IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services; ROBERT P. CHARROW, in his official capacity as General Counsel of the U.S. Department of Health and Human Services; THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; *and* HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	CIV. NO. _____ ADMINISTRATIVE PROCEDURE ACT REVIEW OF AGENCY DECISION

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 short time since it went into effect, more than 1,700 covered entities that lack an on-site pharmacy have registered a contract pharmacy, through which AstraZeneca has offered 340B pricing on 340B drugs.

4. AstraZeneca was open and transparent with HRSA about its policy from the beginning. Yet, despite repeated requests, HRSA has ignored AstraZeneca's requests for a meeting to discuss the new policy. And when AstraZeneca asked HRSA to post a Notice to Covered Entities on HRSA's 340B website—a step HRSA has taken numerous times in the past to facilitate the functioning of the 340B program, including 49 manufacturer notice letters in 2020 alone—HRSA refused. Instead, HRSA responded with a letter stating that it was considering whether AstraZeneca was in violation of Section 340B and threatening AstraZeneca with civil monetary penalties.

5. Now, several months later, HHS has finally and unequivocally (but without statutory authority) taken a firm stance on the contract pharmacy question: HHS General Counsel Robert P. Charrow issued an Advisory Opinion declaring that the agency has "conclude[d] 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. That conclusion is patently wrong. Section 340B requires manufacturers to "offer" 340B drugs at 340B prices to covered entities, which is exactly what AstraZeneca's policy does. The statute, on its face, does not require manufacturers to recognize *any* contract pharmacies, much

less unlimited contract pharmacies. *A fortiori*, AstraZeneca's policy of recognizing one contract pharmacy per covered entity that does not have an on-site pharmacy fully complies with the law—indeed, it goes beyond AstraZeneca's obligations under Section 340B.

7. The agency's contrary reading of Section 340B is irreconcilable with the statute's plain text, history, and purpose. It was also issued without any authority: Section 340B does not authorize Defendants to "engag[e] in prophylactic non-adjudicatory rulemaking regarding the 340B program." *Pharmaceutical Research & Manufacturers of Am. v. HHS*, 43 F. Supp. 3d 28, 42-43 (D.D.C. 2014) (*Orphan Drug I*).

8. Beyond that, the Advisory Opinion has caused, and is continuing to cause, substantial harm to AstraZeneca (as well as the covered entities who buy its products). Under the Advisory Opinion, unless drug manufacturers like AstraZeneca offer 340B discounts to all contract pharmacies, they risk potential civil monetary penalties of up to $5,000 *per occurrence*; face the potential revocation of their ability to participate in Medicare and Medicaid; and risk penalties under the False Claims Act. Every day that the Advisory Opinion remains on the books, AstraZeneca is exposed to a threat of greater and greater potential liability.

9. AstraZeneca therefore brings this action seeking an order for preliminary and permanent injunctive relief: (1) declaring that the Advisory Opinion violates the Administrative Procedure Act because it was issued without following proper procedure, is in excess of statutory authority, and is otherwise not in accordance with law; (2) setting aside and vacating the Advisory Opinion; (3) declaring that AstraZeneca is not required to offer 340B discounts to contract pharmacies; (4) preliminarily and permanently enjoining enforcement of the Advisory Opinion and all actions by Defendants inconsistent with that declaratory relief; and (5) ordering HRSA to post AstraZeneca's notice.

JURISDICTION AND VENUE

10. 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.

11. Defendants' issuance of *Advisory Opinion 20-06 on Contract Pharmacies Under the 340b Program* on December 30, 2020, constitutes a final agency action and is therefore judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

12. Defendants' refusal to post AstraZeneca's Notice to Covered Entities on HRSA's website constitutes final agency action and is therefore judicially reviewable under the APA. 5 U.S.C. §§ 551(13), 704, 706. It also constitutes "agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

13. 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

14. 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.

15. Defendant Alex M. Azar II 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.

16. Defendant Robert P. Charrow is the General Counsel of HHS. His official address is in Washington, D.C. He issued the Advisory Opinion that sets forth HHS's legal opinion on contract pharmacies under the 340B program, which is a final agency action complained of herein. He is sued in his official capacity.

17. Defendant Thomas J. Engels is the Administrator of HRSA. His official address is in Rockville, Maryland. Administrator Engels is directly responsible for the administration of the 340B program and the actions complained of herein. Administrator Engels, among his 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. Administrator Engels is sued in his official capacity.

18. 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.

19. 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

20. 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. *Orphan Drug I*, 43 F. Supp. 3d at 31 (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).

21. 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.

22. 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).

23. 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, 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*).

24. 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

25. Section 340B does not require manufacturers to provide discounts 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).

26. 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.*

27. 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 "many gaps in the legislation." *Id.* at 43,550.

28. 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.

29. 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.

30. 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.

31. 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, though it also emphasized "the

responsibility of the covered entity to ensure against diversion and duplicate discounts." 75 Fed. Reg. 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.

32. 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

33. 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.[1] 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

[1] 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 many multiples of that. *See* 2018 GAO Report at 20.

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.

34. Make no mistake: The boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B discounted drugs. 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-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 enables the pharmacy to enjoy the 340B discount 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.

35. 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.

36. 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.

37. 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.*

38. 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 the surveyed covered entities that used *in-house* pharmacies reported offering discounts to their patients. *Id.*

39. 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.

40. 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.

41. 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.").

42. 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, and HRSA Fails to Post AstraZeneca's Notice to Covered Entities

43. 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 A).

44. 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 B). 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.*

45. After nearly a month had passed without any response from HRSA, AstraZeneca began informing its distributors directly of its new policy. *See* Ex. A. 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 C). 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.

46. 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 D). 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.

47. Finally, HRSA refused to post AstraZeneca's notice, thus depriving covered entities of information on how to access AstraZeneca medicines: The agency stated that as it "continues to evaluate this issue, it will not be posting AstraZeneca's 'Notice to Covered Entities Regarding 340B Pricing' until this matter is resolved." *Id.* at 2.

48. AstraZeneca replied to HRSA's response letter on September 15. *See* Letter from Christie Bloomquist to Krista Pedley dated Sept. 15, 2020 (Exhibit E). 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 approach. *Id.* at 1.

49. 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.*

50. 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.

51. Regarding the notice that AstraZeneca had asked HRSA to post, AstraZeneca explained that "HRSA's refusal to post our notice to covered entities is causing very real and tangible harm, as it is denying covered entities access to vital information on how to register their designated pharmacy." *Id.* at 2. AstraZeneca again requested "that HRSA immediately post our notice on its website so that covered entities can learn how they may enroll and designate their pharmacy to receive AstraZeneca medicines." *Id.*

52. And 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.

53. In light of HRSA's failure to respond to its letters, or to honor AstraZeneca's request to post AstraZeneca's notice to covered entities on the agency's website, 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 F). 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.*

54. On November 2, 2020, AstraZeneca sent another letter to HRSA. *See* Letter from Odalys Caprisecca to Krista Pedley dated Nov. 2, 2020 (Exhibit G). 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.*

55. To this day, notwithstanding the passage of nearly *six months* since AstraZeneca's initial meeting request, HRSA has neither agreed to meet with AstraZeneca nor posted AstraZeneca's notice to covered entities on its website. *See* HRSA, Manufacturer Notices to Covered Entities, https://www.hrsa.gov/opa/manufacturer-notices/index.html (database of manufacturer notices posted by HRSA). 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

56. On December 30, 2020, Defendants issued *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*. The Advisory Opinion sets out HHS's definitive response to the legal question of whether the 340B Statute requires manufacturers to sell 340B drugs to contract pharmacies. The Advisory Opinion "conclude[s]" that manufacturers' obligations to offer discounted drugs under the 340B Statute extend not just to purchases by covered entities, but also to purchases by contract pharmacies. 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.").

57. Although it purports to be grounded in "the plain text of the statute," Advisory Opinion 3, the opinion nowhere explains how its reading of Section 340B complies with the plain

statutory requirement that covered entities must "offer" discounted drugs to a "covered entity." 42 U.S.C. § 256b(a)(1). Nor does 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). Nor does it 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).

58. Instead, to the extent the Advisory Opinion engages in any textual analysis at all, it focuses solely on the phrase "purchased by." Advisory Opinion 2-3. The opinion begins with the assertion that "[i]t is difficult to envision a less ambiguous phrase," *id.* at 2, thereby repudiating (without acknowledging that it is doing so) Defendants' own previous statements that the 1996 Guidance and 2010 Guidance were filling "gaps in the legislation," 61 Fed. Reg. at 43,550. The Advisory Opinion then contends that the phrase "purchased by" unambiguously grants covered entities the right to use a contract pharmacy to acquire 340B drugs on its behalf. Advisory Opinion 2. The opinion asserts that this conclusion is supported by current practice "as we understand it, [under which] the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor." *Id.* at 3. From that observation, the Advisory Opinion offers the hyperbole that "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" to a manufacturer's Section 340B obligations. *Id.*

59. HHS issued the Advisory Opinion despite the fact that Congress did not grant Defendants general rulemaking authority or authority to promulgate regulations with respect to Section 340B(a).

60. 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 Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 33 (D.D.C. 2015) (*Orphan Drug II*). 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 authorize the agency to "engag[e] in prophylactic non-adjudicatory rulemaking regarding the 340B program." *Id.* at 42-43.

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

61. Notwithstanding the Advisory Opinion's claim that it engages in "straightforward textual interpretation," Advisory Opinion 3, the opinion ignores the statute's key provision: Section 340B's must-offer provision requires a manufacturer solely to "offer" discounted drugs to a "covered entity," an obligation that the manufacturer fully satisfies by making drugs available to the covered entity itself. Nothing in the statute supports that a manufacturer violates its obligation by declining *also* to make drugs available to contract pharmacies.

62. 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.

63. 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 has gone beyond Section 340B's textual requirements, by allowing a covered entity that lacks an in-house pharmacy to purchase drugs through a contract pharmacy of its choosing.

64. 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 require that manufacturers must make 340B drugs available to multiple contract pharmacies per covered entity. 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.

65. Defendants' new interpretation, as set forth in the Advisory Opinion, is that manufacturers must make drugs available to contract pharmacies because Section 340B requires drugs to be available for "purchase by" a covered entity, without limitation. According to the opinion, that means a manufacturer must make drugs available for purchase *anywhere* or through

any means—even on the "lunar surface." Advisory Opinion 3. But that interpretation focuses on the wrong words and thus reaches the wrong result. A manufacturer's statutory obligation is to "offer" 340B drugs to a covered entity; the manufacturer complies with that command when it makes the drugs available for purchase by the covered entity itself.

66. Indeed, the phrase "purchased by," on which the Advisory Opinion rests its interpretation, does not even appear in the must-offer provision. Instead, it appears in a *separate sentence* that imposes obligations on the HHS Secretary: It requires the Secretary to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity" at discounted prices. 42 U.S.C. § 256b(a)(1) (emphasis added). Even in that context, the phrase merely specifies which purchases give rise to *the Secretary's obligation* to reimburse the manufacturer—namely, those purchases made "by a covered entity" at 340B discount prices.

67. The Advisory Opinion also purports to rely on state agency law, asserting that contract pharmacies act solely as "agents" of the covered entities, which themselves retain title to the 340B drugs even as they are sold by the pharmacies. Advisory Opinion 6. Even on its own terms, that assertion is highly dubious: Whether one person acts as another's agent (as opposed to its contractor) turns on a variety of factors under the various laws of 50 different States. Among other things, state laws look to how liability is apportioned in practice between the two parties, the division of profits among them, the specific terms of each arrangement, and the parties' course of dealing. Resolving the status of any particular relationship between a covered entity and a contract pharmacy would likely be case-specific and fact-dependent—the opposite of the "straightforward textual interpretation" that the Advisory Opinion claims to engage in. Advisory Opinion 3.

68. But even if—contrary to fact—contract pharmacies were agents of covered entities, that still could hardly affect *a manufacturer's* obligations. The manufacturer fulfills its statutory obligation when it "offers" 340B drugs to the covered entity; that obligation does not turn on the covered entity's choice of agency relationships. The state-agency-law argument also ignores that when Congress intends to include agents within the scope of federal law, it does so expressly. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C) (creating safe harbor to Anti-Kickback Act liability for amounts "paid by a vendor of goods or services to *a person authorized to act as a purchasing agent for*" a reimbursement-seeker). Here, Congress made no such specification. Indeed, "covered entity" is a narrowly defined term, buttressing the inference that Congress did not want to include agency relationships for purposes of 340B obligations. As the Supreme Court recognized in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), when it comes to interpreting the obligations imposed by the 340B statute, Congress's words must control, not common-law principles. *See id.* at 118-21.

69. Section 340B's history and purpose also demonstrate that Congress did not intend to guarantee access to deeply discounted 340B drugs for 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.

70. 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 them 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. 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.").

71. The agency's interpretation also raises substantial constitutional issues. In *Eastern Enterprises v. Apfel*, 524 U.S. 498 (1998), a plurality of Justices concluded that "legislation might be unconstitutional if it imposes severe retroactive liability on a limited class of parties that could not have anticipated the liability, and the extent of that liability is substantially disproportionate to the parties' experience." *Id.* at 528-29. The plurality found the law at issue there to be a regulatory taking because it essentially forced a company to assume $50-$100 million worth of liabilities to third-parties that the company had not created and could not have anticipated. In a separate opinion concurring in the judgment, Justice Kennedy agreed that the law was unconstitutional, but expressed the view that the appropriate constitutional lens was due process.

72. Here, the agency's approach, as set forth in the Advisory Opinion, forces manufacturers to offer steeply discounted 340B drugs to third-parties—the contract pharmacies, which resell the drugs at a massive profit—in essence requiring manufacturers to transfer sale proceeds to the pharmacies. That command reflects a new and unexpected assertion of

administrative power to impose financial obligations on manufacturers. In its 2010 Guidance, HRSA concluded that the agency *lacked* the power to require contract pharmacies to adopt use of a bill-to/ship-to approach, and instead issued non-binding interpretive guidance merely recommending its approach. *See* 75 Fed. Reg. at 10,273; 61 Fed. Reg. at 43,550.

73. As recently as summer 2020, in fact, HRSA continued to maintain its prior longstanding position that the contract pharmacy guidance was not enforceable. *See* Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://bit.ly/2X0I1xe.

74. The agency's sudden reinterpretation of Section 340B, which now purports to obligate manufacturers to facilitate price arbitrage by an unlimited number of for-profit contract pharmacies, has no basis in preexisting law. And as in *Eastern Enterprises*, the "remedy created by the [reinterpretation] bears no legitimate relation to the interest which the Government asserts in support of the statute," 524 U.S. at 549 (Kennedy, J.), since the point of the statute is to make medical care accessible to underserved patients, not to provide windfalls for contract pharmacies.

75. Even if the interpretive question were close, therefore, because Defendants' construction of Section 340B "would raise serious constitutional problems," *United States v. Grier*, 475 F.3d 556, 567 (3d Cir. 2007) (citation omitted), the doctrine of constitutional avoidance favors AstraZeneca's alternative construction of the statute, which raises no such constitutional concerns. *See Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Const. Trades Council*, 485 U.S. 568, 575 (1988) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."); *see also Ashwander v. Tennessee Valley Authority*, 297 U.S. 288, 345-48 (1936) (Brandeis, J., concurring).

HHS's Advisory Opinion and HRSA's Failure to Post AstraZeneca's Notice to Covered Entities 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, the Advisory Opinion marks the "consummation" of the agency's decision-making process: HHS's analysis is not contingent, tentative, or interlocutory. The opinion conclusively announces the agency's legal interpretation of the statute; it does not contemplate any further deliberation or the need for further factual development. The opinion finds that the plain text of Section 340B is unambiguous and thus "dispositive" of the legal question. Advisory Opinion 3. And the opinion's conclusion is 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, the Advisory Opinion adopts 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) will accrue every day that AstraZeneca does not submit to the agency's interpretation. *See Sackett*, 566 U.S. at 126-27.

79. This risk of potential liability is not speculative. For example, on January 7, 2021, a group representing 340B hospitals and hospital associations sent a letter to AstraZeneca declaring that, in light of the Advisory Opinion, "AstraZeneca's policy of not providing 340B discounts to 340B providers when AstraZeneca's drugs are dispensed through all but one contract pharmacy is in clear violation of the statute, and AstraZeneca should immediately discontinue its illegal practice." Letter from William B. Schultz dated Jan. 7, 2021 (Exhibit H). The letter demanded that AstraZeneca "reimburse 340B entities for the damages they have incurred due to AstraZeneca's policy." *Id.* at 2. And the letter further threatened that "[i]f AstraZeneca continues its illegal practice, we will continue to seek to require that HHS enforce the 340B statute, covered entities are reimbursed for damages caused by the illegal policy, and the matter is referred to the HHS Inspector General for the imposition of civil money penalties." *Id.* Defendants have put AstraZeneca to the "painful choice" of either complying with the incorrect "obligation[s]" that result from Defendants' mistaken 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]").

80. The threat of liability has become even more concrete following HRSA's recent publication of 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 panel members must be drawn from the 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. Each three-member ADR panel must be composed of "one member from HRSA, CMS, and OGC with relevant expertise to review claims and make final agency decisions." *Id.*

81. HRSA has made clear that it intends to use the ADR process to impose liability on manufacturers for failure to follow the Advisory Opinion's approach to contract pharmacies. Although Section 340B vests HHS with limited authority to establish ADR procedures by which to resolve "claims," *see* 42 U.S.C. § 256b(d)(3)(A)-(C), the ADR Final Rule purports to arrogate authority to the ADR panel "to resolve related issues"—including purely *legal* questions "such as . . . whether a pharmacy is part of a 'covered entity.'" *Id.* at 80,633. Even if that were a proper exercise of authority, which it is not, the Advisory Opinion already conclusively announces HHS's legal position on the contract pharmacy issue. Accordingly, any attempt by a manufacturer to contest the Advisory Opinion on the contract pharmacy issue in proceedings before an ADR panel would be an exercise in futility. 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").

82. Even apart from the effects of the Advisory Opinion, moreover, HRSA's refusal to post AstraZeneca's notice on the HRSA website—so that covered entities can view the notice and participate in AstraZeneca's new contract pharmacy policy—constitutes final agency action that is causing real harm now. Such a posting would inform all covered entities of how they may access AstraZeneca's medicines. Failing to post that notice denies those covered entities access to information that could be beneficial to them and to the 340B program; it has resulted in confusion by covered entities and delay in designating contract pharmacies under AstraZeneca's policy, to the detriment both of AstraZeneca and of covered entities.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

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

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

84. 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).

85. 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).

86. 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).

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

88. 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))).

89. 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

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

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

91. 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).

92. 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).

93. 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.

94. 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.

95. 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 pharmacies 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).

96. 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

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

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

98. 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).

99. 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.*

100. 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, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (citation and alterations omitted).

101. 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.

102. 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.

103. 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 to contract pharmacies. The Advisory Opinion thus arbitrarily and capriciously fails to explain the Defendants' change in policy.

104. 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

(Declaratory/Injunctive Relief – Defendants' Failure to Post AstraZeneca's Notice Exceeds Defendants' Statutory Authority Under 42 U.S.C. § 256b and Constitutes Agency Action Unlawfully Withheld under 5 U.S.C. § 706(1))

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

106. Defendants' failure to post AstraZeneca's Notice to Covered Entities on HRSA's website constitutes final agency action judicially reviewable under the APA. 5 U.S.C. §§ 551(13), 704, 706. It also constitutes "agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

107. For the reasons stated, Defendants' failure to post AstraZeneca's Notice to Covered Entities on HRSA's website—which is based on Defendants' erroneous and unlawful interpretation of Section 340B—is "not in accordance with law"; it is "in excess of statutory jurisdiction, authority, or limitations"; and it is *ultra vires.*

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;

B. Set aside and vacate the Advisory Opinion;

C. Declare that AstraZeneca is not required to offer 340B discounts to contract pharmacies;

D. 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;

E. Issue preliminary and permanent injunctive relief preventing Defendants from implementing or enforcing the Advisory Opinion;

F. Direct Defendants to post AstraZeneca's Notice to Covered Entities on HRSA's website.

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

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

Dated: January 12, 2021

Respectfully submitted,

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