THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. XAVIER BECERRA, Secretary of Health & Human Services, et al., Defendants.	C.A. No. 21-27-LPS ADMINISTRATIVE PROCEDURE ACT REVIEW OF AGENCY DECISION

BRIEF OF AMICI CURIAE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGEMENT

Leslie Spoltore
Obermayer Rebmann Maxwell & Hippel LLP
123 Justison St Suite 100
Wilmington, DE 19801
(302) 274-3062
Counsel to National Association of Community Health Centers, Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc, and FamilyCare Health Center

Matthew Sidney Freedus
Rosie Dawn Griffin
Brendan Michael Tyler
Feldesman Tucker Leifer Fidell LLP
1129 20th St. NW, 4th Floor
Washington, DC 20036
(202) 466-8960
Counsel to National Association of Community Health Centers

Ronald S. Connelly
Powers Pyles Sutter & Verville, PC
1501 M Street, Northwest, 7th Floor
Washington, DC 20005
(202) 466-6550
Counsel to Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc, and FamilyCare Health Center

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Federal Registers

Other Authorities

INTRODUCTION

Nonprofit covered entities have relied on contract pharmacy arrangements for over twenty years to distribute drugs to their patients. Many 340B covered entities do not operate in-house pharmacies. Because the requirements to obtain a pharmacy license are complex and operating a pharmacy can be expensive, many covered entities choose not "to expend precious resources to develop their own in-house pharmacies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("Contract Pharmacy Notice") (recognizing that since the beginning of the 340B Program, covered entities purchased 340B discounted drugs under contract from third-party pharmacies, a well-settled aspect of the drug distribution system).

The longstanding history of the 340B Program and the welfare of safety-net providers was compromised when, last fall, AstraZeneca unilaterally advanced a self-serving reinterpretation of Section 340B and joined other drug companies on a campaign to undermine the 340B Program by cutting off discounts on drugs shipped to covered entities' contract pharmacies. Now, having failed to convince HHS to bless its unlawful and unprecedented acts,[1] and with both houses of Congress evidently against it,[2] AstraZeneca has turned to the judiciary to condone its unlawful behavior.[3] AstraZeneca seeks to upend this vital federal drug pricing

[1] *See, e.g.*, Letter from Krista Pedley to Christie Bloomquist (Sept. 2, 2020), D.I. 13-1 at 18-19; HHS Gen. Counsel, Advisory Op. 20-06 on Contract Pharmacies Under the 340B Program, D.I. 40-3 at 1-8 ("Advisory Opinion").

[2] *See* Letter from Members of Congress to Alex M. Azar II at 1 (Sept. 14, 2020), D.I. 40-4 at 1127-1139; Letter from United States Senators to Alex M. Azar II at 1 (Sept. 17, 2020), D.I. 40-4 at 1146-1148; Letter from House Committee on Energy & Commerce to Alex M. Azar II at 1 (Sept. 3, 2020), D.I. 40-4 at 1112-1114.

[3] AstraZeneca's litigation strategy is not limited to this suit. *See, e.g.*, Mem. in Supp. of AstraZeneca's Mot. to Intervene, ECF No. 29-1, *RWC-340B v. Azar*, Case No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020), D.I. 40-7 at 1913-1939. Two other major drug companies are also

program by asking the court to invalidate the Advisory Opinion of the HHS General Counsel, which affirms that over two decades of industry practice is in line with and supported by a plain reading of the 340B statute.

The Nation's healthcare safety-net and countless underserved communities will be significantly harmed if covered entities cannot dispense 340B drugs through contract pharmacies. This case impacts *thousands* of covered entities delivering health care to *millions* of Americans, many of whom are among the most medically underserved and vulnerable in our Nation. To divert attention from its own profit motive, AstraZeneca attempts to villainize large chain pharmacies and mischaracterizes them as de facto covered entities. But AstraZeneca cannot erase covered entities and their patients by shining the spotlight on CVS and Walgreens any more than it can hide the true motivation behind this suit in meritless arguments asserted under the Administrative Procedure Act against an *opinion* that merely confirms the legality of over twenty years of well-recognized practice within the U.S. drug distribution system. The truth is that AstraZeneca's unlawful acts damage covered entities that treat the most vulnerable.

Weakening a significant portion of the health care safety net runs counter to the public interest in the best of times; here, AstraZeneca boldly asks this Court to ratify its anti-social actions during the worst public health crisis in a century. AstraZeneca asks this court to evade Congress's statutorily mandated ADR process to declare that AstraZeneca and other manufacturers may continue to refuse to offer covered entities' 340B discount pricing when

---

acting in close concert with AstraZeneca. *See, e.g.*, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Human Servs.*, 3:21-cv-00634 (D.N.J. filed Jan. 12, 2021); *Eli Lilly and Co v. Azar*, No. 1:21-cv-00081 (S.D. Ind. filed Jan. 12, 2021); Mem. in Supp. of Sanofi-Aventis U.S. LLC's Mot. to Intervene, ECF No. 13-1, *RWC-340B v. Azar*, Case No. 1:20-cv-02906, D.I. 40-7 at 1704-1713; Mem. in Supp. of Eli Lilly and Co's Mot. to Intervene, ECF No. 12-1, *RWC-340B v. Azar*, Case No. 1:20-cv-02906, D.I. 40-7 at 1675-1702.

drugs are shipped to their contract pharmacies. Without access to 340B pricing and contract pharmacy distribution systems, covered entities will inevitably cut services supported by 340B discounts, and patients will lose access to low-cost medications, leaving many to face the potentially life-threatening choice of forgoing their prescriptions altogether. The Amici therefore oppose Plaintiff's Motion for Summary Judgment and Opening Brief and urge the Court to protect the U.S. safety-net as Congress intended. D.I. 42; D.I. 43.

ARGUMENT

I. AstraZeneca Seeks to Reverse a Program Required by the 340B Statute That It Participated in for More Than Two Decades

AstraZeneca asks this Court to reverse the Advisory Opinion in an effort to protect its unlawful conduct, which upsets more than two decades of practice, violates AstraZeneca's legal and contractual obligations, runs counter to Congress's plans for how covered entities should operate, and significantly damages the viability of the Nation's healthcare safety-net. Until AstraZeneca and other drug companies unilaterally violated federal law by cutting off 340B pricing at contract pharmacies, covered entities relied on contract pharmacies to dispense their 340B-purchased drugs and otherwise best serve their patients' pharmaceutical needs, consistent with Congress's intent and HHS's longstanding interpretations of both Sections 330 and 340B of the PHS Act. Congress intended drug manufacturers to honor their obligation to provide discounted drugs to covered entities, allowing covered entities to rely on 340B savings to fund crucial aspects of their operations.

A. Contract Pharmacies Have Been a Critical Component of the 340B Program for More Than Two Decades

AstraZeneca mischaracterizes the 340B contract pharmacy program as a massive giveaway to large, corporate chain pharmacies. D.I. 43 at 3-5. But a contract pharmacy does not purchase 340B drugs. It is simply a dispensing agent for the covered entity: the covered entity

purchases drugs at 340B discounts and directs the drugs' shipment to a contract pharmacy, which, in exchange for a dispensing fee, stores and dispenses the drugs to the covered entity's patients, and, importantly, relinquishes third-party payments and/or patient co-payments to the covered entity, while providing much-needed pharmaceutical access and convenience to often-underserved communities.

As noted in the Advisory Opinion, HHS, through its Health Resources and Services Administration ("HRSA"), has consistently interpreted the 340B statute to require drug companies to sell discounted drugs for shipment to covered entities' contract pharmacies. *See, e.g.*, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996) ("Contract Pharmacy Notice") ("There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. . . . 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."); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,275 (Mar. 5, 2010). In 1996, HRSA explained why contract pharmacies are essential for the "many covered entities" that "do not operate their own licensed pharmacies":

> 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.

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

Despite honoring contract pharmacy arrangements for over 24 years, in October of 2020, AstraZeneca implemented a policy to refuse to honor contract pharmacy arrangements unless

covered entities agreed to onerous conditions that effectively eliminate their access to drugs at 340B pricing. *See* Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020).[4] Apparently in concert with AstraZeneca, other drug companies took similar actions to halt 340B pricing on drugs shipped to contract pharmacies, effective during October 2020. *See* Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020);[5] Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020).[6] More recently, Novo Nordisk, Inc. and United Therapeutics Corporation adopted limitations similar to AstraZeneca's. *See* Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020);[7] Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[8] Hundreds of other drug company participants continue to honor their contract pharmacy obligations consistent with the established practice described in the Advisory Opinion, but these drug companies may be emboldened to follow AstraZenca's and its compatriots' lead if that Advisory Opinion is invalidated.

B. When Congress Enacted the 340B Statute, It Knew Providers, Including FQHCs and RWCs, Would Dispense Drugs Through Contract Pharmacies

When Congress created the 340B Program in 1992, it had every reason to anticipate that Federally Qualified Health Centers ("FQHCs"), Ryan White Clinics ("RWCs"), and other covered entities would use pre-existing authority and flexibility to provide drugs to their patients

[4] https://www.rwc340b.org/wp-content/uploads/2020/12/AstraZeneca-CE-Letter_Aug-17-2020.pdf
[5] https://www.rwc340b.org/wp-content/uploads/2020/12/Sanofi-340B-Program-Integrity-Initiative-Notification-7.2020.pdf.
[6] Novartis has since retreated, in part, by shipping to federal grantees' contract pharmacies and to hospital contract pharmacies within a 40-mile radius. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020).
[7] https://bit.ly/2NQlzpc.
[8] https://bit.ly/3pNrfgZ.

through contracts with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy. Indeed, contract pharmacy arrangements have been used by all types of covered entities, even before 340B was enacted.

As community and patient-based providers, FQHCs necessarily have flexibility to determine how best to meet the needs of their patients and communities, but FQHCs must—and do—use any 340B savings and revenue (as well as any other income generated from grant-supported activities) in furtherance of their health center projects. 42 U.S.C. § 254b(e)(5)(D). FQHCs have also long had an express grant of authority to provide their services, including pharmacy services, either directly through their own staff or through contracts or cooperative arrangements with other entities, or a combination thereof. *See*, *e.g.*, Public Health Service Act, Pub. L. 78-410, § 330(a), 58 Stat. 682, 704 (1944) ("For purposes of [Sec. 330], the term 'health center' means an entity that serves a population that is medically underserved . . . either through the staff an (sic) supporting resources of the center or through contracts or cooperative arrangements"); Special Health Revenue Sharing Act of 1975, Pub. L. 94-63, § 501, 89 Stat. 304, 342–43 (1975) (amending § 330(a) of the PHS Act to read: "For purposes of this section, the term 'community health center' means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides" health care services, including "pharmaceutical services").

Contract pharmacy arrangements are not unique to the 340B Program. These arrangements are a well-settled aspect of non-profit healthcare entities' drug distribution systems. In 2010, the Federal Trade Commission ("FTC") formally recognized the right of certain non-profit organizations to contract with for-profit retail pharmacies to dispense drugs subject to discounts negotiated and used within the parameters of the Robinson-Patman

Antidiscrimination Act ("Robinson-Patman Act") and the Non-Profit Institutions Act ("NPIA").[9] *See* Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).[10] Absent an exemption like the NPIA, the resale of discounted drugs purchased by a non-profit hospital to its patients could violate antitrust laws. The FTC examined and approved the exact contract pharmacy model described in the Advisory Opinion at issue here, with only one difference—the drugs dispensed by the contract pharmacies were subject to discounts obtained under the NPIA, not the 340B statute. *Id.* Both the 340B statute and NPIA provide for the purchase and restrict the resale of discounted drugs by non-profit healthcare entities. 15 U.S.C. § 13-13c; 42 U.S.C. § 256b(a)(5)(B).

The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). For nearly twenty-five years in the long life of that program—from 1996 until mid-2020—drug manufacturers, either directly or through wholesale distributors, shipped covered outpatient drugs purchased by covered entities to their contract pharmacies. All but a handful of the hundreds of drug manufacturers participating in the 340B Program continue to do so.

[9] Congress enacted the Robinson-Patman Act to protect small businesses from larger businesses using their size advantages to obtain more favorable prices and terms from suppliers and to prohibit discrimination in the sale of fungible products, including drugs. 15 U.S.C. §§ 13–13b. The Robinson-Patman Act added the NPIA, which permits manufacturers to sell discounted medical supplies, including drugs, to certain non-profit entities by exempting "purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" from the Robinson-Patman Act's prohibitions against price discrimination. 15 U.S.C. § 13c.

[10] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

Covered entities have long used 340B Program savings and revenue, as Congress intended, to expand health care and enabling services within their service areas to populations desperately in need of care, whether due to an acute public health crisis or to serious chronic conditions. Money saved or generated through 340B Program participation is used to cover the cost of medications for uninsured or underinsured patients who could not otherwise afford it, and funds expanded access to necessary medical and crucial enabling services. These services include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

AstraZeneca attacks the Advisory Opinion to prolong its unprecedented and self-serving refusal to provide covered entities' access to drugs at 340B discount pricing in violation of federal law. AstraZeneca ignores that, for decades, covered entities have, as Congress intended, structured their safety-net operations in reliance on 340B discounts, which are often accessible only through contract pharmacies.

II. An Order Granting AstraZeneca's Motion for Summary Judgment Will Inflict Significant Harms on Covered Entities and Their Patients and Compromise Vital Safety-Net Services Throughout the Nation

Nowhere in AstraZeneca's court filings does it discuss the vast uncompensated or undercompensated safety-net services provided by covered entities by virtue of 340B savings and revenue, much of which is attainable only from contract pharmacy arrangements.[11] Indeed,

[11] Safety-net services are deeply rooted in our Nation's legal and economic history, having been introduced by President Lyndon B. Johnson who coined the "War on Poverty" in conjunction with the Civil Rights Act of 1964. Studies by HHS indicate that, while economic inequality has increased substantially over the past 20 years, "the full social safety net has cut poverty substantially and its impact on poverty rates . . . has grown since the start of the War on

AstraZeneca mischaracterizes the purchase of drugs by covered entities that are dispensed at contract pharmacies as drug purchases by contract pharmacies. D.I. 43 at 2, 3, 6, 8, 9. The harms currently being suffered by covered entities, their patients, and underserved communities will continue and intensify if the Court grants AstraZeneca's motion to invalidate the Advisory Opinion.

AstraZeneca seeks to upend the 340B program and contract pharmacy arrangements by requesting an order invalidating the Advisory Opinion. Such an order would give AstraZeneca and other drug companies a free pass to continue to violate 340B Program statutory requirements by depriving covered entities of 340B discounted pricing. Covered entities are on the front lines of caring for our Nation's most vulnerable patients and use 340B discounts to support their missions of increasing access to care, improving health outcomes, and fortifying the Nation's safety-net.

Denying 340B pricing is antithetical to Congress's design of the 340B Program, which was intended to expand care to the patient populations served by safety net providers. Without 340B funding, covered entities cannot possibly "reach[] more eligible patients and provid[e] more comprehensive services" to those patients. H.R. Rep. No. 102–384(II), at 12 (1992). Indeed, AstraZeneca's deprivation of 340B Program benefits has already harmed covered entities, their patients, and their broader communities, because covered entities have had to reduce critical services supported with 340B-derived funding. Eliminating 340B contract pharmacy arrangements will directly and indirectly harm our Nation's most vulnerable

---

Poverty." HHS, *Poverty in the United States: 50-Year Trends and Safety Net Impacts*, Off. of the Assistant Sec'y for Planning and Evaluation (Mar. 2016), https://aspe.hhs.gov/system/files/pdf/154286/50YearTrends.pdf. Accordingly, increases in use of the 340B Program by safety-net providers have been in lockstep with Congress's intent for the 340B program, the War on Poverty, and rising economic inequality within the United States.

communities by depriving them of affordable medications, critical health care, and related services that covered entities provide through 340B Program participation. Covered entities' losses—financial and otherwise—will not be fully recoverable if the Court grants AstraZeneca's motion. Other drug companies will likely believe that the Court has authorized them also to violate the 340B program. Such an outcome could cause many safety-net providers to shutter their doors. These outcomes would be tragic at any time, but during the COVID-19 pandemic, they are unconscionable.

A. Covered Entities Use 340B Contract Pharmacy Savings to Provide Deep Discounts on High-Cost Medications to Eligible Patients

Covered entities are able, through 340B Program participation, to offer discounted drugs to financially needy patients. For example, West Virginia-based FQHC FamilyCare's drug discount program allows indigent patients to pay only FamilyCare's cost for the drug. Glover Aff. ¶ 17, D.I. 40-7 at 1883.[12] Because 340B discounted prices are significantly lower than non-340B prices, patients who relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30, D.I. 40-7 at 1886. Vermont-based FQHC Little Rivers operates a similar drug discount program that subsidizes the costs of drugs for financially needy patients. Auclair Aff. ¶ 18 (explaining patients pay a percentage of costs, including $0, on an income-based sliding scale). Little Rivers, and other covered entities, are now bearing the increased cost of AstraZeneca's drugs for prescriptions filled at contract pharmacies. Auclair Aff. ¶¶ 21, 30, 31–34 (indicating Little Rivers will struggle financially if forced to continue

[12] The following declarations, which are attached to this brief, were either originally submitted as exhibits in the Amici's lawsuit against HHS or recently updated, Mot. for TRO and Prelim. Inj., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24, (stayed Jan. 13, 2021): Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (Ex. A, "Glover Aff."); Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Inc. (Ex. B, "Auclair Aff."); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (Ex. J, "Dickerson Aff.").

incurring these increased costs). Little Rivers reviewed the increase in price due to AstraZeneca's policy for drugs prescribed to some of its uninsured patients and found that the cost of Bevespi Aerosphere®, an inhaler produced by AstraZeneca to treat chronic obstructive pulmonary disorder (COPD), and for which no generic substitute is available, increased from a 340B price of $90.30 to an average wholesale price of $474.13. Auclair Aff. ¶ 35. Covered entities like Little Rivers can only afford to bear these unanticipated costs for so long before they will have to fall on individual patients.

Through contract pharmacy arrangements, uninsured and under-insured covered entity patients can fill prescriptions at convenient locations, often at a greatly reduced cost or at no cost at all. FQHC and Ryan White covered entities care for increasing numbers of patients with chronic conditions managed primarily through prescription medications. From 2013 through 2018, the number of FQHC patients with HIV increased 66% (from 115,421 to 191,717), patients presenting with substance use disorders increased 80% (from 506,279 to 908,984), and patients with depression and mood and anxiety disorders increased by 72% (from 2,740,638 to 4,724,691). Sara Rosenbaum et al., *Cmty. Health Ctrs. Ten Years After the Affordable Care Act: A Decade of Progress and the Challenges Ahead*, Geiger Gibson RCHN Community Health Foundation Research Collaborative (Mar. 2020), https://www.rchnfoundation.org/wp-content/uploads/2020/03/FINAL-GG-IB-61-ACA-CHC-3.4.20.pdf.

With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients have lost access to lifesaving medications. AstraZeneca has made a tiny concession to allow covered entities to use one contract pharmacy if they do not operate their own retail, in-house pharmacies, but AstraZeneca's policy does little to aid many indigent covered entity patients who cannot access such pharmacies. For example, FamilyCare serves a

very large area in rural West Virginia and uses contract pharmacy arrangements across its service area to meet its patients' pharmaceutical needs. *See, e.g.*, Glover Aff. ¶ 19 (noting that its contract pharmacy network enables FamilyCare to provide patients discounted drugs near their homes), D.I. 40-7 at 1883.

Amicus National Association of Community Health Centers ("NACHC") filed affidavits in its ADR petition, on behalf of 225 FQHC covered entities, against AstraZeneca and other manufacturers for unlawful overcharging.[13] The affidavits illustrate the significant harm to the public interest that AstraZeneca's actions have already caused. Covered entities serving remote or rural areas in particular have lost access to discount drugs over large geographic areas, making it nearly impossible for their patients to access affordable medications. *See, e.g.*, Simila Aff. ¶ 27 ("[t]he travel distance between our northern most and southern most clinical delivery sites is 200 miles."); Francis Aff. ¶ 19 ("Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships."); Chen Aff. ¶ 21 ("NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel [35-180 miles] (one-way trip), to reach the closest of NCHC's in-

[13] The following declarations, which are attached to this brief as exhibits, were submitted as exhibits to amicus NACHC's Petition for Declaratory and Injunctive Relief against Plaintiff before the HHS ADR Panel, *Nat'l Ass'n of Cmty. Health Ctrs. v. Eli Lilly and Co., et al.*, ADR Pet. No. 210112-2 (Jan. 13, 2021): Declaration of Donald A. Simila, Upper Great Lakes Health Center, Inc. (Ex. C, "Simila Aff."); Declaration of Lee Francis, Erie Family Health Center (Ex. D, "Francis Aff."); Declaration of Kimberly Christine Chen, North County HealthCare, Inc. ("NCHC") (Ex. E, "Chen Aff."); Declaration of Ludwig M. Spinelli, Optimus Health Care Inc., (Ex. F, "Spinelli Aff."); David Steven Taylor, Appalachian Mountain Community Health Centers (Ex. G, "Taylor Aff."); Declaration of J.R. Richards, Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus (Ex. H, "Richards Aff."); Declaration of Heather Rickertsen, Crescent Community Health Center (Ex. I, "Rickertsen Aff."); and Declaration of Jackson Mahaniah, Lynn Community Health Center (Ex. K, "Mahaniah Aff.").

house pharmacies").

The affidavit from Optimus Health Care Inc. provides just a few examples of the negative impact AstraZeneca's actions have already had on covered entity patients. Spinelli Aff. ¶¶ 21, 25. One Optimus patient, who suffers from severe asthma that has been difficult to control, had been paying only $15 a month since 2014 for an inhaler manufactured by AstraZeneca. Spinelli Aff. ¶ 25. In October 2020, he was faced with a $315 cost for the same drug due to AstraZeneca's unilateral restrictions and, unfortunately, suffered an interruption in his asthma therapy. *Id*. He also expressed concern about what might befall him if other pharmaceutical companies block access to 340B pricing. *Id.*

Likewise, the affidavit from North Country HealthCare, Inc. ("NCHC") explains how AstraZeneca's refusal to offer 340B pricing to covered entities on contract-pharmacy shipments of the drug Symbicort directly threatens the lives of homeless populations. Chen Aff. ¶ 34. NCHC provides indispensable safety-services to homeless patients suffering with asthma. *Id*. There is no approved generic equivalent to Symbicort, a respiratory inhaler used to treat asthma in individuals not adequately controlled on other medications. Chen Aff. ¶ 34.[14] NCHC's homeless patients have tried and failed other alternative treatments. *Id.* NCHC's clinical pharmacist was able to stabilize certain patients' asthma conditions with Symbicort, causing a "marked improvement in their asthma, decrease in their exacerbations, and quality of life due to the medication change." *Id.* As a result of AstraZeneca's actions to cutoff 340B pricing on

[14] AstraZeneca recently convinced the U.S. District Court for the Northern District of West Virginia to block a proposed generic formulation of Symbicort that had received tentative approval from the FDA, thus denying relief to underprivileged patients. *See*, AstraZeneca, *US court decision favours Symbicort in patent litigation* (Mar. 3, 2021), https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2021/us-court-decision-favours-symbicort-patents.html.

Symbicort, these homeless individuals can no longer rely on local contract pharmacies to obtain life-saving asthma medication for which there is no alternative. *Id.* Most importantly, these individuals whose asthma goes uncontrolled or improperly treated risk permanent lung damage and breathing incapacitation.[15]

The affidavit from Appalachian Mountain Community Health Center (Appalachian Mountain) provides yet another example of the life-threatening impact of AstraZeneca's actions on vulnerable patient populations. Taylor Aff. ¶ 18, 21. Appalachian Mountain's patients who were on Farxiga, an AstraZeneca drug used in the treatment of diabetes, have been forced to take an inferior class of medications because the only similar alternative, Invokana, was intolerable due to certain contraindicated comorbidities. *Id.* Thus, these patients have also been left without safety-net protections for which Congress drafted the 340B statute.

Moreover, in response to AstraZeneca's actions, covered entities have generally struggled to switch patients' medications to affordable alternatives, especially given that certain medications do not have an approved generic formulation. Chen Aff. ¶ 34; Francis Aff. ¶¶ 24, 26. Many patients want to continue taking familiar medications or are fearful of the negative health impact of changing to a new medication. Richards Aff. ¶ 23; Francis Aff. ¶ 26. Additionally, before a patient can change medications, a medical provider must "review the patient chart, consider comorbidities, and assess the appropriate dosing for the substitute medication." Francis Aff. ¶ 26. If the new drug treatment has different dosing, this could require significant patient education and "provider troubleshooting" to avoid adverse health outcomes. *Id*. The administrative and clinical burden of largescale shifts in patient medication regimes

[15] Kian Chung, *International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma*, European Respiratory Journal (Feb. 2014) at 350.

presents an unanticipated strain on covered entity staffing, removing resources from day-to-day patient care.

Yet another destressed covered entity, Crescent Community Health Center (Crescent Community Health) in Dubuque, Iowa, notes that AstraZeneca's and other drug companies' actions will cause many patients to lose access to diabetes, hypertension, asthma/COPD, and heart disease medications. Rickertsen Aff. ¶ 30. The clinical pharmacy director for Crescent Community Health determined that approximately thirty-two uninsured patients will be unable to afford asthma/COPD medications, 76 diabetic patients will lose access to critical oral medications to treat diabetes, 51 patients will lose access to their insulin, and 40 patients will no longer have access to medications to treat other acute and chronic conditions. Rickertsen Aff. ¶ 30. These patients are being faced with the dismal and undignified choice of rationing their medications, which will result in a decline in their health status and an increase in uninsured hospital expenses for the rural community as it copes with the COVID public health emergency. Rickertsen Aff. ¶ 12, 19, 30.

B. Covered Entities Rely on 340B Contract Pharmacy Savings to Pay for Necessary and Required Health Care and Related Services

Covered entities use 340B Program savings and revenue to subsidize the cost of important and life-saving care and services. For patients with prescription insurance, covered entities benefit from the difference between the 340B price and the insurer's reimbursement. Covered entities use these funds to supplement their federal grants and other program income, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992).

Many of the programs and services covered entities support with 340B funding are critical to treating the whole patient, but are not reimbursed by public or private insurance, and

regardless are often most needed by patients who lack insurance altogether. Auclair Aff. ¶ 22; Glover Aff. ¶ 15, D.I. 40-7 at 1883; Simila Aff. ¶ 18. Congress designed the 340B Program to provide a funding stream for just these sorts of programs and services. And, for decades, FQHCs have structured their operations in reliance on 340B funding, just as Congress intended. *See, e.g.*, Auclair Aff. ¶¶ 10–11; Glover Aff. ¶¶ 11, 25, D.I. 40-7 at 1882, 1885.

FQHCs and RWCs provide, among other services, case management to assist patients with transportation, insurance enrollment, linkage to affordable housing, food access, patient care advocacy, in-home support, and education for chronic health care conditions. Auclair Aff. ¶¶ 12–16, 22 (also noting provision of behavioral health services at local public schools for students and families); Glover Aff. ¶¶ 11, 14–15, D.I. 40-7 at 1883. Case management and care coordination are particularly important for homeless and indigent individuals, who require these services to enable their receipt of necessary primary health care services. Auclair Aff. ¶ 17; Glover Aff. ¶ 26, D.I. 40-7 at 1885; *see also* 42 U.S.C. § 254b(a)(1) (designating homeless as one of four general patient populations to be served); RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020) (Ryan White patients are more likely to be homeless than general HIV/AIDS population). Education and in-home assistance for patients with chronic health conditions are also vitally important for disease management and the prevention of exacerbation or deterioration that would require more costly care. Glover Aff. ¶¶ 15, 27, D.I. 40-7 at 1883, 1885-86; *see also* NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-11 (number of health center patients diagnosed with a chronic health condition grew 25% from 2013 to 2017), 1-10 (21% of FQHC patients have diabetes compared to national rate of 11%).

Covered entities also rely on 340B funding to provide a range of other critical services responsive to serious ongoing public health crises, such as medication assisted treatment programs and other treatment options for opioid use disorder. *See* Auclair Aff. ¶ 15; Glover ¶ 14; Simila Aff. ¶ 5; Francis Aff. ¶ 9; *see also* HRSA, Bureau of Primary Health Care, *2018 Health Center Data: National Data, Other Data Elements* (2019) (FQHCs are "the first line of care in combatting the Nation's opioid crisis," screening and identifying nearly 1.4 million people for substance use disorder, providing medication-assisted treatment to nearly 143,000 patients, providing over 2.7 million HIV tests, and treating 1 in 5 patients diagnosed with HIV nationally).

AstraZeneca's deprivation of 340B discounts has already resulted in cuts and reductions to critical FQHC and RWC services supported in whole or in part with 340B-derived funding. *See, e.g.*, Auclair Aff. ¶ 23 (Little Rivers will lose approximately $36,070 annually in 340B savings as a result of the decision by AstraZeneca not to honor contract pharmacy arrangements); Glover Aff. ¶ 22, D.I. 40-7 at 1884; Dickerson Aff. ¶ 6; Spinelli Aff. ¶¶ 28–30 (estimating annual revenue loss of over $560,000 from AstraZeneca's and other manufactures refusal to offer 340B pricing, which risks vital primary care services including dental, podiatry, clinical nutrition, and others); Richards Aff. ¶¶ 24, 25 (estimating covered entity will lose approximately $350,000 in annual net revenue due to 340B restrictions, forcing reduction in services); Rickertsen Aff. ¶¶ 34, 36 (estimating approximate annual loss of $1 million in revenue and $500,000 to $2 million increase in cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program). Just last week, Community HealthCare System in St. Marys, Kansas announced that it would close its emergency room and reduce its inpatient beds due, in part, to manufacturers' restrictive 340B contract pharmacy policies. WIBW, *Community HealthCare*

System in St. Marys to close emergency room doors, adjust services (Apr. 28, 2021).[16]

Without preventive and enabling services, patient health will undoubtedly suffer. Patients will require additional, more expensive health care visits at the Amici's locations and more expensive hospital and specialist care. Auclair Aff. ¶¶ 26–27; Glover Aff. ¶¶ 26–27, D.I. 40-7 at 1885-1886; *see also* Robert S. Nocon, et al., *Health Care Use and Spending for Medicaid Enrollees in Fed. Qualified Health Ctrs. Versus Other Primary Care Settings*, Am. J. Public Health (Sep. 15, 2016) ("Medicaid patients who obtain primary care at FQHCs had lower use and spending than did similar patients in other primary care settings"). The cost of providing additional health care visits will further strain covered entities' resources.

AstraZeneca's and other drug companies' refusal to offer drugs at 340B discount pricing has also already resulted in covered entities reducing staff. *See, e.g.*, Simila Aff. ¶ 29 (health center forced to reduce staffing for OB/GYN services and planning other major service reductions—including service delivery site closures, employee terminations, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services); Mahaniah Aff. ¶ 20 (health center preparing to permanently eliminate 5% of employees); Chen Aff. ¶ 42 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations); Richards Aff. ¶ 25 (significant financial loss will result in reduction in clinical and patient services). FQHC and RWC covered entities will also have to divert remaining staff to attempt to provide alternative or palliative services to vulnerable patients and seek out additional federal grants or other sources of funding to make up for lost 340B funding. *See, e.g.*, Chen Aff. ¶ 40; Auclair Aff. ¶ 28; Glover Aff. ¶ 28, D.I. 40-7 at 1886; Dickerson Aff. ¶ 9. Expending

[16] https://www.wibw.com/2021/04/28/community-healthcare-system-in-st-marys-to-close-emergency-room-doors-adjust-services/.

already scarce financial and human resources will further burden tight budgets and cause additional and unbearable operational expenses. Auclair Aff. ¶ 28; Glover Aff. ¶ 28, D.I. 40-7 at 1886; Dickerson Aff. ¶ 9.

Many covered entities, including numerous NACHC and RWC-340B members as well as Amici Little Rivers and FamilyCare, rely entirely on contract pharmacies to dispense covered outpatient drugs to their patients. *See, e.g*, Auclair Aff. ¶ 19; Glover Aff. ¶ 18, D.I. 40-7 at 1883. For some covered entities, 340B Program revenue has meant the difference between remaining in operation and closing their doors. For FamilyCare, revenue from its contract pharmacy arrangements is comparatively almost half of the funding it receives from federal grants. Glover Aff. ¶ 21, D.I. 40-7 at 1884; Dickerson Aff. ¶¶ 4-5. The loss of all 340B savings to the Amici would be even more "devastating" to their operations and the patients they serve. Auclair Aff. ¶ 31; Glover Aff. ¶ 31, D.I. 40-7 at 1886; Dickerson Aff. ¶ 11. Little Rivers currently operates at a loss and FamilyCare's revenue barely exceeds its operating expenses. Dickerson Aff. ¶ 7. In 2019, Little Rivers' average cost per patient was $1,270.64; FamilyCare's average cost per patient was $764.39. HRSA, *Health Center Program Data*.[17] Per patient costs will increase dramatically if these providers are burdened with covering the full price of AstraZeneca's drugs. Many covered entities, including Amici Little Rivers and FamilyCare, lack the financial resources necessary to bear the additional costs of drugs for indigent patients. Auclair Aff. ¶ 34.

CONCLUSION

Granting AstraZeneca's motion would significantly harm covered entities, their patients, their staff, and their broader communities by enabling AstraZeneca and other drug companies to violate their 340B Program obligations and upend an over two-decades-long status quo on which

[17] https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited May 4, 2021).

FQHCs and RWCs depend. The Advisory Opinion describes what AstraZeneca and others in the U.S. drug distribution system have understood for decades—drug companies that choose to participate in the 340B federal drug pricing program are required to "offer" to covered entities 340B pricing, regardless where the drugs are dispensed to the covered entity's patients. Amici therefore respectfully request that the Court deny AstraZeneca's motion for summary judgment and preserve over twenty-years of established practice that has allowed U.S. safety-net providers to serve their patients and communities as Congress intended.

Dated: May 4, 2021

Respectfully submitted,

/s/ Leslie Spoltore
Leslie Spoltore
DE Bar No. 3605
Obermayer Rebmann Maxwell & Hippel LLP
123 Justison St Suite 100
Wilmington, DE 19801
(302) 274-3062
F: (302) 655-1092
Leslie.Spoltore@Obermayer.com
Counsel to National Association of Community Health Centers, Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc, and FamilyCare Health Center

s/ Matthew S. Freedus
Matthew Sidney Freedus*
D.C. Bar No. 475887
Rosie Dawn Griffin
D.C. Bar No. 1035462
Brendan Michael Tyler
D.C. Bar No. 1672687
FELDESMAN TUCKER LEIFER FIDELL LLP
1129 20th St. NW, 4th Floor
Washington, DC 20036
T: (202) 466-8960
F: (202) 293-8103
mfreedus@ftlf.com
rgriffin@ftlf.com
btyler@ftlf.com

/s/ Ronald S. Connelly
Ronald S. Connelly*
D.C. Bar No. 488298
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 466-6550
Fax (202) 785-1756
Ron.Connelly@PowersLaw.com
Counsel for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc, and FamilyCare Health Center

Counsel for Amicus Curiae National Association of Community Health Centers

* *Pro hac vice applications pending*

CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of May 2021, a true and correct copy of a Brief Of Amici Curiae National Association Of Community Health Centers, Ryan White Clinics For 340b Access, Little Rivers Health Care, Inc., And Womencare, Inc., dba Familycare Health Center In Opposition To Plaintiff's Motion For Summary Judgement with Exhibits A-K were electronically filed with this Court, and thereby simultaneously served via CM/ECF upon all counsel of record.

By: */s/ Leslie Spoltore*
Leslie B. Spoltore, Esquire (#3605)