UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

RYAN WHITE CLINICS FOR 340B ACCESS, et al.,

Plaintiffs,

v.

ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 20-cv-2906-KBJ

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF THEIR MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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INTRODUCTION

Right now, patients cannot access lifesaving medications because several drug companies are denying discounted drugs to safety-net health care providers, discounts that are required by the 340B statute, 42 U.S.C. § 256b. The Secretary of Health and Human Services ("Secretary") has failed both to enforce this statute and to provide a statutorily required mechanism for providers to adjudicate this dispute with the drug companies. Plaintiffs therefore respectfully move for a temporary restraining order and preliminary injunction. The requested relief would direct the Secretary and other federal Defendants, pending resolution of this civil action, to enforce Plaintiffs' rights under the 340B program.[1] Absent the requested relief, Plaintiffs and the vulnerable patients that they serve will suffer immediate and irreparable harm.

The drug companies at issue have taken an extreme position that, if unaddressed by the Secretary, will eviscerate the federal 340B drug discount program for thousands of safety-net providers and their patients. For more than 24 years, the clinics and hospitals participating in the 340B program—called "covered entities" under the 340B statute—have been able to dispense their 340B-discounted drugs through community and specialty pharmacies. About one-third of 340B program participants rely on these contract pharmacy arrangements because they are the most effective way of serving their patients. Until just a few weeks ago, absolutely every manufacturer has respected a covered entity's right to dispense its 340B drugs through contract pharmacies, and the government has been unwavering in its expectation that manufacturers do so. Manufacturers that choose to participate in the program—there are currently more than 700—have essentially one obligation: not to charge more than a statutory ceiling price for the outpatient drugs purchased by covered entities. However, in a unilateral move that can only be viewed as a direct repudiation of the statute, four manufacturers have decided not to observe

[1] All federal Defendants are referred to herein collectively as the "Secretary" unless stated otherwise.

their ceiling price obligations for contract pharmacy drugs. This blatant violation of the law jeopardizes one third of the program's participants and is currently depriving uninsured and underinsured patients of affordable medications and services.

The Plaintiffs in this case are "covered entities" that participate in the 340B program and a trade association representing certain covered entities (collectively, the "Covered Entities"). The Covered Entities qualify for the 340B program because they serve the most vulnerable Americans, including people living with HIV/AIDs, rural communities, and the homeless. Under the 340B program, drug companies voluntarily agree to provide discounted drugs to covered entities in exchange for the Secretary permitting the companies to participate in the federal Medicaid and Medicare Part B insurance programs. The program therefore costs taxpayers nothing while benefiting heath care providers that survive on paper thin margins and also drug companies that earn the privilege of participating in federal health insurance programs.

For 24 years, covered entities have used contract pharmacies to obtain 340B discounted drugs. Under these arrangements, a covered entity purchases a discounted drug and directs delivery to a third-party pharmacy, where it is picked up by the patient. This system is necessary for several reasons. Some covered entities are too small to operate their own pharmacies. Also, many covered entities serve large geographic areas, and it is not feasible for their patients to travel long distances to obtain their prescriptions from the covered entity itself. Indeed, this system should be familiar to anyone who has ever had a prescription. Rarely does anyone receive a prescription drug from their health care provider's in-house pharmacy. The benefits of receiving prescription drugs at the neighborhood pharmacy are obvious—the pharmacy is conveniently close to home, thus promoting adherence to the medication regimen.

Contract pharmacy arrangements are used by one out of three covered entities.[2] Inexplicably, in the middle of a pandemic, four drug companies suddenly decided to stop selling drugs at 340B discounts when those drugs are shipped to contract pharmacies or to severely restrict those sales. Three companies, Eli Lilly and Company ("Lilly"), AstraZeneca PLC ("AstraZeneca") and Sanofi-Aventis U.S. LLC ("Sanofi"), will not provide 340B discounts at all when the drug is shipped to a contract pharmacy. A fourth company, Novartis Pharmaceuticals Corporation ("Novartis"), will only honor contract pharmacy arrangements within 40 miles of covered entities that are hospitals. (Collectively, Plaintiffs refer to Lilly, Sanofi, AstraZeneca, and Novartis as the "Drug Companies.")[3] The Drug Companies' actions violate the 340B statute and implementing regulation.

The Secretary *agrees* with the Covered Entities that the 340B statute obligates participating drug companies to furnish discounted drugs through contract pharmacy arrangements. This has been the Secretary's unwavering interpretation of the 340B statute since 1996. In 2017, the Secretary promulgated a regulation expressly defining manufacturer overcharges as including orders placed by covered entities through their agents, which includes contract pharmacies. 42 C.F.R. § 10.11(b)(1). Nonetheless, the Secretary has taken no action against the Drug Companies and has not explained why he permits them to flout the law.

The Covered Entities are wholly reliant upon the Secretary to vindicate their rights. All other paths to bring the Drug Companies into compliance have been cut off. One of the four Drug Companies, AstraZeneca, fought all the way to the Supreme Court to establish that 340B

[2] https://www.gao.gov/assets/700/692697.pdf (last reviewed Nov. 2020).

[3] The actions of each of these manufacturers has not affected all of the Plaintiffs. For example, one of these manufacturers has adopted different policies with respect to covered entities that are hospitals and covered entities that are grantees, another granted an individualized exception to its policy to one of the Plaintiffs and another Plaintiff does not purchase drugs from each of the manufacturers. In the interest of brevity, however, we refer to the drug manufacturers collectively.

covered entities cannot sue drug companies for violating 340B requirements. *Astra USA v. County of Santa Clara*, 563 U.S. 110 (2011) ("*Astra*"). This should have left covered entities with administrative remedies because in 2010 Congress required the Secretary to establish a 340B administrative dispute resolution ("ADR") process no later than September 19, 2010. Indeed, the Court's holding that 340B covered entities cannot sue drug companies was based upon the Secretary's assurance that ADR regulations would be forthcoming. *Id.*, 563 U.S. at 116. More than ten years after Congress's September 19, 2010 deadline, the Secretary has still not implemented ADR regulations. Only after this suit was filed, the Secretary sent ADR regulations to the Office of Management and Budget ("OMB") for approval.

The contents of the ADR regulations are not public and, if they are approved by OMB, will not take effect until it is too late to remedy the harms caused by the Secretary's inaction. They will surely establish a process that stretches into months if not years. Meanwhile, the Covered Entities and their patients are suffering irreparable harms. The Covered Entities are losing discounts that support many of their key health care programs. Some covered entities may even become insolvent. Patients will lose access to inexpensive medications that they need to survive. Such an outcome would be tragic at any time, but in the midst of the COVID-19 pandemic, it is unconscionable.

The Secretary's failure to implement ADR regulations violates the Covered Entities rights to Due Process under the Fifth Amendment. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). This Court has broad equitable powers to remedy the Secretary's due process violation. *See Milliken v. Bradley*, 433 U.S. 267, 281-282 (1977). To remedy the Secretary's violation, the Court should order the Secretary to issue ADR regulations within 60 days, issue a declaration that the 340B statute entitles covered entities to purchase covered outpatient drugs at

340B discounts, and order the Secretary to enforce the Covered Entities' rights to 340B discounts for contract pharmacy orders.

LEGAL BACKGROUND

I. The 340B Program

The 340B program provides significant discounts on drugs to safety-net healthcare providers *at no cost to the federal government*. The discounts are provided by drug companies in exchange for the privilege of their products being covered under the federal Medicaid and Medicare Part B insurance programs. Congress established the 340B program in 1992 by adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b. Veterans Health Care Act of 1992, Pub. L. No. g-585, § 602, 106 Stat. 4943, 4967-71. Section 340B (along with provisions of the Medicaid statute) requires the Secretary to execute Pharmaceutical Pricing Agreements ("PPAs") with manufacturers as a condition of their participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1). 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 set by a statutory formula. *Id.* § 256b(a)(1)-(2). The Secretary has delegated authority to administer the 340B program to the Health Resources and Services Administration ("HRSA), a unit of the Department of Health and Human Services ("HHS").

Health care providers that participate in the 340B program serve as the nation's healthcare "safety net," providing health care to the neediest individuals, regardless of ability to pay. The 340B statute limits participation in the program to certain defined health care providers, referred to as "covered entities." 42 U.S.C. § 256b(a)(4). Each category of covered entity receives some form of federal assistance to treat the nation's most vulnerable patients.

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). By spending less on medications, covered entities can devote more of their precious resources to patient care. The program is a vital and indispensable tool to help offset the costs of uncompensated or under-compensated care. Without the 340B program, taxpayers would have to absorb the costs of uncompensated care or covered entities would be forced to restrict access to services or even cease operations.

The program is designed to permit covered entities to determine how best to use the discounts. Many covered entities choose to pass the discounts on to their most needy patients, particularly the uninsured. For patients with health insurance, covered entities are typically paid for the drugs by the health insurer at a rate set by the insurer. The difference between the insurer's rate and the discount is income to the covered entity to supplement federal funds, thus stretching scarce federal resources as far as possible and enabling the covered entity to reach more eligible patients and provide more comprehensive services. *Id.* This is exactly how Congress intended the program to function.

The Covered Entities that are plaintiffs to this suit qualify under three categories: Ryan White clinics, FQHCs, and sole community hospitals. The 340B statute defines a Ryan White clinic as: "[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)." 42 U.S.C. § 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). 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. Part C grantees are small "local community-based organizations." *See* HRSA, *Part C: Early Intervention Services and Capacity Development Program Grants*.[4] Many Part C grantees lack the financial resources to operate an in-house pharmacy.

The second category of Plaintiffs is a type of primary care clinic known as Federally-qualified health centers ("FQHCs"), which are defined at 42 U.S.C. 1396d(l)(2)(B); 42 U.S.C. § 256b(a)(4)(A). FQHCs must provide "care on a sliding fee scale based on ability to pay." HRSA, *Federally Qualified Health Centers*.[5] An FQHC is an entity that provides "required primary health services" to "a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or *through contracts or cooperative arrangements*." 42 U.S.C. § 254b(a)(1) (emphasis added). Pharmaceutical services are among the "required primary health services" that an FQHC must provide. *Id.* § 254b(b)(1)(A)(i)(V). An FQHC "look alike" or FQHC-LA is category of FQHC that meets the same requirements as an FQHC, but does not receive federal grant funding. 42 U.S.C. § 1396d(l)(2)(B)(iii).

The third Plaintiff category, sole community hospitals ("SCHs"), also qualify as covered entities under the 340B statute. 42 U.S.C. § 256b(a)(4)(O). The Centers for Medicare and Medicaid Services ("CMS") designates hospitals that meet certain criteria as SCHs. *Id*. at § 1395ww(d)(5)(C)(iii); 42 C.F.R. § 412.92. As its names implies, an SCH is typically a hospital that is the only provider of general acute-care inpatient services in a rural service area. *Id*.

[4] https://hab.hrsa.gov/about-ryan-white-hivaids-program/part-c-early-intervention-services-and-capacity-development-program-grants (last reviewed Oct. 2020).
[5] https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index html (last reviewed May 2018).

II. 340B Contract Pharmacies

Many 340B covered entities, including the 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 do not "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"). Consequently, most covered entities participate in the 340B program by contracting with third-party pharmacies. In a contract pharmacy arrangement, a covered entity orders 340B discounted drugs, which are then shipped to the contract pharmacy, where the patient takes possession of the medication.

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.

In 1995, the Secretary 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 (Nov. 1, 1995). In 1996, after considering comments submitted in response to its November 1, 1995 notice, the Secretary 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). Under these arrangements, the covered entities purchase 340B drugs from manufacturers and direct the manufacturers to ship the 340B drugs to the contract pharmacy. In the August 23, 1996, guidance, the Secretary noted that "many covered entities … do not operate their own licensed pharmacies." *Id.* at 43,549. The Secretary 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 "encourage[d]" covered entities that did not operate their own licensed pharmacies to utilize contract pharmacy services. *Id.* at 43,555. The Secretary'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 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.

Id. at 43,549-50.

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

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

Id. at 43,550. The Secretary was also clear that covered entity arrangements with contract pharmacies are agency relationships. *Id.*[6]

Although the Secretary indicated that the 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," he 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. In 2010, the Secretary published a notice that clarifying that covered entities may contract with multiple pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010). The Secretary responded to a comment regarding its action as follows:

> Comment: The proposed revisions 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.

[6] "ODP" is the Office of Drug Pricing within HRSA.

> 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.

III. 340B Administrative Dispute Resolution

On March 23, 2010, Congress enacted the Affordable Care Act, a major reform to health insurance and delivery in America. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 823 (2010) ("ACA"). The ACA also amended the 340B program in several respects, including mandating 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 . . . 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)). The Secretary's 180-day deadline to promulgate ADR regulations fell on September 19, 2010.

A day after the deadline, 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).

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 drug 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.

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*.[7] Only after this suit was filed, the Secretary sent ADR regulations to OMB for final approval. Those regulations have not been published.

IV. Temporary Restraining Orders and Preliminary Injunctions

Courts consider the same factors when ruling on a motion for a temporary restraining order. *Morgan Stanley DW Inc. v. Rothe,* 150 F.Supp.2d 67, 72 (D.D.C. 2001). A party is entitled to a temporary restraining order or a preliminary injunction when the following criteria have been met: (1) there is a substantial likelihood of success on the merits; (2) the moving party would suffer irreparable injury if the preliminary injunction was not granted; (3) the preliminary injunction would not substantially injure the other party; and (4) the preliminary injunction would further the public interest. *Id*. (citations omitted). All four criteria must be considered together, and "no one factor is necessarily dispositive as to whether … relief is warranted." *See also League of Women Voters v. Newby*, 838 F.3d 1, 6 (D.C. Cir. 2016). Parties seeking a temporary restraining order or preliminary injunction "are not required to prove their case in full at the preliminary injunction stage, but only such portions that enable them to obtain the injunctive relief that they seek." *Jacinto-Castanon de Nolasco v. U.S. Immigration & Customs*

[7] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90 (last visited Nov. 22, 2020).

Enf't, 319 F. Supp. 3d 491, 499 (D.D.C. 2018). At the preliminary injunction stage, this Court has routinely granted the moving parties' requested relief upon a finding that the moving party is "likely to succeed on at least one of their claims." *Id*.

FACTUAL BACKGROUND

Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, four out of 700 manufacturers participating in the 340B program announced that they would either refuse to honor contract pharmacy arrangements or impose onerous conditions on contract pharmacy arrangements.

I. The Four Drug Companies

Lilly. On July 1, 2020, HRSA published a "limited distribution plan" on its official manufacturer notices website for several formulations of Lilly's drug Cialis. HRSA, *Manufacturer Notices to Covered Entities* (July 2020).[8] 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*. Lilly later expanded its policy to all its retail drug products, with a qualified exception for its insulin products:

> 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).[9]

[8] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

[9] https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf.

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.

In response to a reporter's inquiry about Lilly's refusal 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).[10]

Sanofi. In July 2020, 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. Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020).[11]

AstraZeneca. In August 2020, AstraZeneca issued letters to 340B covered entities, including the 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).[12]

Novartis. Like Sanofi, Novartis sent letters to the Covered Entities requesting them to

[10] https://340breport.substack.com/p/breaking-hrsa-is-investigating-whether.
[11] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.
[12] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.

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 Covered Entities' patients at contract pharmacies as a condition of receiving 340B discounts. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020). Novartis has since retreated, in part. By letter dated October 30, 2020, Novartis informed covered entities that "all federal grantees, including Ryan White Clinics and Community Health Centers, will continue to receive 340B discounts" at contract pharmacies. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020). The letter also stated that, effective November 16, 2020, Novartis will honor contract pharmacy arrangements with 340B hospitals if the contract pharmacy is located within a 40-mile radius of the main hospital facility. *Id*.

II. Covered Entities' Requests for Help From the Secretary

Numerous 340B stakeholders have asked the Secretary to take action against the Drug Companies by enforcing 340B program requirements. In mid-July 2020, the 340B Coalition, a group of 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).[13] In August 2020, the trade association, National Association of Chain Drug Stores, asked the Secretary 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).[14] In September 2020, a bipartisan group of 243 members of the U.S. House of Representatives wrote to the Secretary urging him to act against Lilly, Sanofi, and AstraZeneca due to their refusals to honor 340B contract pharmacy

[13] https://www.dropbox.com/s/2m4mjvtx1dwpkyu/340B%20Coalition%20Letter%20to%20HHS%2007.16.2020.pdf.
[14] https://strategichealthcare net/wp-content/uploads/2020/08/NACDS-letter.pdf.

arrangements. Letter from David B. McKinley *et al*., Members of Cong., to Alex M. Azar II, Sec'y, HHS (Sept. 14, 2020).[15]

By letter dated September 11, 2020, Plaintiff RWC-340B 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).[16] 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 civil monetary penalties ("CMPs") against Lilly, Sanofi, Novartis, and AstraZeneca. *Id*. The Secretary neither responded to these letters nor took the requested actions.

ARGUMENT

The Covered Entities are entitled to immediate relief while this litigation proceeds and a temporary restraining order and preliminary injunction is the proper remedy to compel the Secretary to enforce the Covered Entities' rights under the 340B statute. The Covered Entities have a substantial likelihood of success on the merits because the Secretary has violated the Covered Entities' rights to Due Process under the Fifth Amendment by depriving them of congressionally mandated ADR procedures. The Secretary's constitutional violation has left the Covered Entities with no recourse to vindicate their rights to 340B contract pharmacy arrangements. Without contract pharmacy purchases, the Covered Entities have no way to participate in the program. They are losing critical funds every day, and their patients are suffering.

The Covered Entities purchased 340B discounted drugs from the Drug Companies before

[15] https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf.
[16] https://www.rwc340b.org/wp-content/uploads/2020/09/Letter-to-HHS-on-Mfr-Actions-from-RWC340B-9-11-2020.pdf.

they halted 340B sales through contract pharmacy arrangements, and the loss of 340B savings has caused the Covered Entities to suffer immediate and irreparable harm by impeding their ability to provide critical health care services. The Secretary and other federal Defendants will not be harmed because 340B discounts do not come from federal funds, and the requested relief will preserve the *status quo* of the 340B program as it currently operates. Immediate relief will serve the public interest because it will enable the Covered Entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive care" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992). The Court should, therefore, order the Secretary to immediately enforce 340B program requirements by directing the Drug Companies to honor the Covered Entities' contract pharmacy agreements.

I. The Covered Entities are Likely to Succeed on the Merits

The Covered Entities are likely to succeed in demonstrating that the Secretary's failure to promulgate ADR regulations has deprived the Covered Entities of a property interest protected by the Due Process Clause of the Fifth Amendment and that the Covered Entities are entitled to a writ of mandamus and an APA injunction compelling the Secretary to issue ADR regulations. The Secretary's failure to issue ADR regulations has left the Covered Entities with no way to vindicate their rights to contract pharmacy arrangements.

A. The Covered Entities Are Likely to Succeed on the Merits of Their Claims That the Secretary Must Issue ADR Regulations

1. The Secretary Has Violated Plaintiffs' Due Process Rights by Withholding the ADR Cause of Action

The Covered Entities have a property interest in ADR procedures that is protected by the Due Process Clause. The Secretary missed the statutory deadline for ADR by more than a decade. The Secretary has thus deprived the Plaintiff Covered entities of this protected property interest by failing to implement 340B ADR procedures. The Secretary's failure leaves the

Covered Entities at the mercy of the Drug Manufacturers, which are now depriving the Covered Entities of 340B discounts that they desperately need to maintain their operations and provide health care to the nation's neediest individuals. Remedying this serious constitutional deprivation now requires more than just ADR regulations. The Court should direct the Secretary to affirm the Covered Entities' right to purchase covered outpatient drugs at 340B discounts via contract pharmacy arrangements.

The Fifth Amendment's Due Process Clause protects individuals' property interests and requires that no person be deprived of his or her property without due process of law. *Kelley v. D.C.*, 893 F. Supp. 2d 115, 123 (D.D.C. 2012). A cause of action is a property interest protected by the Due Process Clause. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982) ("a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause.")[17]; *Patchak v. Jewell*, 828 F.3d 995 (D.C. Cir. 2016) ("The Supreme Court has 'affirmatively settled' that a cause of action is a species of property requiring due process protection." (quoting *Zimmerman Brush Co.*, 455 U.S. at 428)). In 2010, Congress created an ADR cause of action for covered entities and directed the Secretary to issue 340B ADR regulations: "not later than 180 days after March 23, 2010, 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." 42 U.S.C. § 256b(d)(3)(A).

The Secretary's deadline to issue ADR regulations was September 19, 2010, which was 180 days from March 23, 2010. We are now more than ten years past the deadline, and the

[17] The Court's holding applies equally to the Fifth Amendment. *See Silverman v. Barry*, 727 F.2d 1121, 1125 (D.C. Cir. 1984) (applying *Zimmerman Brush* to Fifth Amendment claim against the District of Columbia); *see also English v. District of Columbia*, 717 F.3d 968, 972 (D.C. Cir. 2013) ("The procedural due process protections under the Fifth and Fourteenth Amendments are the same.").

Secretary has still not promulgated regulations to establish and implement an ADR process as required by Congress. The Secretary has, therefore, deprived the Covered Entities of their property interest in the ADR cause of action. *Zimmerman Brush Co.*, 455 U.S. at 428.

2. APA and Mandamus: the Secretary has Unlawfully Withheld and Unreasonably Delayed ADR Regulations

The Covered Entities are entitled to a writ of mandamus, 28 U.S.C. § 1361, and an order compelling agency action unlawfully withheld and unreasonably delayed, 5 U.S.C. 706(1). The Covered Entities meet the three jurisdictional requirements for mandamus: "(1) the plaintiff has a clear right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to plaintiff." *Power v. Barnhar*t, 292 F.3d 781, 784 (D.C. Cir. 2002) (quoting *Northern States Power Co. v. U.S. Dept. of Energy*, 128 F.3d 754, 758 (D.C. Cir. 1997)).

Here, the Secretary has a clear, nondiscretionary duty to promulgate ADR regulations. 42 U.S.C. § 256b(d)(3). Congress used the mandatory term "shall" when directing the Secretary to promulgate the regulations: "Not later than 180 days after March 23, 2010, the Secretary *shall* promulgate [ADR] regulations . . ." *Id.* § 256b(d)(3)(A) (emphasis added). The Covered Entities have a clear right to ADR procedures and the Secretary has failed to promulgate these procedures for a decade. *Id.* The Covered Entities have no adequate remedy available other than an order from this Court directing the Secretary to comply with Congress's mandate.

In cases alleging an unlawful delay, the D.C. Circuit has established a six-factor inquiry to determine whether to order an agency to act. *Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) ("*TRAC*"). This inquiry applies in both mandamus and APA cases. *Id.*, at 79. The "*TRAC* factors," consider the following: 1) the time agencies take to make decisions must be governed by a "rule of reason"; 2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed, that statutory scheme

may supply the basis for the "rule of reason"; 3) delays in the sphere of economic regulation are more tolerable than delays when human health and welfare are at stake; 4) the court should consider the effect of expediting delayed action on agency priorities; 5) the court should also take into account the nature and extent of the interests prejudiced by the delay; and 6) the court is not required to find any "impropriety" in the agency's delay. *Id.*, at 80. No single factor in this analysis is dispositive, and a court will for weigh the factors against each other and against the plaintiff's cause for equitable action. *Id.*

The Covered Entities satisfy the *TRAC* test for an order compelling the Secretary to issue ADR regulations. The first and second factors are easily met—the "rule of reason" to be used in determining the time for issuing ADR regulations is directly specified in the ACA, which required the Secretary to issue regulations within 180 days of enactment. 42 U.S.C. § 256b(d)(3)(A). The third factor is also met because human health and welfare is at stake.

The fourth factor is also met. The Secretary has already promulgated a final ADR rule, which purportedly is at OMB. The Secretary only needs to follow through and publish it in final form. No further effort is required to put the rule into effect. The Covered Entities also satisfy the fifth factor. Congress mandated 340B discounts, and the Drug Companies are now overcharging the Covered Entities by refusing to provide discounts for drugs shipped to contract pharmacies. The Secretary's inaction hampers Congress's goal of enabling covered entities to treat more patients and provide more services. Finally, the sixth factor also weighs in favor of the Covered Entities. Although the Court is not required to find impropriety, the Secretary's ten-year delay is plainly improper.

Therefore, all six *TRAC* factors weigh in favor of the Covered Entities. The Secretary has unlawfully withheld and unreasonably delayed the Covered Entities' statutory right to ADR

regulations. The Court should issue a writ of mandamus and an injunction on the APA ordering the Secretary to issue ADR regulations within 60 days.

B. The 340B Statute Entitles the Covered Entities to Purchase and Dispense Drugs at 340B Discounts Through Contract Pharmacy Arrangements

The 340B statute provides the Covered Entities the right to purchase and dispense drugs at 340B discounts through contract pharmacy arrangements. 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 Secretary has acknowledged since 1996 that the 340B statute requires pharmaceutical manufacturers to offer these discounted prices without any restrictions on the delivery location, including to contract pharmacies. Contract Pharmacy Notice, 61 Fed. Reg. at 43,551.

The 340B statute entitles covered entities to purchase 340B drugs via contract pharmacy arrangements. The statute focuses entirely on the *purchase* of drugs, not the delivery location of the drugs. This is apparent from the beginning of the statute, which is titled, "limitation on prices of drugs purchased by covered entities." 42 U.S.C. § 256b. The manufacturer's PPA with the Secretary "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 statute directs the Secretary to assess CMPs on "any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds" the 340B ceiling price. *Id.* § 256b(d)(1)(B)(vi)(III).

The Secretary has correctly stated that the statute does not permit drug companies selectively to refuse purchases at 340B discounts based upon the delivery location of the drugs:

> 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.

Indeed, two types of covered entities are expressly authorized by statute to use contract pharmacy arrangements. The statutory term "covered entity" includes FQHCs "as defined in section 1905(l)(2)(B) of the Social Security Act," 42 U.S.C. 1396d(l)(2)(B). 42 U.S.C. § 256b(a)(4)(A). Section 1905(l)(2)(B) of the Social Security Act defines an FQHC as an entity that "meets the requirements to receive a grant under section 254b of this title." 42 U.S.C. § 1396d(l)(2)(B). Section 254b obligates FQHCs to furnish certain "required primary health services," which includes "pharmaceutical services as may be appropriate for particular centers." 42 U.S.C. § 254b(b)(1)(A)(i)(V). An FQHC must provide these required primary health services, including pharmaceutical services, "either through the staff and supporting resources of the center or *through contracts or cooperative arrangements*." *Id.* § 256b(b)(a)(1) (emphasis added). Thus, an FQHC covered entity is defined as one that provides pharmacy service "through contracts."

Another category of covered entity, Ryan White Part D grantees, is also expressly authorized by statute to use contract pharmacies. "Covered entity" includes "Any entity receiving assistance under subchapter XXIV" of the Public Health Service Act, which spans 42 U.S.C. §§ 300ff–300ff-140. 42 U.S.C. § 256b(a)(4)(J). Subchapter XXIV includes the Ryan White Part D grant program at 42 U.S.C. § 300ff-71. Part D grantees must provide "family-

centered care involving outpatient or ambulatory care (directly or *through contracts or memoranda of understanding*) for women, infants, children, and youth with HIV/AIDS." *Id.* § 300ff-71(a) (emphasis added). Thus, contract pharmacy arrangements are incorporated by reference in the definition of Ryan White Part D covered entities.

When it enacted the 340B statute, Congress included in the definition of "covered entity" organizations that generally do not have in-house pharmacies, such as Ryan White CARE Act Part D grantees, FQHCs, and FQHC-LAs. *See* 42 U.S.C. § 256b(a)(4)(D). By including these types of covered entity organization, Congress clearly intended that maintaining in-house pharmacy is not a condition for participation in the 340B program. Congress also intended, therefore, that as a condition of participation in Medicaid and Medicare Part B, drug manufacturers must provide 340B pricing to covered entities that order covered outpatient drugs for delivery to contract pharmacies.

Congress has known for decades that "many health care facilities do not maintain their own onsite pharmaceutical services. Rather, they look to the community pharmacist to provide such services on a contract basis." Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and Means, 91 Cong. 2129 (1969) (Statement of Jacob W. Miller). Congress has also long been aware that contract pharmacy arrangements are common in the 340B program. For example, in 2005, Congress considered a bill that would have expressly authorized the "use of *multiple* contract pharmacies." Healthy America Act of 2005, S. 4, 109th Cong. § 332 (2005) (emphasis added). Congress knew that contract pharmacies were already used by 340B covered entities and wanted to clarify that multiple contract pharmacies could be used.

The Secretary has also recognized the Covered Entities' rights to purchase 340B drugs through contract pharmacies in the manufacturer CMP Final Rule. 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 and 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(a), (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. When finalizing the CMP final rule, the Secretary stated that "All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply ***regardless of the distribution system***." CMP Final Rule, 82 Fed. Reg. at 1,225.

Thus, the Drug Companies are violating the 340B statute and the CMP regulations by refusing to sell their drugs through the Covered Entities' contract pharmacy arrangements. The Secretary has failed to protect the Covered Entities' rights under the 340B statute by permitting the Drug Companies to overcharge the Covered Entities for drugs subject to 340B discounts.

II. The Covered Entities Will Continue to Suffer Irreparable Harm in the Absence of the Requested Relief

As described above, HRSA has abandoned its responsibility to enforce the 340B statute's requirements for contract pharmacies. The results of HRSA's inaction are severe: 1) financially needy patients will no longer have access to discounted drugs and will forgo taking prescribed medications or request less costly medications that may not be as efficacious; 2) some Covered Entities will have to reduce or eliminate the services that they provide to patients, resulting in harm to their patients, an increase in the need for more expensive healthcare services and creating obstacles to the ability of the Covered Entities to carry out their safety net missions; 3)

the Covered Entities are deprived of their due process rights; and 4) other manufacturers will be emboldened to stop providing 340B discounts at contract pharmacies, causing some Covered Entities to close operations.[18]

In order to show irreparable harm, the movant must demonstrate that: (1) the harm is "'certain and great,' 'actual and not theoretical,' and so 'imminent that there is a clear and present need for equitable relief to prevent irreparable harm;'" and (2) the harm is "beyond remediation." *Nat'l Fair Hous. All. v. Carson*, 330 F. Supp. 3d 14 (D.D.C. 2018) (citing *League of Women Voters*, 838 F.3d at 7-8). In addition, the movant must show "a real and immediate — as opposed to merely conjectural or hypothetical — threat of future injury." *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 2020 WL 5232076 at *9 (D.D.C. 2020) (quoting *Nat. Res. Def. Council v. Pena*, 147 F.3d 1012, 1022 (D.C. Cir. 1998)), but is only required to show, "a threat of irreparable harm, not that irreparable harm already has[s] occurred." *New York v. United States Dep't of Homeland Se*c., 408 F. Supp. 3d 334, 350 (S.D.N.Y. 2019), aff'd as modified, 969 F.3d 42 (2d Cir. 2020). In this case, irreparable harm has already occurred and will continue unless HRSA takes action to enforce its contract pharmacy guidelines.

A. The Secretary's Inaction Causes Irreparable Harm to Covered Entities and Their Patients

The Covered Entities, members of RWC-340B, and their patients are suffering harm in myriad ways, and will continue to suffer harm, as the result of the Secretary's failure to enforce

[18] These harms are more fully described in the attached affidavits (Ex. A-G). These affidavits are submitted, respectively, by Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Health Care Inc. (Ex. A, "Auclair."); Shannon Stephenson, CPA, MBA, CEO of Chattanooga C.A.R.E.S. DBA Cempa Community Care (Ex. B, "Stephenson."); Cynthia T. Burton, R.N., CEO of Matthew 25 AIDS Services, Inc. (Ex. C, "Burton."); Craig Glover, MBA, MA, FACHE, CMPE, CEO of WomenCare, Inc., dba FamilyCare Health Center (Ex. D, "Glover"); Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (Ex. E, "Dickerson"); Ex. F, Peter Johnson, Rph., Chief of Pharmacy and Ancillary Services at Springhill Medical Center (Ex. F, "Johnson"); James Daniel Duck, owner of The Corner Drug Store (Ex. G, "Duck").

contract pharmacy requirements. First, the Covered Entities offer discounts on drugs to financially need patients through contract pharmacy arrangements and these programs are premised on the Covered Entity being able to purchase the drugs at 340B discounted prices. Two Covered Entities have drug discount programs for financially needy patients under which the Covered Entity charges the patient only the amount that the Covered Entity pays for the drug. Glover Aff. ¶ 17; Johnson Aff. ¶ 11. Because the 340B discounted price, however, is significantly lower than non-340B prices, patients that relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30; Johnson Aff. ¶¶ 12, 15; Duck Aff. ¶¶ 7-8, 10-11, 15-16, 18. As one example, due to the Secretary's inaction, the cost filling a prescription for Lantus®, a very effective and widely prescribed insulin product manufactured by Sanofi, increased from $17.20 (340B price) to $1360.57 (non-340B price) for patients of Springhill seeking to fill their prescriptions at a contract pharmacy. Johnson Aff. ¶ 12; Duck Aff. ¶¶ 7-8, 10-11. At least two financially needy individuals were not able to fill the prescription at the $1360.57 price. Johnson Aff. ¶ 12; Duck Aff. ¶¶ 8-9, 11-12. One individual returned to fill the Lantus® prescription and requested that the pharmacy submit a claim for the drug using the individual's Medicare benefits, which required a copayment of $300 that the patient said she would not be able to afford in the following month. Duck Aff. ¶ 9. The other individual returned with a prescription for an insulin product that is available at 340B pricing because it is not manufactured by one of the Drug Companies. Johnson Aff. ¶ 12; Duck Aff. ¶ 12. For patients that are dependent on a certain formulation of insulin, switching to another product often requires multiple trips to the physician and blood sugar tests. Johnson Aff. ¶ 13; Duck Aff. ¶ 5. Moreover, for some diabetics, one formulation of insulin works best for them and switching to another product is not optimal for their health. Johnson Aff. ¶ 13. A Springhill

patient with multiple heart conditions presented a prescription for the blood thinner Brilinta® produced by AstraZeneca at a Springhill contract pharmacy. Because the non-340B price for Brilinta® is more than triple the 340B price, the patient left the pharmacy without the drugs. Duck Aff. ¶¶ 16-17. The patient's inability to purchase the Brilinta® because of the increased cost will have obvious and detrimental effects on the patient's health.

Lilly has made a tiny concession to allow covered entities to designate one pharmacy as a contract pharmacy if they do not operate their own retail pharmacies, but this concession still means that financially needy patients are left without 340B drugs. Springhill is located in a rural area and has a wide service area. One of its outpatient clinics is located in Homer, Louisiana, which is over thirty miles from Springhill's main facility. Johnson Aff. ¶ 18. Springhill had two contract pharmacy arrangements in Homer to allow financially needy patients to access its drug discount program. Springhill has named The Corner Drug Store, located close to Springhill, as its designated contract pharmacy under Lilly's policy. Johnson Aff. ¶ 18; Duck Aff. ¶ 2. The result is that a patient who is eligible for Springhill's drug discount program, who lives in Homer and receives services at the Springhill clinic located in Homer, will have to drive over thirty miles to fill his or her prescription at the Corner Drug Store in Springhill in order to obtain the 340B discounted price for the drug. Johnson Aff. ¶ 18.

Similarly, the drug manufacturer Novartis has adopted a policy applicable to Covered Entity hospitals that limits their contract pharmacy arrangements to a 40-mile limit around the main facility. Springhill has contract pharmacy arrangements with specialty pharmacies that are located more than 40 miles from its main facility. Johnson Aff. ¶ 19. Many drugs are available only through specialty pharmacies due to a manufacturer's limited distribution networks and/or special storage and handling requirements. Because of the Novartis 40-mile restriction,

Springhill's financially needy patients will not be able to access 340B discounts for the specialty drugs dispensed by these pharmacies. Johnson Aff. ¶ 19.

Other Covered Entities subsidize the costs of drugs for their financially needy patients under their drug discount programs. Under these programs, the patient does not incur any cost for the drug, or pays a percentage of the cost of the drug, depending on the patient's income level. Auclair Aff. ¶ 18; Stephenson Aff. ¶ 15. The Covered Entities that offer these programs are now bearing the increased cost of drugs produced by the Drug Companies and filled at contract pharmacies. Auclair Aff. ¶¶ 21, 30; Stephenson Aff. ¶ 16. These Covered Entities, however, will struggle financially if they are forced to continue to bear these increased costs. Auclair Aff. ¶¶ 31-34. The CEO of Little Rivers, Gail Auclair, reviewed the increase for two drugs that some its uninsured patients are currently prescribed from a 340B price to a non-340B price and found that the cost of a 30-day supply of Humulin®, an insulin product manufactured by Lilly for which no biosimilar is available, increased from $117.24 to $450.17.[19] Auclair Aff. ¶ 33. Ms. Auclair found that the cost of Bevespi Aerosphere®, an inhaler produced by AstraZeneca to treat chronic obstructive pulmonary disorder, and for which no generic substitute is available, increased from $198.42 to $1910.13. Auclair Aff. ¶ 34. Little Rivers has operated at a loss for the last two fiscal years does not have the financial resources to bear these costs. [20] Auclair Aff. ¶ 34; Ex. H. The increased costs to Little Rivers to pay for the drugs under its drug discount program will exacerbate its already precarious financial position.

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[19] The ever-increasing cost of insulin is well publicized, with several products increasing from about $93 in 2019 to close to $300 in 2019. Rachel Gillett & Shayanne Gal, *One Chart Reveals How the Cost of Insulin Has Skyrocketed in the US, Even Though Nothing About it Has Changed*, Business Insider (Sept. 18, 2019) https://www.businessinsider.com/insulin-price-increased-last-decade-chart-2019-9. The cost of HIV/AIDS anti-retroviral drugs is also exorbitant. Burton Aff. ¶ 10 (estimating the co-payment for some anti-retroviral drugs, used to suppress the HIV/AIDS virus, is as much as $5,000 per month).

[20] Little Rivers 2019 Annual Report, https://irp-cdn multiscreensite.com/cca16267/files/uploaded/FY2019%20Annual%20Report_gx0WPXrQb2KqTNIv6OIZ.pdf (Ex. H).

Lilly has made a meaningless exception to allow contact pharmacies to offer insulin through contract pharmacies if four conditions are met.[21] However, these four requirements make the exception totally unworkable and legally suspect. For example, one of the requirements is that the pharmacy not charge a dispensing fee for providing the drug. While this requirement may seem at first glance to be laudable; in fact, it could subject the Covered Entities to violations of the federal law that prohibits offering financial inducements to patients.[22] 42 U.S.C. § 1320a-7a(a)(5). Moreover, it is entirely impractical to expect a pharmacy to fill a prescription for free. Johnson Aff. ¶ 16. Thus, the Covered Entities will not be able to use Lilly's insulin exception for their patients.

Second, the Covered Entities also use the revenues from payments for 340B drugs to subsidize the cost of important and life-saving health care and support programs for their patients. For Covered Entities that are federal grantees, examples of these services include case management services to assistance patients with transportation, insurance enrollment, linkage to affordable housing, food access, patient care advocacy, in-home support, education for chronic health care conditions, and food pantries. Auclair Aff. ¶¶ 12-16, 22; Burton Aff. ¶¶ 13-14; Glover Aff. ¶¶ 11, 14-15. Without care coordinators, many patients will not be able to access the health care that they need or obtain affordable housing or food. These services are critical in preventing patients' health from deteriorating. Care coordination is particularly important for homeless and indigent individuals, who require additional support services to ensure that they

[21] The four exceptions are: (1) Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price at the point-of-sale; (2) Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin; (3) No insurer or payer is billed for the Lilly insulin dispensed; and (4) The covered entity provides claim-level detail demonstrating satisfaction of these terms and conditions.

[22] Offering inducements to Medicare or Medicaid beneficiaries can subject a provider or supplier of services that are payable by Medicare or Medicaid to Civil Monetary Penalties. 42 U.S.C. § 1320a-7a(a)(5). While there are exceptions to the prohibition against offering patient inducements, routinely providing drugs free of charge to all patients, regardless of ability to pay is not one of the exceptions. 42 U.S.C. § 1320a-7a(i)(6); 42 C.F.R. § 1003.110 .

continue to receive necessary health care services. Auclair Aff. ¶ 17; Burton Aff. ¶ 14; Glover Aff. ¶ 26. Education and in-home assistance for patients with chronic health conditions is also vitally important to manage the patients' diseases and prevent the need for more costly care. Glover Aff. ¶¶ 15, 27. 340B revenues also enable the Covered Entities to provide health, behavioral, and dental services to local school children. Auclair Aff. ¶¶ 10-11; Glover Aff. ¶¶ 11, 25. For Covered Entities that are Ryan White clinics, services that link individuals who have recently been diagnosed with HIV/AIDS to appropriate care, and keeping those patients in care, is vital to suppress their viral loads and reduce the chance of spreading the HIV infection.[23] Stephenson Aff. ¶ 23; Burton Aff. ¶¶ 13-14, 19. Springhill provides free health screenings and a financial assistance policy that allows it to provide free or reduced cost inpatient and outpatient services to financially needy individuals. Johnson Aff. ¶ 10.

Most of the above services are not paid by insurance or through grant funds. Auclair Aff. ¶ 22; Glover Aff. ¶ 15; Stephenson Aff. ¶ 17; Burton Aff. ¶¶ 13-14. The Covered Entities use the revenue from their 340B contract pharmacy arrangements to pay for these services and the revenues from drugs purchased from the Drug Companies is significant for some of the Covered Entities. Little Rivers realizes approximately $200,000 annually by purchasing products from the Drug Companies through contract pharmacy arrangements. Auclair Aff. ¶ 23. FamilyCare realizes at least $449,178 annually by purchasing products from the Drug Companies for delivery at contract pharmacies. Glover Aff. ¶ 22.; Dickerson Aff. ¶ 6. Springhill realizes approximately $288,000 annually by purchasing products from the Drug Companies for delivery

[23] Rupali Kotwal Doshi, et al. High Rates of Retention and Viral Suppression in the US HIV Safety Net system: HIV Care Continuum in the Ryan White HIV/AIDS Program, 2011. Clinical Infectious Diseases, Infectious Diseases Soc'y of Am., 60(1), 117–125 (2015) https://pubmed ncbi nlm nih.gov/25225233/. High rates of retention and viral suppression in the US HIV safety net system: HIV care continuum in the Ryan White HIV/AIDS Program, 2011. Clinical infectious diseases: an official publication of the Infectious Diseases Society of America, 60(1), 117–125. https://pubmed.ncbi nlm nih.gov/25225233/

at contract pharmacies. Johnson Aff. ¶ 8. Loss of these revenues will force the Covered Entities to curtail or even terminate the additional services that they provide. Auclair Aff. ¶ 25; Burton Aff. ¶ 19; Glover Aff. ¶ 24; Dickerson Aff. ¶ 8; Johnson Aff. ¶¶ 9, 20.

Loss of these 340B discounts, therefore, threatens the ability to provide critical health services and would "perceptibly impair[]" the Covered Entities' "ability to provide services" to their patients, leading to consequent implications for their health. *Whitman-Walker*, 2020 WL 5232076 at *38. An organization is irreparably harmed if the "actions taken by the defendant have perceptibly impaired the organization's programs." *League of Women Voters*, 838 F.3d at 8 (citations omitted). Thus, the Covered Entities face a "well-established threat to their ability to deliver timely and effective care to their patients" and therefore "clear the irreparable-harm threshold." *Whitman-Walker*, 2020 WL 5232076, at *39.

If the Covered Entities' patients do not have access to the additional services described above, which focus on preventive care and ensuring that the patient obtains needed health care and related support services, the patients' health will undoubtedly decline. As a result, they will require additional, more extensive and expensive health care visits at the Covered Entities, as well as more expensive care from hospitals and specialists. AuClair Aff. ¶¶ 26-27; Glover Aff. ¶¶ 26-27. The cost of providing additional health care visits will cause an additional strain on the resources of the Covered Entities. These types of additional "financial and operational burdens" on a healthcare provider demonstrate irreparable harm. *Whitman-Walker Clinic*, 2020 WL 5232076, at *38.

The Covered Entities will also have to divert staff to seek out and apply for additional federal grants or other sources of funding to make up for the lost 340B savings. Auclair Aff. ¶ 28; Stephenson Aff. ¶ 17; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9. Expending already scarce

financial and human resources "will further burden budgets that are already severely strained" and cause irreparable harm in the form of additional operational expense. *Whitman-Walker*, 2020 WL 5232076, at *39; *see also Dist. of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 41 (D.D.C. 2020). Moreover, the Covered Entities have no assurances that they will be able to obtain additional funding. Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9.

Curtailing services will mean that the Covered Entities will be irreparably harmed because they will not able to carry out their organizational missions, which focus on providing a full range of primary care and related services. Auclair Aff. ¶ 29; Glover Aff. ¶ 29; Dickerson Aff. ¶ 10. *Whitman-Walker*, 2020 WL 5232076, at *39 ("Obstacles that unquestionably make it more difficult for an organization to accomplish its primary mission ... provide injury for purposes both of standing and irreparable harm.") (quoting *League of Women Voters*, 838 F.3d at 9). The mission of Little Rivers includes providing "comprehensive primary health care for all residents in our region" and to "continually reduce the burden of illness, injury, and disability, and to improve the health and quality of life of those for whom we care." Auclair Aff. ¶ 3. The inability to provide comprehensive and wholistic care unquestionably makes it more difficult for the Covered Entities to carry out their missions, thereby causing irreparable harm.[24]

The third irreparable harm suffered by the Covered Entities is loss of their due process rights. As discussed above, the Secretary has still not promulgated regulations to establish and implement an ADR process as required by Congress, thereby depriving the Covered Entities of their property interest in the ADR cause of action. *Zimmerman Brush Co.*, 455 U.S. at 428. It is well established that the "loss of constitutional freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Mills v. District. of Columbia*, 571 F.3d 1304,

[24] A reduction in services is also in conflict with the purpose of the 340B statute, which is to allow covered entities use the to stretch scarce federal resources to reach more patients and provide access to comprehensive services. H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).

1312 (D.C. Cir. 2009) (internal citations omitted).

The fourth, and quite imminent, irreparable harm that will befall the Covered Entities if the Secretary does not act is that they will lose even more of their 340B revenues, including revenue from manufacturers other than the Drug Companies. By failing to enforce the Covered Entities' right to purchase 340B drugs at contract pharmacies, the Secretary is signaling that the 340B statute and subsequent HRSA guidance does not require any of the 700 manufacturers participating in the program to honor contract pharmacy arrangements. The inevitable consequence is that all the other manufacturers will follow the lead of the Drug Companies and refuse to provide 340B pricing at contract pharmacies. This issue is of grave concern to the Covered Entities, none of which operate a retail pharmacy. Auclair Aff. ¶ 19; Stephenson Aff. ¶¶ 24-25; Burton Aff. ¶¶ 16-17; Glover Aff. ¶ 18.

The Covered Entities' fear is not "merely conjectural or hypothetical." *Whitman-Walker*, 2020 WL 5232076 at 9 (citing *Nat. Res. Def. Council v Pena*, 147 F.3d 1012, 1022 (D.C. Cir. 1998)). Members of Congress have written to the Secretary expressing this very concern. In September, 243 members of the U.S. House of Representatives ("House") wrote to the Secretary expressing concern that the Drug Companies' actions will "establish a dangerous precedent for other manufacturers to follow if immediate action is not taken."[25] Similarly, the House Energy and Commerce Committee wrote to the Secretary with the same concern:

> Allowing manufacturers to institute extralegal requirements on covered entities under the threat of refusing to ship drugs as required, or allowing manufacturers to pick and choose where they will comply with program requirements, *could set us on a treacherous path where program participants might disregard any or all of their legal obligations*.[26]

[25] Letter from David B. McKinley, U.S. House of Representatives, to Alex Azar, Sec'y of HHS (Sept. 14, 2020), https://mckinley.house.gov/uploadedfiles/congressional_member_340b_letter_to_azar_9.14.20.pdf (emphasis added).

[26] Letter from Frank Pallone, Chairman of U.S. House of Representatives Committee on Energy and Commerce, to Alex M. Azar II, Sec'y, HHS (Sept. 3, 2020),

Members of Congress have also written to the Pharmaceutical Research and Manufacturers of America (PhRMA), a drug company trade association, raising concerns about the "retaliatory actions" of the Drug Companies, stating that the "trend does not appear to be slowing," and citing one industry report indicating that at least "six more manufacturers will begin conditioning access to 340B drugs on excessive data requests.[27] Thus, there is a "substantial risk" that drug manufacturers other than the Drug Companies, and even all drug manufacturers, will refuse to honor contract pharmacy arrangements. *See Susan B. Anthony List v. Driehaus*, 573 U.S. 149 (2014) (concluding that "[a]n allegation of future injury may suffice if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." (citation and internal quotation marks omitted)).

None of the Covered Entities operates its own pharmacy for the purpose of dispensing self-administered drugs. Auclair Aff. ¶ 19; Stephenson Aff. ¶ 25; Burton Aff. ¶¶ 16-17; Glover Aff. ¶ 18. Therefore, these Covered Entities are entirely reliant on contract pharmacies to dispense self-administered drugs purchased with 340B discounts to their patients.[28]

For Springhill, the revenue from the 340B program has meant the difference between remaining in operation and closing its doors. Johnson Aff. ¶ 9. For FamilyCare, revenue from its contract pharmacy arrangements is almost half of the income that it receives from its grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5. Thus, the harm caused to the Covered Entities is certain, actual, and imminent and, and there is a "clear and present" need for equitable relief to

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https://energycommerce house.gov/sites/democrats.energycommerce house.gov/files/documents/HHS.2020.9.3.%20Final.pdf (emphasis added).

[27] Letter to Stephen J. Ubl, President and CEO, PhRMA (Sept. 15, 2020), https://www.blumenthal.senate.gov/imo/media/doc/2020.09.15_Letter%20to%20PhRMA%20on%20340B%20Contract%20Pharmacies%20FINAL%20SIGNED.pdf (citing Tom Mirga, BREAKING: Novartis the Latest to Seek 340B Contract Pharmacy Claims Data, 340B Report (Aug. 18, 2020), https://340breport.substack.com/p/breaking-novartis-the-latest-to-seek.)

[28] Springhill obtains 340B pricing on outpatient drugs that are administered on an outpatient basis in its hospital, but these purchases are minimal as compared to its contract pharmacy purchases. Johnson Aff. ¶ 7.

prevent such irreparable harm. *Ashland Oil, Inc. v. F.T.C.*, 409 F. Supp. 297, 307 (D.D.C.), *aff'd*, 548 F.2d 977 (D.C. Cir. 1976). The loss of all 340B savings to the Covered Entities would be even more "devasting" to the Covered Entities' operations and the patients they serve. Auclair Aff. ¶ 31; Stephenson Aff. ¶ 24; Burton Aff. ¶ 19; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11.

The direct economic impact that the Secretary's inaction has and will have on the Covered Entities is substantiated and not based on speculation. *Cf. Am. Meat Inst. v. U.S. Dep't of Agric.*, 968 F. Supp. 2d 38, 79 (D.D.C. 2013), *aff'd*, 746 F.3d 1065 (D.C. Cir. 2014*), reh'g en banc granted*, *opinion vacated*, 35 ITRD 2763 (D.C. Cir. 2014), *judgment reinstated*, 760 F.3d 18 (D.C. Cir. 2014) (finding no irreparable harm where the alleged harm is based on speculation). Annual financial statements prepared by certified public accountants clearly show that Little Rivers currently operates at a loss[29] and FamilyCare's operating expenses barely exceeds its revenue.[30] *Wisconsin Gas Co.*, 758 F.2d at 674 ("[M]ovant must provide *proof* that the harm has occurred in the past and is likely to occur again, or *proof* indicating that the harm is certain to occur in the near future."). These grim financial situations are confirmed by the CEO of Little Rivers, Auclair Aff. ¶ 24, and the Chief Financial Officer ("CFO") of FamilyCare. Dickerson Aff. ¶ 7.

Data from the HRSA webpage shows that, in 2019, Little Rivers' average cost per patient was $1,270.64 and FamilyCare's average cost per patient was $764.39. HRSA, *Health Center Program Data*, Little Rivers Health Care, Inc, Bradford, Vermont.[31] The cost per patient will increase dramatically if these providers are shouldered with the obligation of covering the full price of drugs manufactured by the Four Drug Manufacturers, such as Humulin®, which carries

[29] Ex. H; Little Rivers 2019 Annual Report, at 13, https://irp-cdn multiscreensite.com/cca16267/files/uploaded/FY2019%20Annual%20Report_gx0WPXrQb2KqTNIv6OIZ.pdf.
[30] FamilyCare 2019 Annual Report, at 4, https://familycarewv.org/wp-content/uploads/2020/05/FamilyCare_AnnualReport2019.pdf (Ex. I).
[31] https://data.hrsa.gov/tools/data-reporting/program-data#titleId (last visited Nov. 23, 2020).

a non-340B price that is almost four times the 340B price and Bevespi Aerosphere®, which carries a non-340B price that is almost ten times the 340B price.[32] Covered entities that already operate at a loss do not have the financial resources necessary to bear the additional costs of drugs for financially needy patients. Auclair ¶ 34. The Secretary's inaction has a direct financial impact on the Covered Entities, which is verifiable and substantiated.

B. The Secretary's Failure to Enforce the 340B Statute Causes the Covered Entities Harm Beyond Remediation

The impact of patients not being able to access affordable drugs and of the Covered Entities not being able to provide needed health care services cannot be recovered in the ordinary course of litigation. *Minney v. U.S. Office of Personnel Mgmt.*, 130 F. Supp. 3d 225, 235 (D.D.C. 2015) (finding irreparable harm where loss of health coverage caused plaintiff to lose access to emergency medical treatment); *Risteen v. Youth For Understanding, Inc*., 245 F. Supp. 2d 1, 16 (D.D.C. 2002); *Planned Parenthood S. Atl. v. Baker*, 941 F.3d 687, 707 (4th Cir. 2019), cert. denied sub nom. *Baker, Dir. SC Dept. of Health v. Planned Parenthood, Et. Al.*, No. 19-1186, 2020 WL 6037212 (2020) (finding irreparable harm where denial of plaintiff's right to select a qualified healthcare provider resulted in diminished access to high-quality health care suited to the individual plaintiff's needs).

Withholding the Covered Entities' ability purchase covered outpatient drugs at 340B discounts via contract pharmacies for *any* period of time causes a harm that could not simply be remedied by repaying 340B savings and restoring critical health services, including discounts on prescribed drugs, at a later time. *See Texas Children's Hospital v. Burwell*, 76 F. Supp. 3d 224, 243 (D.D.C. 2014) (granting preliminary injunction and finding irreparable harm where

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Little Rivers compared the 340B price and non-340B price of two drugs that its financially needy patients are commonly prescribed. A 30-day supply of Humulin® increased from $117.24 to $450.17 and Bevespi Aerosphere® increased from $198.42 to $1910.13. Auclair Aff. ¶ 33.

"[p]laintiffs . . . are not for-profit entities facing the loss of profit; rather, they are non-profits for whom lost funds would mean reducing hospital services for children . . . ."). As in *Texas Children's*, a reduction in health care services, including the loss of discounts on drugs that are shared with patients, cannot be remediated at a later date.

C. The Covered Entities' Financial Harms are Not Recoverable In the Ordinary Course of Litigation

Allowing the Secretary to undermine the 340B program by not enforcing 340B contract pharmacy arrangements will result in economic losses that are not recoverable absent immediate action taken by this Court. The economic losses to the Covered Entities have a real and immediate impact on the health and well-being of their patients. In addition, the economic loss to the Covered Entities as the result of the Secretary's inaction against the Drug Companies will be "devasting" and cause some Covered Entities to have to cease operations. Auclair Aff. ¶¶ 32, 34; Stephenson Aff. ¶ 24; Burton Aff. ¶ 19; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11; Johnson Aff. ¶¶ 9, 20. These economic losses are irreparable harms because they are not recoverable through "'compensatory or other corrective relief . . . at a later date, in the ordinary course of litigation.'" *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985) (quoting *Va. Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir.1958); *see also Population Institute v. McPherson*, 797 F.2d 1062, 1067 (D.C. Cir. 1986) (preliminary injunction issued where funds sought by plaintiff would be disbursed to others and unavailable at the conclusion of litigation). The D.C. District has recognized that "a lesser showing is permissible when the economic injury is unrecoverable." *Whitman-Walker*, 2020 WL 5232076, at *40; *see also Everglades Harvesting & Hauling, Inc. v. Scalia*, 427 F. Supp. 3d 101, 115 (D.D.C. 2019) (concluding that plaintiffs' businesses would suffer without injunctive relief, and that plaintiffs would have no cause of action to recover lost money).

Regardless of the effect that the loss of 340B savings would have on the Covered Entities, the operational and financial losses are unrecoverable absent the requested relief. The Supreme Court has held that 340B covered entities may not sue drug companies for failing to comply with 340B requirements. *Astra*, 563 U.S. 110. Thus, the Covered Entities cannot recover lost 340B savings through "the ordinary course of litigation" and must rely on the Secretary to enforce 340B program requirements. *Wisconsin Gas Co.*, 758 F.2d at 674. Absent the requested relief, the Covered Entities do not have the means to recoup the 340B savings that have been lost as the result of the Secretary's inaction.

III. The Covered Entities Would Face Far Greater Harm from Failure to Grant Relief than Defendants Would Face from the Order of Relief

In determining whether to grant a temporary restraining order or preliminary injunction, courts must consider the hardship that would be imposed on the moving party if the requested relief is not awarded, compared to the harm that would be imposed on the non-moving party if the relief was granted. *League of Women Voters*, 838 F.3d at 12. In this case, Defendants are government agencies and its officials who would not suffer any economic or direct harm if the requested injunction to require manufacturers to provide 340B discounts were granted. Indeed, the Defendants agree that the 340B statute requires drug companies to honor contract pharmacy arrangements. The requested injunction would preserve the status quo of the 340B program as it currently operated only a few months ago. *Sherley v. Sebelius*, 644 F.3d 388, 398 (D.C. Cir. 2011). In contrast, not granting the requested relief imposes significant and crippling burdens on the Covered Entities and their patients and would encourage hundreds of other manufacturers to withdraw from contract pharmacy arrangements.

IV. The Requested Relief Is in the Public Interest

The public interest favors the temporary restraining order and preliminary injunction

because, if the Covered Entities lose access to the savings generated from the 340B program, our country's most vulnerable patients will be harmed and the cost of care will be shifted to taxpayers. The Covered Entities are on the front lines of caring for our country's low-income and most vulnerable patients and support the broad goals of increasing access to care, reducing the rate of new HIV infections, and improving health outcomes. For example, the President's National HIV/AIDS Strategy recognizes the importance of the Ryan White Program and the work that Ryan White clinics do to achieve these goals. HIV.gov, *National HIV/AIDS Strategy: Updated to 2020*, (July 2015).[33] In meeting these goals, the 340B Program plays a vital role in helping the Covered Entities to support the complex array of health care and social services needed by persons living with HIV/AIDS.

Moreover, it is generally in the public interest for government agencies to implement the statutes that they administer lawfully. *League of Women Voters*, 838 F.3d at 12 ("There is generally no public interest in the perpetuation of unlawful agency action.") (citations omitted). The Covered Entities are likely to show that the Secretary's failure to take action to enforce the Covered Entities' rights to 340B contract pharmacy arrangements violates the 340B statute and CMP regulation. The public interest, therefore, weighs heavily in favor of remedying the unlawful action.

The harms caused by the Secretary's refusal to enforce the Covered Entities' rights to purchase and dispense drugs at 340B discounts through contract pharmacy arrangements is further exacerbated by the COVID-19 pandemic. The Covered Entities "are serving on the frontlines of this pandemic, supporting clients and communities at higher risk from COVID-19." Without the requested relief, the Covered Entities cannot as effectively fight COVID-19. HHS, *HHS Awards $90 Million to Ryan White HIV/AIDS Program Recipients for COVID-19 Response*

[33] https://files hiv.gov/s3fs-public/nhas-update.pdf.

(Apr. 15, 2020).[34] This public health concern clearly outweighs any interest the Defendants have in the requested relief not being granted.

REQUESTED RELIEF

I. Injunction Directing the Secretary to Promulgate ADR Regulations

The Court should issue an injunction ordering the Secretary to issue ADR regulations. After ten years, covered entities still do not have ADR procedures. The Secretary has apparently sent ADR regulations to OMB for review. Those regulations, however, have not been published in final form and are not in effect. Indeed, the Secretary has an extremely poor record of finalizing 340B regulations. The Secretary proposed ADR regulations almost six years after the statutory deadline to issue final regulations. 42 U.S.C. § 256b(d)(3); 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016). In 2017, the Secretary withdrew the proposed regulations without explanation. Only after this suit was filed did the Secretary send a final rule to OMB.

The Secretary's track record with other 340B regulations is just as grim. In the ACA, Congress also directed the Secretary to issue regulations governing CMPs against manufacturers that overcharge 340B covered entities. The CMP rule had the same deadline as the ADR rule: September 19, 2010. ACA, Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (codified at 42 U.S.C. § 256b(d)(1)(B)(vi)(I)). The Secretary did not issue a proposed rule until five years after the deadline, on June 17, 2015. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (June 17, 2015). On January 5, 2017, the Secretary finalized the regulations with an effective date of March 6, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed.

[34] https://www hhs.gov/about/news/2020/04/15/hhs-awards-90-million-ryan-white-hiv-aids-program-recipients-for-covid-19-response html.

Reg. 1,210, 1,211 (Jan. 5, 2017). On March 6, 2016, the Secretary delayed the rule until March 21, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date, 82 Fed. Reg. 12,508 (Mar. 6, 2017). On March 20, 2017, the Secretary again delayed the rule until May 22, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 14,332 (Mar. 20, 2017). On May 19, 2017, the Secretary again delayed the rule to October 1, 2017. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 22,893 (May 19, 2017). On September 29, 2017, the Secretary delayed the rule once more to July 1, 2018. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 45,511, 45,512 (Sept. 29, 2017). On June 5, 2018, the Secretary delayed it again to July 1, 2019. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 25,943 (June 5, 2018). A group of 340B covered entities then sued the Secretary to force him to issue the CMP rule. *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 18-cv-02112 (filed Sept. 11, 2018). The Secretary finally published the final CMP rule only after that lawsuit was filed. 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61,563 (Nov. 30, 2018).

In short, the Covered Entities have no confidence that the rule currently at OMB will be finalized any time soon, and the Court should be equally skeptical. The Secretary's actions with both the ADR and CMP rules show that delay is the norm and only the intervention of this Court will ensure that the Covered Entities have access to ADR procedures as Congress intended.

II. Declaration That Covered Entities Are Entitled to 340B Discounts for Purchases Through Contract Pharmacies

The Court should issue a declaration affirming that 340B covered entities are entitled to

purchase covered outpatient drugs at 340B discounts from contract pharmacies. The Secretary must implement ADR, but at this late date, ADR alone will not cure the Secretary's Due Process violation. The Covered Entities and their patients are suffering immediate, irreparable, severe, and ongoing harms from the Drug Companies' refusal to honor 340B contract pharmacy arrangements. If the Secretary had implemented ADR ten years ago as Congress dictated, the Covered Entities could have challenged the Drug Companies' actions as soon as July 1, 2020, when Lilly first announced its deviation from 340B contract pharmacy requirements. *See* HRSA, *Manufacturer Notices to Covered Entities* (July 2020).[35] Critical months have been lost while Lilly expanded its unlawful policy and other manufacturers followed. If OMB approves the ADR rule, it will not take effect for at least 30 days. 5 U.S.C. 553(d). Thus, the Covered Entities would not even be able to initiate ADR until early 2021, and the ADR process would then have to play out for months. The soonest that the Covered Entities could reasonably expect relief through ADR would be mid-2021.

The Covered Entities and their patients simply cannot wait that long, and immediate relief is necessary. The Supreme Court has long been recognized that "once constitutional right and violation have been shown, scope of district court's equitable powers to remedy past wrongs is broad, for breadth and flexibility are inherent in equitable remedies." *Roman v. Wolf*, 977 F.3d 935, 937 (9th Cir. 2020). A court may remedy all conditions that "flow from" the constitutional violation. *Milliken v. Bradley*, 433 U.S. 267, 281-282 (1977). The harm that flows from the Secretary's failure to implement ADR is the Covered Entities inability to purchase covered outpatient drugs at 340B discounts, a harm that could have been addressed by ADR if the Secretary had put the program in place by Congress's deadline.

The Covered Entities cannot vindicate their rights to contract pharmacy arrangements by

[35] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

an action directly against the Drug Companies because 340B covered entities do not have a private right of action against the Drug Companies to require them to comply with the 340B statute and honor contract pharmacy agreements. *Astra*, 563 U.S. at 113-14. The Court's holding in *Astra* was premised on the Secretary's promise to issue ADR regulations. *Astra*, 563 U.S. at 116. The Covered Entities have been forced to rely on the Secretary to enforce their rights to purchase covered outpatient drugs at 340B prices through contract pharmacy arrangements, yet the Secretary has permitted the Drug Companies to flout the law. The Covered Entities are thus left with no recourse to vindicate their rights under the 340B statute other than the immediate intervention of this Court.

This Court should issue a declaration affirming that the 340B statute and the 340B CMP regulation entitles the Covered Entities to 340B discounts for purchases shipped to contract pharmacies, as explained above. This remedy should be uncontroversial because the Secretary *agrees* with the Covered Entities that the 340B statute entitles covered entities to purchase 340B drugs via contract pharmacy arrangements and has held this position consistently since 1996. Contract Pharmacy Notice, 61 Fed. Reg. at 43,549. In 2010, the Secretary reaffirmed that the 340B the right to contract pharmacy arrangements comes from the statute. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010).

III. An Injunction Directing the Secretary to Protect the Covered Entities' Rights to 340B Contract Pharmacy Arrangements

In addition, the Court should order the Secretary to take appropriate steps to ensure that the Covered Entities can purchase 340B discounted drugs through contract pharmacy arrangements. 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). These PPAs require the Drug Companies to provide 340B discounts as a condition of receiving the privilege of selling their products in the federal Medicaid and Medicare Part B insurance programs. The Secretary can take several actions to bring the Drug Companies in line. The Secretary can order the Drug Companies to honor contract pharmacy arrangements. If they fail to comply, the Secretary can impose CMPs upon the Drug Companies, or the Secretary can revoke their PPAs, thus excluding them from participation in Medicaid and Medicare Part B.

The 340B statute entitles covered entities to purchase 340B discounted drugs through contract pharmacies, as consistently affirmed by the Secretary. By failing to take action on his own initiative to enforce the 340B statute's requirements on manufacturers to honor contract pharmacy arrangements, the Secretary has deprived the Covered Entities of their protected property interests under the Due Process Clause of the Fifth Amendment to the U.S. Constitution, and the Secretary has thereby deprived the Covered Entities of their due process rights. Curing this harm now requires more than ADR. The Court should, therefore, order the Secretary to enforce the Covered Entities' rights to purchase 340B discounted drugs through contract pharmacies.

CONCLUSION

For the reasons stated above, Plaintiffs have demonstrated that the Court should issue a temporary restraining order and a preliminary injunction, and immediate relief is necessary. Plaintiffs respectfully requests that this Court enter an order directing the Secretary to enforce the 340B statute and order drug manufacturers that have executed PPAs to sell drugs to the Covered Entities at 340B discounts when purchased through contract pharmacies.

Respectfully submitted,

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