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,

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