UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

RYAN WHITE CLINICS
FOR 340B ACCESS
1501 M Street, N.W., Suite 700
Washington, DC 20005,

and

MATTHEW 25 AIDS SERVICES, INC.
452 Old Corydon Road
Henderson, KY 42420,

and

CHATTANOOGA C.A.R.E.S., DBA CEMPA COMMUNITY CARE
1000 E. 3rd Street, Suite 300
Chattanooga, TN 37403,

Plaintiffs,

vs.

ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

and

THOMAS J. ENGELS, in his official capacity as Administrator for the Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857,

Case No. 20-cv-2906

and

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

Defendants.

COMPLAINT FOR DECLARATORY, MANDAMUS, AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs ask this Court to compel the Secretary of Health and Human Services ("Secretary") and other federal Defendants to permit and enable Plaintiffs to use contract pharmacy arrangements under the federal 340B drug pricing program ("340B program") as mandated by statute and regulation. 42 U.S.C. § 256b (2018); 42 C.F.R. § 10.11 (2019). The 340B program, established at 42 U.S.C. § 256b ("340B program"), requires pharmaceutical manufacturers to sell discounted drugs to certain statutorily defined health care providers, known as "covered entities," as a condition of the manufacturers participating in the Medicaid and Medicare Part B insurance programs. Plaintiffs include a covered entity trade association and several covered entities (collectively, the "Plaintiff Covered Entities") that participate in the 340B program primarily, or exclusively, through agency relationships with third-party pharmacies, referred to as "contract pharmacies." Under these arrangements, the Plaintiff Covered Entities place orders for 340B discounted drugs that are shipped to the contract pharmacy and billed to the covered entity. 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. In 2017, the Secretary enshrined this requirement in regulation. 42 C.F.R. § 10.11(b)(1).

2. Recently, however, four pharmaceutical manufacturers have flouted the 340B statute and regulation by openly refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements. These manufacturers are Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), AstraZeneca PLC ("AstraZeneca"), and Novartis Pharmaceuticals Corporation ("Novartis") (collectively, the "Drug Companies"). The Drug Companies have denied 340B discounts to the Plaintiff Covered Entities by refusing to sell their drugs through the 340B wholesaler accounts associated with contract pharmacies.

3. Only the Secretary can remedy these violations by the Drug Companies, and he has taken no action to bring them into compliance. Congress required the Secretary to implement administrative dispute resolution ("ADR") procedures that would have enabled the Plaintiff Covered Entities to challenge the Drug Companies' actions before a tribunal within the Department of Health and Human Services ("HHS"), but the Secretary has now missed the statutory deadline for issuing ADR regulations by a decade. Moreover, the Supreme Court held in 2011 that 340B covered entities may not sue pharmaceutical manufacturers for failing to comply with 340B requirements. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110, 113-14 (2011) ("*Astra*"). The Court's holding was premised, in part, on the Secretary's promise to implement ADR regulations. *Id*. at 116, 121. The Plaintiff Covered Entities are thus wholly reliant on the Secretary to enforce 340B program requirements, which he has failed to do by permitting the Drug Companies to overcharge the Plaintiff Covered Entities for drugs subject to 340B discounts.

4. The Secretary has violated the Due Process Clause of the Fifth Amendment to the U.S. Constitution by failing in his duties and obligations under federal law to protect the rights of the Plaintiff Covered Entities to pursue ADR actions subject to judicial review. The Secretary's

constitutional violation has harmed the Plaintiff Covered Entities and their patients, and during a national public health emergency brought about by the novel coronavirus ("COVID-19") pandemic, the Secretary has also deprived the nation's most vulnerable individuals of crucial health care services in a manner that causes irreparable harm contrary to the public interest.

5. The Plaintiff Covered Entities are suffering immediate and irreparable harms from the Secretary's failure to enforce the Plaintiff Covered Entities' rights to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements. The savings from 340B discounts enable the Plaintiff Covered Entities to provide health care services that will be scaled back or eliminated altogether unless the Secretary acts now. Patient health is compromised, which is a serious and irreparable harm in the best of times and more so during a pandemic. The Secretary must promulgate ADR regulations. However, those regulations will take months to finalize, and the ADR process will be lengthy. Thus, the due process harms to the Plaintiff Covered Entities can only be cured in the short term by an order from this Court directing the Secretary to act now against the Drug Companies.

6. The Secretary has also violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1), by unlawfully withholding the ADR regulations and enforcement of 340B program requirements. Likewise, the Plaintiff Covered Entities request a writ of mandamus requiring the Secretary to implement ADR regulations and to enforce the Plaintiff Covered Entities' rights to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331, which grants federal district courts original jurisdiction of all civil actions arising under the Constitution.

8. This Court also has subject matter jurisdiction under 28 U.S.C. § 1361, which grants each district court jurisdiction over "any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff."

9. The APA requires courts to hold unlawful and set aside agency action, findings, and conclusions determined to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C) (2018). The APA also directs courts to "compel agency action unlawfully withheld." *Id*. § 706(1). The APA authorizes judicial review of "final agency action for which there is no other adequate remedy in a court." *Id*. § 704.

10. This Court has jurisdiction over the person of the Defendants.

11. Venue for this action lies in this judicial district under 28 U.S.C. § 1391(e)(1).

PARTIES

12. Ryan White Clinics for 340B Access ("RWC-340B") is a national association of human immunodeficiency virus ("HIV")/acquired immunodeficiency syndrome ("AIDS") health care clinics and service providers that receive funding under the Ryan White Comprehensive AIDS Resources Emergency Act ("Ryan White CARE Act"), either through a primary grant or subgrant and participate as covered entities in the 340B program by virtue of receiving this federal funding. Entities that receive grants or subgrants under the Ryan White CARE Act are commonly referred to as "Ryan White clinics." Ryan White clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and, as Defendant Secretary Azar has acknowledged, "are serving on the frontlines of this pandemic, supporting clients and communities at higher risk from COVID-19." HHS, *HHS Awards $90 Million to Ryan White*

HIV/AIDS Program Recipients for COVID-19 Response (Apr. 15, 2020), https://www.hhs.gov/about/news/2020/04/15/hhs-awards-90-million-ryan-white-hiv-aids-program-recipients-for-covid-19-response.html. RWC-340B's members rely on the savings generated from the 340B program to help finance their mission of serving low-income patients, including savings generated by contract pharmacy arrangements.

13. Matthew 25 AIDS Services, Inc. ("Matthew 25") is a not-for-profit health care provider with facilities in Henderson, Owensboro, and Bowling Green, Kentucky and a facility in Evansville, Indiana. Matthew 25 is a member of RWC-340B. Matthew 25 receives grant and subgrant funding through the Ryan White CARE Act. Matthew 25 participates in the 340B program as a covered entity by virtue of receiving this funding. Matthew 25 has been registered as a covered entity in the 340B program since 2002 and is still registered as a covered entity today. Matthew 25 does not operate an in-house pharmacy. Matthew 25 obtains 340B discounted drugs for its patients exclusively through contract pharmacies.

14. Chattanooga C.A.R.E.S., dba Cempa Community Care ("Cempa") is a not-for-profit health care provider located in Chattanooga, Tennessee. Cempa is a member of RWC-340B. Cempa is certified by HHS as an FQHC "look-alike" ("FQHC-LA") and receives grant funding under the Ryan White CARE Act. Cempa also receives funding from the federal Centers for Disease Control and Prevention ("CDC") as a sexually transmitted disease ("STD") clinic. Cempa is eligible to participate as a covered entity in the 340B program by virtue of being designated as an FQHC-LA, receiving Ryan White CARES Act funds, and receiving CDC STD clinic funds. Cempa has been registered in the 340B program since February 2020 and is still registered as a covered entity today. Cempa does not operate an in-house pharmacy. Cempa obtains 340B discounted drugs through multiple contract pharmacy arrangements.

15. Defendant Alex M. Azar II is the Secretary of Health and Human Services and is responsible for the conduct and policies of HHS, including conduct and policies of HRSA. He maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201. He is sued in his official capacity.

16. Defendant HHS is a cabinet-level department of the United States government. HHS is headquartered at 200 Independence Avenue, S.W., Washington, D.C. 20201.

17. Defendant Health Resources and Services Administration ("HRSA") is the agency within HHS that is charged with administering the 340B program. HRSA is headquartered at 5600 Fishers Lane, Rockville, MD 20857.

18. Defendant Thomas J. Engels is the Administrator for HRSA and is the federal official responsible for administering the 340B program. He maintains an office at 5600 Fishers Lane, Rockville, MD 20857. He is sued in his official capacity.

BACKGROUND

I. The 340B Program

19. Congress established the 340B program in 1992 by enacting Section 602 of the Veterans Health Care Act of 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b. Section 340B (in conjunction with certain related provisions of the Medicaid statute) requires the Secretary to execute Pharmaceutical Pricing Agreements ("PPAs") with manufacturers of certain outpatient drugs covered by the Medicaid program as a condition of the manufactures' participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1) (2018). The PPAs "shall require that the manufacturer offer each covered entity covered outpatient drugs for

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

20. Congress intended the 340B program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest individuals, regardless of ability to pay. The 340B program is a vital and indispensable tool for 340B covered entities that qualify for the program based on receiving federal grants. The 340B program helps them offset the costs of uncompensated or under-compensated care, enabling covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B program, many covered entities would be forced to restrict access significantly or, in some cases, cease operations. For these reasons, ensuring the accuracy of 340B discounts and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

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

22. The 340B statute defines as a covered entity "[a]n entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early

intervention services for HIV disease)." *Id.* § 256b(a)(4)(D). Subchapter XXIV of the Public Health Service Act is commonly referred to as the Ryan White CARE Act. *See* Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Pub. L. No. 101-381, 104 Stat. 576 (codified at 42 U.S.C. §§ 300ff–300ff-140 (2018)). Part C of the Ryan White CARE Act provides grants to entities that provide "core medical services" to individuals with HIV/AIDS. 42 U.S.C. § 300ff–51. With the exception of certain funds reserved pursuant to 42 U.S.C. § 300ff-51(c)(1), at least 75% of Part C grant funds must be used for core medical services, which include AIDS pharmaceutical assistance. *Id.* § 300ff–51(c)(1), (c)(3)(C). Part C grantees are small "local community-based organizations." *See* HRSA, *Part C: Early Intervention Services and Capacity Development Program Grants*, https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-c-early-intervention-services-and-capacity-development-program-grants (last reviewed Oct. 2020). Many Part C grantees lack the financial resources to operate an in-house pharmacy.

23. The Ryan White HIV/AIDS Program provides primary health care, pharmaceutical treatments, and support services for low-income people with HIV/AIDS and treats over 500,000 HIV-positive individuals in all 50 states, the District of Columbia, Puerto Rico, and the Pacific Island jurisdictions. HRSA, *About the Ryan White HIV/AIDS Program*, https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program (last reviewed Feb. 2019); HRSA, *HIV/AIDS Bureau Fact Sheets*, https://hab.hrsa.gov/publications/hivaids-bureau-fact-sheets (last reviewed Aug. 2020). The Secretary reports that the Ryan White HIV/AIDS Program is "critical" and "serves as an important source of ongoing access to HIV medication that can enable people living with HIV to live close to normal lifespans." HRSA, *About the Ryan White HIV/AIDS Program*,

https://hab.hrsa.gov/about-ryan-white-hivaids-program/about-ryan-white-hivaids-program (last reviewed Feb. 2019). "In 2017, 85.9 percent of Ryan White HIV/AIDS Program clients were virally suppressed, exceeding the national average of 59.8 percent." *Id.*

24. The 340B statute also defines as a covered entity "[a] Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)," 42 U.S.C. 1396d(l)(2)(B) (2018). 42 U.S.C. § 256b(a)(4)(A). An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last reviewed May 2018). FQHCs must provide "care on a sliding fee scale based on ability to pay." *Id.* A FQHC-LA is category of FQHC that meets the requirements to be designated as an FQHC but does not receive federal grant funding. 42 U.S.C. § 1396d(l)(2)(B)(iii).

25. The Secretary has delegated authority to administer the 340B program to HRSA, a unit of HHS. The 340B statute provides HRSA with regulatory authority over the 340B program in three areas: (1) the establishment of an ADR process for resolving manufacturer and covered entity price disputes, (2) "the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions" against manufacturers for overcharging for 340B drugs. *Pharm. Research & Manufacturers of Am. v. United States Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014). In other areas of the 340B program, HRSA has issued interpretive guidance, often published as a final notice in the Federal Register after providing notice and soliciting comment from the public.

II. 340B Manufacturer Program Integrity Requirements

26. On March 23, 2010, the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA") was signed into law. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 823 (2010). The ACA amended the 340B statute to include "improvements in program integrity," including "manufacturer compliance." *Id.* § 7102 (codified at 42 U.S.C. § 256b(d)(1)).

27. Among the required improvements was the imposition of civil monetary penalties ("CMPs") upon pharmaceutical manufacturers that "knowingly and intentionally" overcharge 340B covered entities. *Id.* Congress directed that "each instance of overcharging" would be subject to a penalty not to exceed $5,000. *Id.*

28. The Secretary issued a CMP regulation on January 5, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017) ("CMP Final Rule") (codified at 42 C.F.R. § 10.11). The regulation subjects manufacturers to CMPs not to exceed $5,000 for each instance of overcharging. 42 C.F.R. § 10.11(a). An "instance of overcharging" is defined as "any order for a covered outpatient drug, by NDC [national drug code], which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug." *Id.* § 10.11(b). Each order for an NDC is a single instance, regardless of the number of units ordered. *Id.* § 10.11(b)(1). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent." *Id.*

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

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

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

III. 340B Administrative Dispute Resolution

31. The ACA, signed into law on March 23, 2010, mandated 340B ADR regulations within 180 days:

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

ACA § 7102(a) (codified at 42 U.S.C. § 256b(d)(3)).

32. The Secretary's 180-day deadline to promulgate regulations for an ADR process fell on September 19, 2010.

33. On September 20, 2010, the Secretary published an "advance notice of proposed rulemaking and request for comments" in the Federal Register "to obtain information and public comment on how to efficiently and effectively implement the requirements to create an administrative dispute resolution process for the 340B Program authorized by Section 7102 of the Affordable Care Act." 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233, 57,234 (Sept. 20, 2010). The September 20, 2010, Federal Register notice did not propose ADR regulations.

34. Nearly six years later, the Secretary published proposed ADR regulations. 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016). Those regulations, if finalized, would have established a panel ("ADR Panel") within HHS to adjudicate disputes between 340B covered entities and pharmaceutical manufacturers. *Id.* at 53,382. Under the proposed regulations, covered entities would have been entitled to bring disputes with drug manufacturers to the ADR Panel, including disputes related to 340B program overcharges. *Id.* at 53,383. The ADR Panel would have been empowered to issue a final, binding decision "to HRSA, as necessary, for appropriate enforcement action." *Id.* at 53,388.

35. On August 1, 2017, the Secretary withdrew the proposed ADR regulations without explanation. Office of Mgmt. & Budget, *RIN: 0906-AA90: 340B Drug Pricing Program; Administrative Dispute Resolution Process*, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90 (last visited Oct. 9, 2020).

IV. 340B Contract Pharmacies

36. Many 340B covered entities do not operate in-house pharmacies. Because the requirements to obtain a pharmacy license are complex and operating a pharmacy can be expensive, many covered entities choose not "to expend precious resources to develop their own in-house pharmacies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("Contract Pharmacy Notice").

37. Thus, from the beginning of the 340B program, HHS recognized that the program could only function if certain covered entities purchased 340B discounted drugs under contract from third-party pharmacies:

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

Id.

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

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

40. "Contract pharmacy services," as HRSA's August 23, 1996 described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id.* at 43,550. Under such arrangements, the covered entities purchase 340B drugs from manufacturers and direct the manufacturers to ship the 340B drugs to an address other than the address listed in HRSA's database for the covered entities.

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

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

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

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

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

Id. at 43,549-50.

43. Responding to a separate comment regarding the requirements of notice and comment rulemaking under the APA, the agency stated:

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

Id. at 43,550.

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

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

Id.

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

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

47. HRSA's March 5, 2010, guidance expanded the availability of contract pharmacy arrangements to accommodate covered entities contracting with multiple contract pharmacies. HRSA responded to a comment regarding its action as follows:

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

Id. at 10,273.

V. The Supreme Court's *Astra* Decision

48. In 2011, the Supreme Court held that 340B covered entities do not have the right to sue manufacturers for 340B overcharges and that only the Secretary may enforce the manufacturer's obligation to charge at or below the 340B ceiling price. *Astra*, 563 U.S. at 113-14.

49. In *Astra*, covered entities sued drug manufacturers for overcharges under the 340B program. AstraZeneca was among the defendant pharmaceutical manufacturers. The defendant manufacturers argued, with the support of the Secretary, that 340B covered entities do not have a private right of action against pharmaceutical manufacturers to enforce 340B program

requirements. At oral argument, the government's attorney stated the following regarding the ADR regulations:

> [T]here were OIG [Office of Inspector General] reports raising concerns with oversight and enforcement at a general level, and the way Congress reacted to that was to put in place this administrative remedy which will allow covered entities to bring these claims.

Transcript of Oral Argument at 28, *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011) (No. 09-1273), https://www.supremecourt.gov/oral_arguments/argument_transcripts/2010/09-1273.pdf. Justice Ginsburg asked, "Are there plans to implement it?" *Id.* The government's attorney responded:

> Yes. The agency is moving ahead with that. The agency has already issued an advanced notice of proposed rulemaking back in the fall. And it has solicited comments about how the—the administrative scheme should look. That comment period has closed, and so now the agency is in the process of—of moving forward.

Id. at 28-29.

50. The Court's holding that covered entities do not have a private right of action against manufacturers was premised, in part, on the government's representations that ADR regulations would be forthcoming:

> The [2010 ADR provision] provides for more rigorous enforcement [and] directs the Secretary to develop formal procedures for resolving overcharge claims. Under those procedures, which are not yet in place, HRSA will reach an 'administrative resolution' that is subject to judicial review under the Administrative Procedure Act (APA).

Astra, 563 U.S. at 116 (citations omitted).

51. Notwithstanding Congress's mandate to implement ADR within 180 days of enactment of the law, as well its assurances to the Supreme Court, the Secretary has never implemented a 340B ADR program. More recently, HRSA has publicly stated that it has no intention of implementing the regulations. Tom Mirga, *HRSA: 340B Dispute Resolution Will*

Stay on Hold Until We Get Broader Regulatory Authority, 340B Report (Mar. 12, 2020), https://340breport.substack.com/p/your-340b-report-for-thursday-march-eae. Over a decade after its congressional mandate, HRSA defies Congressional intent and its own assurances to the U.S. Supreme Court regarding the mechanism mandated by law for covered entities to pursue complaints against manufacturers for overcharges under the 340B program.

VI. Manufacturer Actions to Reject Contract Pharmacy Arrangements

52. Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, several drug manufacturers announced their intentions either to refuse to honor contract pharmacy arrangements or to impose conditions on covered entities before honoring contract pharmacy arrangements.

A. Eli Lilly and Co.

53. On or around July 1, 2020, HRSA published a "limited distribution plan" on its official manufacturer notices Web page for several formulations of Lilly's drug Cialis. HRSA, *Manufacturer Notices to Covered Entities* (July 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf. The limited distribution plan states that, effective July 1, 2020, Lilly will not offer 340B pricing for these drugs if a covered entity sought to purchase the drugs through a contract pharmacy arrangement. *Id*.

54. On information and belief, Lilly no longer offers Cialis in the specified formulations at or below the 340B ceiling price if a covered entity attempts to purchase the drug through a contract pharmacy.

55. On or around September 1, 2020, Lilly prepared and implemented a plan to cease offering 340B prices on drugs purchased by covered entities through contract pharmacy

arrangements for all of its retail drug products, with a qualified exception for its insulin products. Lilly prepared a limited distribution plan that was effective on September 1, 2020, but not published on HRSA's website:

> Effective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only. Covered entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy.
>
> Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products*, 340B Health, (Sept. 1, 2020), https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

56. Lilly's September 1, 2020, limited distribution plan "grant[s] an exception to the limited distribution program described above for Lilly insulin products," subject to several conditions not stated in the 340B statute:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;
- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;
- No insurer or payer is billed for the Lilly insulin dispensed; and,
- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Id.

57. Immediately thereafter, the Plaintiff Covered Entities confirmed that Lilly no longer offered several of its drugs at or below the 340B ceiling price if they attempted to purchase the drug to ship to an address for one of their contract pharmacies.

58. On or around September 2, 2020, in response to a reporter's inquiry regarding Lilly's actions to refuse to honor 340B contract pharmacy arrangements, HRSA provided the following response:

> HRSA is not posting [Lilly's September 1] letter at this time as HRSA is considering whether manufacturer policies, including Lilly's, violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the PHSA.
>
> The 340B statute does not specify the mode by which 340B drugs may be dispensed. However, the Agency believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies. Without comprehensive regulatory authority, HRSA has only limited ability to issue enforceable regulations to ensure clarity in program requirements across all the interdependent aspects of the 340B Program.
>
> We believe that manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Bronwyn Mixter, *BREAKING: HRSA Is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute*, 340B Report (Sept. 2, 2020), https://340breport.substack.com/p/breaking-hrsa-is-investigating-whether.

59. Nevertheless, on information and belief, neither HRSA nor the Secretary took any enforcement action against Lilly to enforce the 340B statutory requirements to honor contract pharmacy arrangements.

B. Sanofi-Aventis U.S. LLC

60. On or around July 28, 2020, drug manufacturer Sanofi issued letters to 340B covered entities, including Plaintiffs Matthew 25 and Cempa, directing the covered entities to provide all of their claims data for 340B drugs purchased through contract pharmacies to a system called the 340B ESP program, which is operated by Second Sight Solutions, a Sanofi-designated vendor. Sanofi's letter stated that it would no longer honor contract pharmacy arrangements for covered entities that refuse to comply:

> Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.

61. In response to the announcements from Lilly and Sanofi, on or around July 30, 2020, the trade association American Hospital Association wrote a letter to the Secretary urging him to act against Lilly and Sanofi. Letter from Thomas P. Nickels, Exec. Vice President, Am. Hosp. Ass'n, to Alex M. Azar II, Sec'y, HHS (July 30, 2020), https://www.aha.org/system/files/media/file/2020/07/aha-urges-hhs-take-action-against-drug-manufacturers-for-limiting-distribution-340b-drugs-letter-7-30-2020.pdf. On information and belief, the Secretary neither responded to the letter nor took the requested action.

C. AstraZeneca

62. On or around August 17, 2020, drug manufacturer AstraZeneca issued letters to 340B covered entities, including the Plaintiff Covered Entities, stating that it would no longer honor most 340B contact pharmacy arrangements effective October 1, 2020:

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

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

63. On information and belief, AstraZeneca ceased offering 340B pricing on drugs dispensed at contract pharmacies on October 1, 2020.

D. Novartis

64. Like Sanofi, Novartis sent letters to the Plaintiff Covered Entities requesting them to register in the 340B ESP program by October 1, 2020, which would require them to provide all claims data related to 340B drugs dispensed to the Plaintiff Covered Entities' patients at contract pharmacies. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020). Novartis stated that all 340B covered entities will be required to register for 340B ESP and "provide 340B claims data originating from [contract pharmacy] utilization in order to receive 340B reimbursements [for contract pharmacy drugs] from Novartis." *Id*.

E. Responses to Manufacturer Actions

65. On or around July 16, 2020, the 340B Coalition, a group of national trade associations whose members are 340B covered entities, wrote to the Secretary urging him to act against Lilly. Letter from the 340B Coal., to Alex M. Azar II, Sec'y, HHS (July 16, 2020), https://www.dropbox.com/s/2m4mjvtx1dwpkyu/340B%20Coalition%20Letter%20to%20HHS%2007.16.2020.pdf?dl=0. On information and belief, the Secretary neither responded to the letter nor took the requested action.

66. On or around August 19, 2020, the trade association National Association of Chain Drug Stores issued a letter to the Secretary urging him to act against Lilly, Sanofi, and AstraZeneca for their refusals to honor 340B contract pharmacy arrangements. Letter from Steven C. Anderson, President & Chief Exec. Officer, Nat'l Ass'n of Chain Drug Stores, to Alex M. Azar II, Sec'y, HHS (Aug. 19, 2020), https://strategichealthcare.net/wp-content/uploads/2020/08/NACDS-letter.pdf. On information and belief, the Secretary neither responded to the letter nor took the requested action.

67. On or around September 14, 2020, 243 Members of the U.S. House of Representatives, including both Democratic and Republican members and spearheaded by leadership of the committees with oversight jurisdiction over HHS and HRSA, issued a letter to the Secretary urging him to act against Lilly, Sanofi, and AstraZeneca considering their refusals to honor 340B contract pharmacy arrangements. Letter from David B. McKinley *et al*., Members of Cong., to Alex M. Azar II, Sec'y, HHS (Sept. 14, 2020), https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf. On information and belief, the Secretary neither responded to the letter nor took the requested action.

68. By letter dated September 11, 2020, Plaintiff RWC-340B wrote to the Secretary and encouraged the agency to act against Lilly, Sanofi, Novartis, and AstraZeneca due to their refusals to honor 340B contract pharmacy arrangements. Letter from Shannon Stephenson, President, RWC-340B, to Alex M. Azar II, Sec'y, HHS (Sept. 11, 2020), https://www.rwc340b.org/wp-content/uploads/2020/09/Letter-to-HHS-on-Mfr-Actions-from-RWC340B-9-11-2020.pdf. In its letter, RWC-340B stated that it required HRSA's assistance, in part, because HRSA never implemented ADR regulations as required by statute. *Id*. RWC-340B requested that HRSA assess CMPs against Lilly, Sanofi, Novartis, and AstraZeneca. *Id*. RWC-340B stated that it "would construe lack of enforcement by HHS prior to October 1, 2020 as an indication that HHS has refused this request." *Id*. Nevertheless, the Secretary neither responded to the letter nor took the requested action.

69. By letter dated September 21, 2020, the HHS General Counsel responded to a letter from Lilly dated September 8, 2020, requesting a pre-enforcement advisory opinion on whether Lilly's "new unilateral policy" on 340B contract pharmacies "would subject Lilly to sanctions." Letter from Robert P. Charrow, Gen. Counsel, Office of the Sec'y, HHS, to Anat Hakim, Senior Vice President & Gen. Counsel, Eli Lilly & Co. (Sept. 21, 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf. The HHS General Counsel stated as follows:

> As we have indicated in earlier correspondence, although the Health Resources and Services Administration ("HRSA") has significant initial concerns with Lilly's new policy, it continues to review that policy and has yet to make a final determination as to any potential action. Correspondingly, Lilly cannot and should not view the absence of any questions from the government as somehow endorsing Lilly's policy especially when this Department is leading the government's response to the COVID-19 pandemic.

Id. The HHS General Counsel also criticized Lilly for implementing its unilateral policy during a public health emergency:

> [W]e believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small businesses have had difficulty making ends meet. Lilly, on the other hand, seems to be enjoying an outstanding year. The price of Lilly's stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020, an increase of more than 14 percent.
>
> In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

Id. The HHS General Counsel closed by warning that a False Claims Act "suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." *Id*.

VII. Facts Related to Plaintiffs' Contract Pharmacy Arrangements

A. RWC-340B

70. RWC-340B "is a national organization of HIV/AIDS health care clinics and service providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as covered entities in the federal 340B Drug Discount Program." RWC-340B, *Ryan White Clinics For 340B Access*, https://www.rwc340b.org/ (last visited Oct. 9, 2020).

71. Approximately 1.2 million people are currently living with HIV/AIDS in the United States. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2 (Sept. 2020), https://www.rwc340b.org/wp-content/uploads/2020/09/RWC340B-White-Paper-FINAL.pdf. Ryan White clinics provide

critical support to this vulnerable population, serving over half a million individuals by furnishing "HIV primary medical care, medications, and support services for underserved and uninsured" to people living with HIV/AIDS. *Id.* at 2-3.

72. Patients of Ryan White clinics are particularly vulnerable. They are "more likely to have less than a high school education, live in poverty, and be homeless" than people living with HIV/AIDS who are not treated in Ryan White clinics. *Id.* at 6.

73. Patients at Ryan White clinics, however, achieve better overall outcomes than patients in other settings of care. Patients at Ryan White clinics are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id.* at 4. Viral load suppression can result in an undetectable level of HIV in a patient's blood, reducing the risk of transmission. *Id.* Ryan White clinics increased the rate of viral suppression from 69.5% in 2010 to 87.1% in 2018, which is far higher than the 62.7% suppression in all people living with HIV/AIDS. *Id.* at 4-5. The success of Ryan White clinics is due, in part, to their higher rates of mental health, substance abuse, and case management services. *Id.* at 6-7.

74. The savings from 340B drugs is critically important to Ryan White clinics. Without 340B savings, these clinics would have to cut services such as case management, dieticians, vaccines, and substance abuse assistance. *See id.* at 8. Loss of these services would create higher risks of severe illnesses in people living with HIV/AIDS and lead to increased health care expenses. *Id.*

75. Losing contract pharmacy arrangements would be devastating to Ryan White clinics. HRSA's database of 340B providers shows that 75% of Ryan White clinics have contract pharmacy arrangements. *See* HRSA, *Welcome to 340B OPAIS*, https://340bopais.hrsa.gov/ (last visited Oct. 9, 2020). For many Ryan White clinics, contract

pharmacy arrangements are the primary, or even sole, path to 340B discounts. Loss of these discounts would jeopardize services provided by Ryan White clinics and irreparably harm the very vulnerable patients they serve.

B. Matthew 25

76. Matthew 25 provides health care services to approximately 487 people living with HIV/AIDS in Kentucky and Indiana. Approximately 58% of Matthew 25's patients have incomes at or below the federal poverty level, and another 22% of patients have incomes between 101% and 200% of the federal poverty level. Matthew 25 provides comprehensive outpatient and case management services to its clients. These case management services assist clients to coordinate their healthcare and support services and to encourage adherence to drug regimens and routine healthcare. Matthew 25 also provides outpatient and specialty medical care and support services for women, infants, children, and youth living with HIV/AIDS.

77. Matthew 25 funds its services with Ryan White CARE Act grants. Matthew 25 uses 340B savings to provide health care and non-health care services to patients that are not funded in whole or part by grants:

- Physicians that oversee the nurse practitioners who are the primary caregivers at its clinics;
- A "retention specialist" whose expertise is in retaining HIV/AIDS patients in care, thus reducing or completely suppressing their viral load and the chance of spreading the HIV infection;
- A "linkage navigator" whose expertise is in linking patients living with HIV/AIDS, and particularly those individuals who have been recently diagnosed, with appropriate treatment providers and support services;

- A food pantry at each of its locations that also delivers food as needed;
- Transportation for Ryan White patients to receive medical care;
- Advice on, and linkage to, low-income housing;
- Outreach to encourage testing for individuals at high risk of contracting HIV/AIDS; and
- Linguistic services for individuals who do not speak English as a first language.

78. Matthew 25 does not operate an in-house retail pharmacy and obtains 340B discounted drugs exclusively through contract pharmacy arrangements. Matthew 25 has 340B contract pharmacy arrangements with Coordinated Care Network ("CCN"), Curant Health Florida LLC and Curant Health Georgia LLC (collectively "Curant Health"). Both CCN and Curant Health specialize in providing pharmaceuticals to treat HIV/AIDS. CCN and Curant Health provide these services through mail order. Prior to October 1, 2020, Matthew 25 purchased drugs from AstraZeneca through these contract pharmacy arrangements. Since October 1, 2020, Matthew 25 has not been able to purchase 340B discounted drugs from AstraZeneca.

79. Loss of contract pharmacy services would devastate the many services that Matthew 25 currently finances with 340B savings. Matthew 25 would have to reduce the services that it provides to its patients, and Matthew 25 will have to reduce the number of its employees or contractors who are responsible for the services listed in paragraph 77. These changes will result in reduced services to Matthew 25's patients and consequent implications for their health.

C. Cempa

80. Cempa serves patients in Chattanooga, Tennessee and also operates a mobile clinic that serves patients in the greater Chattanooga area. Cempa participates in the 340B program both as an FQHC-LA and as a Ryan White Clinic. Cempa provides health care services regardless of the patient's ability to pay and charges for services on a sliding fee scale according to the patient's financial resources. Cempa also operates a program in which it subsidizes retail drugs dispensed to uninsured individuals whose income is at or below 200% of the federal poverty level. If such a patient is uninsured, Cempa pays the full cost of the patient's drugs, and if the patient is insured, Cempa pays the copayment for those drugs.

81. Cempa does not operate an in-house retail pharmacy. Cempa obtains 340B discounted drugs solely through contract pharmacy arrangements. Cempa has multiple contract pharmacy relationships, including arrangements for its FQHC-LA, mobile unit, and Ryan White Clinic. Cempa purchased 340B discounted drugs from the four Drug Companies before they halted 340B sales through contract pharmacy arrangements.

82. If Cempa loses 340B savings from its contract pharmacy purchases, its program to subsidize drugs for low-income patients will be imperiled. The cost of drugs dispensed to uninsured individuals will rise dramatically, and the saving from 340B purchases will no longer be available for these subsidies.

COUNT I
Declaratory Judgment

83. Plaintiffs reallege and incorporate by reference paragraphs 1–82 as if fully set forth below.

84. Plaintiffs request a declaration pursuant to 28 U.S.C. § 2201 that they are entitled to purchase and dispense drugs at 340B discounts through arrangements with contract pharmacies.

85. The 340B statute directs the Secretary to execute PPAs with manufacturers 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). The 340B statute contains no exemption permitting pharmaceutical manufacturers to restrict 340B sales based upon the delivery location of the drugs.

86. The 340B statute includes covered entity organizations, including Ryan White CARE Act grantees and FQHC-LAs, that lack in-house pharmacies. *See id.* § 256b(a)(4)(D). Congress therefore intended that an in-house pharmacy is not a condition for participation in the 340B program. Congress therefore also intended that, as a condition of participation in Medicaid and Medicare Part B, pharmaceutical manufacturers must provide 340B pricing to covered entities that order through third-party agents, such as contract pharmacies.

87. The Secretary has consistently, and correctly, interpreted the 340B statute to require manufacturers to honor 340B contract pharmacy arrangements. In 1996, the Secretary interpreted the statute to entitle covered entities to purchase at 340B discounts through contract pharmacies:

> The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.
>
> It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating

> manufacturer, the statute directs the manufacturer to sell the drug at the discounted price.

Contract Pharmacy Notice, 61 Fed. Reg. at 43,549.

88. The Secretary has consistently, and correctly, stated that his contract pharmacy guidance interprets preexisting statutory requirements. *Id.* at 43,550; Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. at 10,273.

89. The Secretary's CMP regulation defines an "instance of overcharging" as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price . . . ." 42 C.F.R. § 10.11(b). An order "includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or ***agent***." *Id.* § 10.11(b)(1) (emphasis added). Contract pharmacies serve as agents of 340B covered entities. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550.

90. Therefore, a manufacturer that charges a covered entity more than the 340B ceiling price for a drug ordered via a contract pharmacy has overcharged the covered entity in violation of the 340B statute, 42 U.S.C. § 256b, and the 340B CMP regulation, 42 C.F.R. § 10.11.

COUNT II
Violation of Due Process

91. Plaintiffs reallege and incorporate by reference paragraphs 1–90 as if fully set forth below.

92. Congress unambiguously required the Secretary to issue ADR regulations no later than September 19, 2010. 42 U.S.C. § 256b(d)(3). The Secretary has missed that deadline by over ten years.

93. The Secretary represented to the Supreme Court in 2011 that the Secretary would issue ADR regulations, leading the Court to hold that 340B covered entities do not have a private right of action against drug manufacturers. *Astra*, 563 U.S. at 116.

94. The Secretary has, therefore, left the Plaintiff Covered Entities with no recourse to vindicate their rights under the 340B statute and the CMP regulation to receive 340B discounts through contract pharmacy arrangements other than the intervention of this Court.

95. By failing to implement ADR as Congress mandated and as the government represented to the Supreme Court, and by failing to take action on its own initiative to enforce the 340B statute's requirements on manufacturers to honor contract pharmacy arrangements, the Secretary has deprived the Plaintiff Covered Entities of their protected property interests under the Due Process Clause of the Fifth Amendment to the U.S. Constitution, and thereby Defendant has deprived the Plaintiff Covered Entities of their procedural due process rights.

96. Covered entities must be permitted to pursue complaints under the ADR process for overcharges against manufacturers that refuse to honor contract pharmacy arrangements. The Secretary has deprived covered entities of any opportunity to pursue such complaints.

97. By failing to implement ADR regulations as Congress mandated and as the government represented to the Supreme Court it would, and by failing to take action on its own initiative to enforce the 340B statute's requirements on manufacturers to honor contract pharmacy arrangements, the Secretary has caused substantial and irreparable harm to Plaintiffs and all 340B covered entities with contract pharmacy arrangements, as well as to their patients.

COUNT III
VIOLATIONS OF THE ADMINISTRATIVE PROCEDURE ACT

98. Plaintiffs reallege and incorporates by reference paragraphs 1–97 as if fully set forth below.

99. The APA requires a court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

100. The Secretary has unlawfully withheld and unreasonably delayed issuing ADR regulations within the deadline set by Congress. 42 U.S.C. § 256b(d)(3).

101. The Secretary has unlawfully withheld from the Plaintiff Covered Entities their rights to purchase drugs at 340B discounts.

102. The Secretary has unlawfully withheld from the Plaintiff Covered Entities their right to refunds from manufacturers that overcharged the Plaintiff Covered Entities by refusing to honor contract pharmacy arrangements. *Id*. § 256b(d)(1)(B)(ii).

103. The Secretary's refusal to enforce the Plaintiff Covered Entities' rights to purchase and dispense drugs at 340B discounts through contract pharmacy arrangements is arbitrary, capricious, an abuse of discretion, not based upon substantial evidence, and not in accordance with the law, in violation of the APA. 5 U.S.C. § 706(2)(A).

COUNT IV
MANDAMUS

104. Plaintiffs reallege and incorporates by reference paragraphs 1–103 as if fully set forth below.

105. The Secretary has a clear, nondiscretionary duty to promulgate ADR regulations. 42 U.S.C. § 256b(d)(3). The Plaintiff Covered Entities have a clear right to ADR procedures. *Id.* The Plaintiff Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to comply with Congress's mandate to issue ADR regulations.

106. The Secretary has a clear, nondiscretionary duty to ensure that manufacturers sell covered outpatient drugs to the Plaintiff Covered Entities at 340B prices. *Id*. § 256b. The Plaintiff Covered Entities have a clear right to purchase covered outpatient drugs at 340B prices.

Id. The Plaintiff Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to order pharmaceutical manufacturers that have executed PPAs to sell drugs to the Plaintiff Covered Entities at 340B discounts when purchased through contract pharmacies.

107. The Secretary has a clear, nondiscretionary duty to establish "procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers." *Id*. § 256b(d)(1)(B)(ii). The Plaintiff Covered Entities have a clear, nondiscretionary duty to procedures to obtain refunds for overcharges by manufacturers. *Id*. § 256b(d)(1)(B)(ii), (d)(3). The Plaintiff Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to establish procedures enabling the Plaintiff Covered Entities to secure refunds from manufacturers. *See Astra*, 563 U.S. at 113-14.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully requests relief as follows:

1. A declaration that the Plaintiff Covered Entities are entitled to purchase and dispense covered outpatient drugs through contract pharmacies at 340B discounts;

2. An order from this Court directing the Secretary to promulgate ADR regulations within 60 days of the Court's order;

3. An order from this Court directing the Secretary to enforce the Plaintiff Covered Entities' right to purchase and dispense covered outpatient drugs via contract pharmacies at 340B discounts;

4. An order from this Court directing the Secretary to use his authority to order Lilly, Sanofi, AstraZeneca, and Novartis to refund overpayments owed to the Plaintiff Covered

Entities as a result of the refusal to sell covered outpatient drugs at 340B discounts to the Plaintiff Covered Entities when ordered via contract pharmacy arrangements;

5. An order from this Court directing the Secretary to use his authority to impose CMPs upon drug manufacturers Lilly, Sanofi, AstraZeneca, and Novartis unless and until they comply with the requirements of the 340B statute and honor contract pharmacy arrangements;

6. An order from this Court directing the Secretary to revoke the PPA of any pharmaceutical manufacturer that does not offer drugs at 340B discounts when ordered via contract pharmacy arrangements, thereby excluding drugs produced by such manufacturer from coverage under the Medicaid and Medicare Part B insurance programs.

7. An order from this Court awarding the Plaintiff Covered Entities the costs and fees incurred in this litigation and granting such other relief in law and/or equity as this Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a jury trial on all issues triable by a jury as of right.

Respectfully submitted,

/s/ Ronald S. Connelly
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Dated: October 9, 2020