-cv-02906; Mem. in Supp. of AstraZeneca's Mot. to Intervene, ECF No. 29-1 at 15, *Ryan White Clinics*, No. 1:20-cv-02906-KBJ (Nov. 24, 2020); Compl. at 16–20, *AstraZeneca Pharmaceuticals v. Azar*, Case No. 1:21-cv-00027 (D. Del. Jan. 12, 2021); Compl. at 2, 15–17, *Sanofi-Aventis U.S. v. Azar*, Case No. 3:21-cv-00634 (D. N.J. Jan. 12, 2021); Compl. at 27–28, *Eli Lilly and Co. v. Azar*, Case No. 1:21-cv-00081 (S.D. Ind. Jan.

12, 2021); *see also* Pet. ¶¶26–36. The drug manufacturers' federal court filings cited in this paragraph are attached as Exhibits A, B, C, D, E, and F, respectively.

The manufacturers' public justifications for their unlawful actions are meritless. The 340B statute imposes a clear duty on the drug manufacturers to offer covered outpatient drugs at 340B discount pricing for covered entities to purchase regardless of a particular covered entity's chosen dispensing mechanism. Equally clear is the unwavering interpretation given to that statute by the U.S. Department of Health and Human Services (HHS), the agency entrusted with overseeing the 340B Program, including by adjudicating disputes like this one.

Preliminary injunctive relief is not only appropriate here, where the joint claimants are all but guaranteed to prevail on the merits of their overcharging claims, but also necessary to prevent further irreparable harm to the joint claimants and their patients while the Panel adjudicates this matter. The 340B statute guarantees "that claims shall be resolved fairly, efficiently, and expeditiously" through the ADR process. 42 U.S.C. § 256b(d)(3)(B)(ii). Because of the absence—until yesterday—of an ADR process, the joint claimants have already been detrimentally delayed in obtaining relief. *See* Compl. ¶¶ 75–86, *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar,* No. 1:20-cv-03032-KBJ (D.D.C. Oct. 21, 2020), attached as Exhibit G. Now, having successfully secured the regulatory implementation of that process through litigation in federal court, the joint claimants implore the Panel to use its equitable authority to compel a return to status quo 340B sales and purchasing through a grant of preliminary injunctive relief.[1]

[1] Before its district court litigation was stayed, Petitioner was poised to seek preliminary injunctive relief to alleviate the harm caused by the drug manufacturers' refusal to allow the joint claimants to purchase covered outpatient drugs at 340B pricing for dispensing through contract pharmacies. Indeed, the declarations attached to this filing—originally prepared and executed for filing in the D.C. District Court—demonstrate the urgent need for equitable relief.

II. BACKGROUND

The 340B Program, *codified at* 42 U.S.C. § 256b *et seq*., requires drug manufacturers, as a condition of having their drugs covered by Medicare and Medicaid, to enter into pharmaceutical pricing agreements (PPAs) with HHS, under the terms of which they must make certain outpatient drugs available to covered entities at prices that do not exceed a statutorily-set ceiling price. 42 U.S.C. § 256b(a)(1). By reducing drug costs to covered entities—which are predominantly safety-net providers serving poor, underserved, and either uninsured or underinsured populations—the 340B Program furthers its legislative objective to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), 12 (1992).

Petitioner's FQHC covered entity members receive, or are deemed eligible to receive, federal grant funds under Section 330 of the Public Health Service ("PHS") Act to provide certain required health care and related services to medically underserved populations regardless of patient insurance status or ability to pay for such services. 42 U.S.C. §§ 254b(a), (e), (k); Pet. ¶ 6. As alleged in the Petition, these statutorily required services include pharmacy services, and FQHCs are permitted to meet their patients' pharmaceutical needs either directly or through contracts or similar arrangements. Pet. ¶¶ 3, 19 (citing 42 U.S.C. § 254b(a), (b)(1)(A)(i)(V)).

Although FQHC covered entities have flexibility in determining how best to meet the needs of their patient population and communities, any operational savings or revenue an FQHC generates—through 340B Program participation or otherwise—must be used to further the health center's project. *See* 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-

grant funds be used to further center's project objectives). As Congress intended, FQHC covered entities use 340B Program savings and revenue to provide additional services within their federally-designated service areas. *See* H.R. Rep. No. 102-384(II), at 12 (1992). For example, FQHCs use their 340B savings to cover the cost of medication for uninsured or underinsured patients who could not otherwise afford such costs. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549-01, 43549 (Aug. 23, 1996) (noting that covered entities can use 340B savings to subsidize patients' prescriptions). FQHC covered entities also use these funds to expand and increase access to necessary medical and crucial enabling services. *See id.* at 43549, 43551 (noting that covered entities can also use 340B savings to increase the number of patients they serve, increase the number of services they provide, and offer more comprehensive services).

As alleged in the Petition and reflected in the drug manufacturers' own public statements and legal filings, the drug manufacturers recently threatened—and then imposed—significant (unlawful) limitations on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable 340B ceiling prices. *See* Pet. ¶¶ 27, 30, 34.

On October 21, 2020, Petitioner, on behalf of the joint claimants, brought suit in federal court to compel the implementation of the statutorily-required ADR process of which Petitioner now avails itself. *See* Ex. G (NACHC Compl.) at 1–2. The final rule establishing that process was published on December 14, 2020, with an effective date of January 13, 2021. Given the publication of the final rule, Petitioner and HHS Secretary jointly moved to stay that matter pending the establishment of this Panel and its adjudication of Petitioner's joint claim. *See* Joint Mot. for Stay, ECF No. 12, *Nat'l Ass'n of Cmty. Health Ctrs.*, No. 1:20-cv-03032, (D.D.C. Dec. 17, 2020) (stay granted Jan. 7, 2021), attached as Exhibit H.

III. ARGUMENT

This Panel should grant Petitioner's request for immediate equitable relief pending final adjudication of the joint claim asserted in its Petition. The joint claimants are almost certain to succeed on the merits of this joint claim, and such interim equitable relief will prevent further irreparable harm to the joint claimants and their patients while their first-of-its-kind claim is pending in this newly established process. Additionally, the delay in the ADR rulemaking and implementation of this process—for which Petitioner bears no blame—renders Petitioner's request for relief all the more pressing.

Preliminary injunctive relief is appropriate where the movant shows it "is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). In the D.C. Circuit—where Petitioner, on behalf of its covered entity members, filed suit seeking the creation of this ADR process—a preliminary injunction is warranted where a movant demonstrates (1) a substantial likelihood of success on the merits, (2) that they will suffer irreparable injury if injunctive relief is not granted, (3) that the injunction would not substantially injure other interested parties, and (4) that the public interest is furthered by the injunction. *See Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006); *see also Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011) (indicating likelihood of success on the merits is key factor).

A. Petitioner is Substantially Likely to Succeed on the Merits.

Petitioner is all but guaranteed to succeed on the merits of its joint claim. The drug manufacturers' refusal to allow the joint claimants to purchase covered outpatient drugs at or

below the drugs' applicable ceiling prices is not only an abrupt departure from decades of past practice and a repudiation of previously accepted agency policies, but also amounts to a prohibited overcharge as defined in 42 C.F.R. § 10.21(c)(1) (defining prohibited overcharging activity to include any "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price").

In longstanding, well-reasoned, and persuasive agency issuances—that are squarely on point and date back nearly twenty-five years—HHS has consistently and repeatedly stated that covered entities may contract with third parties to provide pharmaceutical services to their patients. For instance, in an August 23, 2006 final notice published in the Federal Register, HHS wrote: "[e]ach covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. at 43549–50. (Aug. 23, 1996). The Agency also provided, in its "Contract Pharmacy Services Revised Final Mechanism" included in that Notice that "[u]nder section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drugs at the discounted price." *Id.* At that time, HHS, considering a situation in which a covered entity directs a drug shipment to its contract pharmacy, saw "no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance." *Id.*

HHS reiterated its unwavering interpretation of the 340B statute in a March 2010 final notice published to "inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies" without individualized Agency approval. Notice Regarding 340B

Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272-01, 10272–73 (Mar. 5, 2010) (replacing all previous 340B Program guidance, including 61 Fed. Reg. 43549). The notice informed all stakeholders that covered entities were free to use contract pharmacies for dispensing "as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.* at 10273.

Roughly a decade after the March 2010 final notice was published, on September 21, 2020, HHS General Counsel Robert P. Charrow responded to a September 8, 2020 request from Lilly for an advisory opinion as to whether Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." *See* Pet. Exhibit E (Sept. 21, 2020 Letter from Robert P. Charrow, General Counsel, U.S. Dep't of Health & Human Servs., to Anat Hakim, Senior Vice President and General Counsel, Eli Lilly & Co.). In that letter, General Counsel Charrow indicated that HHS "ha[d] significant initial concerns" with Lilly's limitations on covered entities' ability to purchase Lilly drugs at 340B discount pricing, advised Lilly that it could not and should not "view the absence of any questions from the government as somehow endorsing Lilly's policy," and warned Lilly that "a [False Claims Act] suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the [340B] program that results in over-charges to grantees and contractors." *Id.* at 1–2; *Cf.* 42 C.F.R § 10.11(a) (providing that a manufacturers' "knowing[] and intentional[]" refusal to offer covered outpatient drugs at 340B pricing is an example of prohibited overcharging subject to civil monetary penalties); *see also* Letter from Krista M. Pedley, Director, Office of Pharmacy Affairs, Health Res. & Servs. Admin., to Derek L. Asay, Senior Director, Government Strategy, Eli Lilly & Co. (Aug. 26, 2020) at 1 (noting "[u]nder 42 U.S.C. 256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices"), attached as Exhibit I; Letter from

Krista Pedley to Christie Bloomquist (Sept. 2, 2020) at 1-2 (asserting AstraZeneca's actions "could have the effect of severely limiting access" to 340B drugs during the COVID-19 pandemic, which "would undermine the 340B Program and the Congressional intent behind enactment of the 340B statute"), attached as Exhibit J. The manufacturer-imposed limitations on purchasing considered in the cited letters from HHS are the same as those at the heart of the joint claimants' Petition.

Finally, as the joint claimants explain in their Petition, a December 30, 2020 HHS Office of General Counsel Advisory Opinion, also written to address the very conduct at issue here, is a particularly persuasive and forceful reiteration of HHS' prior interpretive guidance:

> to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

Pet. Exhibit B (HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* at 1 (Dec. 30, 2020)). As HHS further notes in that Advisory Opinion, the 340B statute, in plain language, requires manufacturers to offer covered outpatient drugs at or below the ceiling price for "purchase by" covered entities and neither qualifies, restricts, nor otherwise conditions this requirement on the mechanism through which a covered entity *distributes* its covered outpatient drugs so long as the covered entity *purchases* the drugs. *Id.* at 2.

The Panel is not only bound by the plain language of the 340B statute, there is no legally justifiable reason for it to depart from HHS's longstanding interpretation of that statute as permitting covered entities to purchase covered outpatient drugs at 340B discount pricing for dispensing to covered entity patients either directly or through contract pharmacies. *See Fed. Commc'ns Comm'n v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (agency generally

may not depart from prior policies without reasoned basis, including acknowledgment of changed position); *Barnhart v. Walton*, 535 U.S. 212, 220 (2002) (noting courts "normally accord particular deference to an agency interpretation of 'longstanding' duration") (*quoting North Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 522 n.12 (1982)); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) (deference inappropriate for agency interpretation initially adopted in litigation, particularly where interpretation departs from prior agency position). The drug manufacturers effectively conceded that the Panel must adhere to its prior interpretive guidance in three separate—but strikingly similar— lawsuits, each filed just the day before the ADR process became available. One of those suits, initiated by Lilly, characterizes HHS's December 30, 2020 Advisory Opinion as a "binding decision under which manufacturers like Lilly must offer full 340B discounts to contract pharmacies on all covered drugs." Ex. F (Eli Lilly Compl.) at 4–5; *see also* Ex. D (AstraZeneca Compl.); Ex. E (Sanofi Compl.).

B. The Joint Claimants Will Continue to Suffer Irreparable Harm Absent Preliminary Injunctive Relief

The joint claimants will be irreparably harmed if the Panel does not grant preliminary injunctive relief. A movant seeking a preliminary injunction demonstrates irreparable harm by showing two things: (1) the harm that will result in the absence of injunctive relief "must be 'certain and great,' 'actual and not theoretical,' and so 'imminen[t] that there is a clear and present need for equitable relief to prevent irreparable harm;'" and (2) that harm cannot be remediated. *See League of Women Voters of the United States v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016) (*quoting Chaplaincy of Full Gospel Churches*, 454 F.3d at 297).

FQHCs currently provide numerous non-reimbursable services in part through 340B savings and program income. These services include, for example, medication therapy management, behavioral health care, dental services, case management and care coordination

services, translation/interpretation services for patients with limited English language ability, and transportation assistance. *See, e.g.,* Declaration of J.R. Richards ¶ 14 (indicating covered entity's "behavioral health, dental, mobile van services, patient assistance program, and free prescription delivery" are funded in part through 340B savings and revenue), attached as Exhibit K; Declaration of Donald A. Simila ¶¶ 15, 16, 17, and 19 (indicating substance abuse, dental, and OB/GYN services supported by 340B funds), attached as Exhibit L; Declaration of Patricia DeShields ¶ 16 (indicating uninsured patients' prescription drug costs, transportation, medical supplies, lab fees, and vaccinations supported by 340B funds), attached as Exhibit M.

If drug manufacturers continue to refuse to provide 340B discounts for contract pharmacies, FQHCs will be forced to drastically reduce or even eliminate these services. Ex. K (Richards Decl.) ¶¶ 24, 25 (estimating that covered entity will lose approximately $350,000 annually—41 percent of its annual budget—as result of 340B restrictions, forcing reduction in services); Declaration of Heather Rickertsen ¶¶ 34, 36 (estimating annual loss of approximately $1 million in revenue and $500,000 to $2 million increase in cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program), attached as Exhibit N; Ex. L (Simila Decl.) ¶¶ 28–30 (estimating annual revenue loss of approximately $600,000 from Lilly's actions alone, resulting in "major reductions in services" and "significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community"); *see also* Declaration of Lee Francis ¶ 30 ("We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue."), attached as Exhibit O.

Reductions in 340B savings and revenue resulting from the drug manufacturer's unlawful overcharging will also result in many covered entities needing to reduce the size of their clinical

staffs, further restricting the amount and scope of care they provide to patients. For example, Upper Great Lakes Family Health Center, an FQHC covered entity which serves approximately 25,000 patients annually in Michigan's remote Upper Peninsula, reports that 340B reductions have already forced it to reduce staffing for OB/GYN services and that it is currently planning other major reductions in services—including closure of service delivery sites, termination of employees, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services. Ex. L (Simila Decl.) ¶ 29; *see also* Ex. K (Richards Decl.) ¶ 25; Declaration of Kiame Jackson Mahaniah ¶ 20 (currently preparing to permanently layoff 5 percent of its employees due to loss of 340B revenue), attached as Exhibit P; Declaration of Kimberly Christine Chen ¶ 42 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations due to manufacturers' restrictions), attached as Exhibit Q.

These harms are also incapable of remediation, especially given the 340B program's purpose. Covered entities cannot retroactively provide, and their patients cannot retroactively benefit from, critical health care and enabling services that must be reduced or eliminated due to manufacturers' noncompliance with 340B pricing requirements.

C. Other Interested Parties Will Not be Substantially Harmed by the Preliminary Injunction

The drug manufacturers will not be substantially harmed by a preliminary injunction that, in effect, restores the status quo ante. First, as a threshold matter, enforcement of a pre-existing federal obligation causes no cognizable harm at all. *See Newsom v. Albemarle Cnty. School Bd.*, 354 F.3d 259, 261 (4th Cir. 2003).

Second, the requested relief would restore the 340B program's status quo as it existed for decades—*i.e.*, drug manufacturer compliance with both the 340B statute's plain language and HHS interpretive rules recognizing the propriety of the contract pharmacy model to dispense

drugs to patients of FQHC covered entities. That longstanding state of affairs changed mere months ago by virtue of the drug manufacturers' own unilateral actions.

From 1996 to late 2020, drug manufacturers honored covered entity's purchases at 340B discount pricing where the purchased drugs are shipped to and dispensed by covered entities' contract pharmacies. While covered entities (and their patients) will suffer irreparable harm in the absence of injunctive relief, *see* Section III.B, *supra*, there is no reason to believe that the drug manufacturers will be substantially, much less irreparably, harmed by continuing to do what they did for more than 20 years during the period it takes the ADR panel to "expeditiously" resolve this dispute. *See*, *e.g.*, Pet. Ex. E at 2 (noting "[t]he price of Lilly's stock has increased by more than 11 percent since January 1, 2020" reflecting jump in comprehensive income "from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020"). Further, given the substantial public equities at stake in providing affordable medications and health care services to vulnerable communities, any private interest asserted by the drug manufacturers should be given little weight. Unlike the deprivation of medical care or the restriction of services to an underserved population, drug manufacturers could only conceivably complain of economic harm, for which they would have a damages remedy in this ADR process. 42 U.S.C. § 256b(d)(3)(A).

D. The Requested Relief is in the Public Interest

Requiring the drug manufacturers to provide 340B-priced drugs to covered entities' contract pharmacies pending the resolution of the ADR proceedings is in the public interest. First, the public interest is not served by the drug manufacturer's continued violation of their statutory obligations. *See Washington Post Guild Majority v. Washington-Baltimore Newspaper Guild, Local 35 (ANG)*, No. 76-0009, 1976 WL 1547 at *4 (D.D.C. 1976) ("the public interest is

served by preventing the violation of a federal statute"); *Laborers' Int'l Union of N. Am. v. Nat'l Post Office Mail Handlers, Watchmen, Messengers & Grp. Leaders Div. of Laborers Int'l Union of N. Am.*, Case No. 88-1731-OG, 1989 WL 251211, at *12 (D.D.C. Jan. 17, 1989) ("The public interest lies in seeing that the statute is complied with.").

Second, the public interest favors a preliminary injunction because it will prevent the substantial direct and indirect harm to covered entities patients' currently resulting from the drug manufacturers' violations of the 340B statute. Due to the drug manufacturers' practical elimination of the joint claimants' ability to purchase the manufacturers' drugs at or below applicable ceiling prices for dispensing through contract pharmacies, the joint complainants' patients have experienced dramatic increases in the price of life-sustaining medications used to treat common, chronic conditions such as diabetes, cardiovascular disease, and respiratory diseases. *See, e.g.,* Declaration of Ludwig M. Spinelli ¶ 21 (asthma and diabetes medication), attached as Exhibit R; Ex. N (Rickertsen Decl.) ¶ 30 (medications treating diabetes, heart disease, hypertension, and asthma/COPD). For instance, a joint claimant FQHC health center located in Connecticut and serving approximately 50,000 patients in the Bridgeport and Stamford regions reports that uninsured health center patients receiving insulin or asthma medication through their health center's contract pharmacy now have to either pay up to $1800 for medication which previously cost them less than $16 for the same amount or, if a substitution is possible, coordinate with and wait for their providers to approve the substitution of a cheaper alternative medication. *See* Ex. R (Spinelli Decl.) ¶ 21 (noting change to $300–600 for a month's supply of medication which previously cost $12–15 per three months' supply); *see also* Declaration of Daniel Fulwiler ¶ 14a (noting change in price for month's supply of insulin from less than $17 to $700), attached as Exhibit S.

Other joint claimants, including those with existing in-house pharmacy capabilities that could theoretically be leveraged to provide discounted medications to needy patients, report that patients would have to travel prohibitive distances to reach such a pharmacy. For example, North Country HealthCare, located in Flagstaff, Arizona, indicates that some of its patients previously served by its contract pharmacies would have to travel up to 180 miles to reach the FQHC's nearest in-house pharmacy. *See* Ex. Q (Chen Decl.) ¶ 21; *see also* Declaration of Ronald E. Castle ¶ 15 (declaring that health center's single in-house pharmacy is located roughly at mid-point of 110-mile service area), attached as Exhibit T. A delay in obtaining life-sustaining and health maintenance medications caused by these sorts of practical barriers to access can result in significant adverse health effects for the joint claimants' patients—including death. Great Salt Plains Health Center, located in northwestern Oklahoma, reports that its "patients will be denied access to medications that are critical to their survival, such as rescue inhalers, blood pressure medications, and insulin." Declaration of Timothy E. Starkey ¶ 16, attached as Exhibit U; *see also* (Declaration of David Steven Taylor ¶ 18 (reporting that numerous patients are already forgoing insulin treatments because of increased cost and/or difficulty in traveling to the FQHC's in-house pharmacy), attached as Exhibit V; Ex. R (Spinelli Decl.) ¶¶ 23–25 (reporting that diabetic and asthmatic patients have been forced to forego medication and/or switch to less effective substitute medication).

A shift to clinical alternative medications—when such alternatives exist—may result in reduced health outcomes due to lower efficacy, serious side effects, or decreased medication compliance as a result of patient confusion or difficulty in adapting to a new regimen. *See e.g.* Ex. Q (Chen Decl.) ¶ 38 (reporting that switching stable diabetic patients to substitute medications reduces adherence to medication regimens and increases weight gain and the risk of

hypoglycemia "which can lead to seizures, coma, and even death"); Ex. K (Richards Decl.) ¶ 23 (reporting that patients whose diabetes is controlled with one medication may develop uncontrolled diabetes or suffer other adverse effects when switching to a substitute medication).

The public interest is served by ensuring the continued viability of the nation's health care safety-net and the health of its most vulnerable patients. *See Lopez v. Heckler*, 713 F.2d 1432, 1437 (9th Cir. 1983) ("Our society as a whole suffers when we neglect the poor, the hungry, the disabled, or when we deprive them of their rights or privileges."). Indeed, the existence of the PHS Act programs at issue here evidences a significant public interest in safeguarding access to health care for those who are medically underserved.

IV. CONCLUSION

For the foregoing reasons a preliminary injunction should issue compelling the drug manufacturers to comply with their statutory obligation to offer the joint claimants' covered outpatient drugs at or below 340B ceiling prices, regardless of whether those drugs are to be dispensed in-house or through a contract pharmacy, until the Panel resolves the merits of Petitioner's joint claim.

Dated: January 14, 2021

Respectfully submitted,

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Exhibit M

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA *et al.*, *Defendants*.	C.A. No. 21-27 (LPS)

DECLARATION OF ODALYS CAPRISECCA

Pursuant to 28 U.S.C. § 1746, I, Odalys Caprisecca, hereby declare and state as follows:

1. I am AstraZeneca's Executive Director for Strategic Pricing & Operations. In this capacity, I am responsible for US Pricing, Trade Operations, Contract Operations, and Government Reporting, which includes oversight of all federal programs such as the 340B program.

2. AstraZeneca is a proud participant in the 340B program. In 2020, for instance, AstraZeneca paid more than a billion dollars in discounts under the program to 340B program participants.

3. Since HRSA revised its contract pharmacy guidance in 2010 to authorize covered entities to contract with an unlimited number of independent pharmacies, we have become increasingly alarmed about the amount of duplicate discounting and drug diversion in connection with sales of our medicines under the 340B program. In the last several years, HRSA's audits of covered entities have identified significant non-compliance among contract pharmacies in particular. Last year, millions of dollars in inappropriate 340B discounts were identified based on

self-reported disclosures from covered entities—which the vast majority of participants in the program do not conduct.

4. At the same time, we have learned that contract pharmacies are earning substantial profit-margins on 340B discounted drugs that are not passed on to patients. Pharmacy profit margins on 340B brand name drugs are now a staggering 72%—more than triple regular margins—and generate hundreds of millions of dollars in profits each year. *See* Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa. For example, Walgreens' SEC filings report that any pricing changes "in connection with the federal 340B drug pricing program[] could significantly reduce our profitability." *Walgreens Boots Alliance, Inc. Form 10-K* (Oct. 15, 2020), https://bit.ly/2MoLX9d.

5. In 2020, we changed our policy specifically to address program abuses. Our goal is to limit the potential for abuse in a manner that complies fully with the 340B statute, while at the same time enabling patients served by covered entities to continue to access our medicines. Under our new policy, effective October 1, 2020, a covered entity that maintains its own on-site pharmacy may obtain our medicines at 340B prices through the covered entity's on-site pharmacy. A covered entity that does not have an on-site pharmacy may recognize one contract pharmacy designated by the covered entity through which it may purchase our medicines at the 340B price. Under our revised policy, every 340B entity can purchase our medicines at the 340B price, either through its own in-house pharmacy or through its designated contract pharmacy. This is the same policy that HRSA had in place from 1996 through March 2010.

6. I understand that, on May 17, 2021, Diana Espinosa, Acting Administrator of HRSA, posted a letter on the HRSA website notifying AstraZeneca that HRSA has finished reviewing AstraZeneca's policy regarding contract pharmacy arrangements under the 340B

Program, and that "HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute."

7. The letter then directs that "AstraZeneca must [1] 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," [2] "credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy," and [3] "work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements." It does so with no discussion of AstraZeneca's actual policy, no acknowledgement that every covered entity can access our medicines through a pharmacy of its choice at the 340B price, and no analysis of the 340B statute supporting that an overcharge is occurring.

8. The letter also threatens that, if AstraZeneca fails to comply with HRSA's demands, HRSA may seek civil monetary penalties (CMPs) of up to $5,883 per instance of noncompliance. The letter orders AstraZeneca to advise the agency of our plan to resume sales of 340B drugs to covered entities through unlimited contract pharmacy arrangements by June 1, 2021.

9. To be clear, we do not agree with HRSA's characterization of our position. The HRSA letter is based on the incorrect premise "that AstraZeneca's actions have resulted in overcharges" to covered entities. AstraZeneca's policy as noted allows each covered entity to access our medicines through either their own in-house pharmacy or a contract pharmacy of their choice. Our policy in no way restricts any covered entity from purchasing any of our medicines at 340B prices, nor does our policy result in any overcharge to a covered entity. If HRSA follows through on any of the threats it makes in its letter, we will vigorously defend our position.

10. However, HRSA's threats, in and of themselves, pose significant and in many ways unquantifiable harms to AstraZeneca. If HRSA follows through on any of its demands, we fail to see how we can effectively remedy the harms that would occur. First, and most obviously, civil monetary penalties are an extremely harsh sanction. According to HRSA's letter, they could amount to as much as $5,883 per instance that the government believes we sold our product to a covered entity at an incorrect price. Although AstraZeneca disputes that it *ever* overcharges a covered entity for 340B drugs, or that such overcharges occur under its contract pharmacy policy, HRSA clearly disagrees. Given the sheer number of 340B sales that we make every year, this could amount to hundreds of millions of dollars in potential penalties *every month* under a broad interpretation of HRSA's threat. For example, based on a comparison between the volume of 340B discounts before and after our new policy came into effect, AstraZeneca estimates that it could face up to approximately $530 million per month in CMPs (which does not include potential reimbursement requests from covered entities). The imposition of a penalty of such size, even if we could ultimately reverse it later on, will cause reputational injuries to our company.

11. Moreover, HRSA's letter, which was posted publicly on HRSA's website, is also adversely affecting our business relationships and causing reputational harm, including among our customers, covered entities, and investors. As a result of HRSA's letter, AstraZeneca's covered entity customers and investors have the impression—in our view, mistakenly—that AstraZeneca is *knowingly and intentionally* violating Section 340B and overcharging for 340B covered medications.

12. Our customer-facing teams have received multiple requests and inquiries from customers seeking a response to the demands in HRSA's letter. We have also received inquiries

from investors arguing that AstraZeneca is violating Section 340B at the expense of covered entities.

13. HRSA's claims have also been the subject of media scrutiny. I am aware of at least 14 national media and trade press organizations that have written articles covering HRSA's letter to AstraZeneca in just the two days since HRSA posted it online. *See, e.g.*, FDA News, *HHS Threatens Six Drugmakers with Legal Action for Withholding 340B Discounts* (May 19, 2021); Kaiser Health News, *Six Drugmakers Warned to Reinstate 340B Discounts to Contract Pharmacies* (May 18, 2021); Bloomberg Law, *Eli Lilly, Sanofi Breached Federal Law by Curbing Drug Discounts* (May 17, 2021).

14. Even if AstraZeneca is eventually successful in challenging HRSA's interpretation of Section 340B and overturning any CMPs imposed in the interim, the lost goodwill and reputational harm caused by HRSA's letter will be difficult to restore.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 19, 2021.

DocuSigned by:

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