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

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HRSA, Bureau of Primary Health Care, 2018 Health Center Data: National Data, Other Data Elements (2019)..... 17

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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

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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

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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,

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* *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)

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

INDEX OF EXHIBITS TO BRIEF OF AMICI CURIAE IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT[1]

Exhibit A	Declaration of Craig Glover, MBA, MA, FACHE, CMPE, CEO of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare").
Exhibit B	Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Health Care Inc ("Little Rivers").
Exhibit C	Declaration of Donald A. Simila, Upper Great Lakes Health Center, Inc.
Exhibit D	Declaration of Lee Francis, Erie Family Health Center.
Exhibit E	Declaration of Kimberly Christine Chen, North County HealthCare, Inc.
Exhibit F	Declaration of Ludwig M. Spinelli, Optimus Health Care Inc.
Exhibit G	David Steven Taylor, Appalachian Mountain Community Health Centers ("Appalachian Mountain").

[1] Exhibits A, B, and J 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). Exhibits C, D, E, F, G, H, I, and K 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 Ctr.s v. Eli Lilly and Co., et al.*, ADR Pet. No. 210112-2 (Jan. 13, 2021).

Exhibit H	Declaration of J.R. Richards, Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus.
Exhibit I	Declaration of Heather Rickertsen, Crescent Community Health Center.
Exhibit J	Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare").
Exhibit K	Declaration of Jackson Mahaniah, Lynn Community Health Center.

Exhibit A

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Ryan White Clinics for 340B Access, et al., Plaintiffs, v. Alex M. Azar, Secretary U.S. Department of Health and Human Services, et al., Defendants.	Case Number: 1:20-cv-02906 KBJ

AFFIDAVIT

I, Craig Glover, MBA, MA, FACHE, CMPE, hereby attest and state as follows:

1) I am the President and Chief Executive Officer of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare"). I have held this position since February 2019, after the retirement of FamilyCare's founder and first Chief Executive Officer.

2) FamilyCare operates several facilities in West Virginia and provides care through three mobile units and at local schools. Most of FamilyCare's facilities provide comprehensive primary care services but three offer specialized care: a birthing center, a pediatric medicine clinic, and an addiction treatment center.

3) As stated on its website, "FamilyCare is committed to making high-quality, whole-person care available to every member of the family and every member of the community."[1]

[1] Source: https://familycarewv.org/about/.

4) FamilyCare provides patient care services covering a wide variety of specialties, which include: adult health care; pediatric health care; prescription savings program; behavioral health; psychiatry; substance use disorder treatment; urgent care; dental care; women's health care; prenatal health care; birth services; school-based health programs; chronic care management; diabetes education; medical nutrition education; and social services.[2]

5) FamilyCare is certified as a Federally Qualified Health Center ("FQHC") by the Health Resources and Services Agency ("HRSA") within the United States Department of Health and Human Services.

6) HRSA awarded FamilyCare a certificate as a 2020 National Quality Leader and designated FamilyCare as a 2020 awardee as a Health Care Quality Leader and in Advancing HIT [Health Information Technology] for Quality.[3] HRSA also designated FamilyCare as a Patient Centered Medical Home ("PCMH").[4] According to the HRSA website, "PCMH recognition assesses a health center's approach to patient-centered care. Health centers can achieve PCMH recognition by meeting national standards for primary care that emphasize care coordination and on-going quality improvement.[5]

7) FQHCs are providers of primary care services that must comply with certain federal requirements, including being operated by a Board of Directors that is comprised of at least 51% of individuals who are active patients of the clinic and who represent the individuals served by the health center in terms of such factors as race, ethnicity, and gender. FQHCs provide health care services regardless of a patient's ability to pay, and

[2] Source: https://familycarewv.org/services/
[3] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId
[4] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .
[5] Source: https://bphc.hrsa.gov/qualityimprovement/clinicalquality/accreditation-pcmh/index.html .

charge for services on a sliding fee scale according to the patient's financial resources. FamilyCare complies with all requirements to be certified as an FQHC.

8) In 2019, FamilyCare provided services to 32,353 patients. Approximately 31.28% of these patients were under the age of 18 and 12.12% were 65 years of age or older. Almost 15% of FamilyCare's patients are a racial or ethnic minority.[6]

9) In 2019, FamilyCare patients included 205 homeless individuals, 67 agricultural workers and families, and 942 veterans.[7]

10) In 2019, FamilyCare provided medical services to 31,292 patients, dental services to 2,136 patients, mental health services to 2,118 patients, substance use disorder services to 450 patients, and enabling services (services that allow access to health care services) to 1,477 patients.[8]

11) FamilyCare provides services in Scott Depot, Charleston, Madison, Eleanor, Hurricane, Barboursville, Buffalo, Winfield, Dunbar, Cross Lanes, and St. Albans, West Virginia. FamilyCare provides services to elementary, middle school and high school students in Putnam County through a mobile unit and expanded these services to two schools in Boone County in 2019.[9]

12) In 2019, 37.11% of FamilyCare's patients had hypertension, 15.76% had diabetes, and 5.08% had asthma. FamilyCare provided prenatal services to 509 patients.[10]

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[6] Source: Health Resources and Services Administration, Bureau of Primary Care: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId
[7] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .
[8] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .
[9] Source: https://familycarewv.org/wp-content/uploads/2020/05/FamilyCare_AnnualReport2019.pdf , p.6.
[10] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .

13) For patients whose income is known, 99.53% have annual incomes at or below 200% of the Federal Poverty Level. Of these patients, 50.43% have annual incomes at or below 100% of the Federal Poverty Level.

14) FamilyCare operates a Medication Assisted Treatment ("MAT") program, which provides services to individuals who are on a drug regimen to treat addiction.

15) FamilyCare employs community health workers to visit patients with chronic illnesses in their homes to provide additional education about addressing their chronic conditions, assess whether their living conditions are conducive to controlling their illness, and determine whether additional support services are needed to support the patient's health. These services are not covered by insurance and are only partially covered by grant funding.

16) FamilyCare's services area is very large, as shown on the HRSA website.[11] Some patients drive for an hour to reach one of our locations.

17) FamilyCare provides a Prescription Savings Program. As stated on our website:

> Our Prescription Savings Program (Federal 340B Drug Pricing Program) allows you to purchase medications at discounted prices. We provide those medications at discounted prices to our patients at local pharmacies. Uninsured patients can receive, on average, a 40% discount on the cost of their drugs.[12]

18) FamilyCare does not operate an in-house retail pharmacy. It relies exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients.

19) FamilyCare has several contract pharmacy locations registered with the 340B program and listed on the Office of Pharmacy Affairs ("OPA") database. FamilyCare believes that it is necessary to have arrangements with contract pharmacies that reach across its

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[11] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .
[12] Source: https://familycarewv.org/service/prescription-savings-program/ .

service area so that its patients may receive discounted drugs through its Prescription Savings Program. FamilyCare has contract pharmacy agreements with pharmacies owned by several chain organizations (Fruth, Kroger, Rite Aid, Wal-Mart, and Walgreens). If a covered entity has contract pharmacy arrangements, HRSA's policy is that the covered entity must registers each of the locations for these chains in the OPA database.

20) The net revenues from FamilyCare's contract pharmacy arrangements allow it to: 1) pay for drugs needed by its patients who cannot afford to pay for the drugs; and 2) pay for support services for its patients that are not covered by insurance or paid for through grant funding.

21) Based on data from January 1 to June 30, 2020 and extrapolated to twelve months, FamilyCare realizes approximately $2,115,422 in net revenues annually through its contract pharmacy agreements with contract pharmacies other than Walgreen's. (FamilyCare was not able to obtain data from Walgreen's at the time that this Affidavit was required.) In comparison, FamilyCare received approximately $4.3 million in FQHC grant funding in the fiscal year ended June 30, 2020. FamilyCare's FQHC grant funding in 2020 was greater than in prior years because of additional federal funding that provided to health care providers that were treating COVID-19 patients and testing for COVID-19.

22) Based on data from January 1 through June 30, 2020 and extrapolated to twelve months, FamilyCare achieves approximately $ 449,178 annually in 340B net revenue for drugs manufactured by Eli Lilly Company ("Lilly"), Zeneca Pharmaceuticals, L.P. ("AstraZeneca"), and Sanofi-Aventis US LLC ("Sanofi"), and their corporate affiliates and filled through contract pharmacies other than Walgreen's.

23) In 2018, FamilyCare's revenues exceeded its expenses by only $168,469. In 2019, FamilyCare's revenues exceed its expenses by only $298,258.[13]

24) FamilyCare will have to cut or scale back some of the services that it provides if FamilyCare loses over $449,178 annually as the result of the actions of Lilly, AstraZeneca, and Sanofi.

25) Cutting or eliminating services to FamilyCare's patients will be detrimental to the patients' health and well-being. As one example, FamilyCare currently operates a dental clinic five days per week. If FamilyCare loses over $449,178 annually as the result of the actions of Lilly, AstraZeneca, and Sanofi, FamilyCare will likely have to offer these services fewer days each week. If FamilyCare has to reduce or eliminate its chronic care management program which educates patients about preventative care, patients will be at an increased risk for developing a preventable illness or condition.

26) If FamilyCare loses over $449,178 annually as the result of the actions of Lilly, AstraZeneca, and Sanofi, FamilyCare, FamilyCare may also have to scale back the scope or amount of services provided by its Community Health workers. Scaling back these services will likely mean that the health care condition of the patients receiving these services, or that would have received these services, is likely to deteriorate. Patients will be at risk of not receiving additional educational support to address their chronic conditions or being linked to necessary support services.

27) If FamilyCare's patients do not receive the full range of support services that FamilyCare currently provides, their health is likely to decline, and they are more likely to require more extensive and expensive health care visits at FamilyCare and at hospitals and

[13] https://familycarewv.org/wp-content/uploads/2020/05/FamilyCare_AnnualReport2019.pdf , p.5.

specialists. The cost of providing additional health care visits not previously accounted for will cause a strain on FamilyCare's resources.

28) In order to continue providing at least some of the services that FamilyCare currently offers to its patients, FamilyCare will have to seek other funding sources and there is no certainty that FamilyCare would be able to obtain additional funding.

29) The mission of FamilyCare, which is to "make high-quality, whole-person care available to every member of the family and every member of the community" will be compromised if FamilyCare is not able to provide the full range of support services that it currently provides due to the unavailability of 340B discounts on drugs manufactured by Lilly, AstraZeneca, and Sanofi. FamilyCare will be hampered in its goal to provide our patients with the affordable, comprehensive, and holistic care they need and deserve.

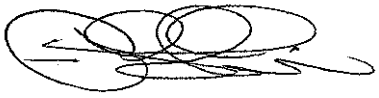
30) FamilyCare's Prescription Savings Program is offered for drugs that are purchased with 340B discounts. If FamilyCare cannot purchase drugs manufactured by Lilly, AstraZeneca, and Lilly with 340B discounts, those drugs will no longer be part of its program. FamilyCare does not have funds allocated to provide discounted drugs to patients absent obtaining the drugs at 340B prices.

31) I am concerned that other drug manufacturers will follow the lead of Lilly, AstraZeneca, and Sanofi and decide to no longer provide 340B pricing through contract pharmacies. If FamilyCare lost access to all 340B drugs at its contract pharmacies, it would be devastating to FamilyCare's operations and the patients it serves.

[*Signature on next page*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 23RD day of November 2020.

Respectfully submitted,



Craig Glover, MBA, MA, FACHE, CMPE
President and Chief Executive Officer
WomenCare, Inc., dba FamilyCare Health Center

Exhibit B

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP Plaintiff, v. Xavier Becerra, Secretary U.S. Department of Health and Human Services, et al., Defendants.	)	C.A. No. 1:21-cv-00027-LPS

AFFIDAVIT

I, Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N., hereby attest and state as follows:

1) I am the Chief Executive Officer of Little Rivers Health Care, Inc. ("Little Rivers"). I have held this position for fourteen (14) years. I have forty (40) years of experience as a nurse.

2) Little Rivers has three facilities in Vermont. The facilities are located in Wells River, Bradford, and East Corinth, Vermont.

3) The stated mission of Little Rivers is as follows:

> Our mission is to provide respectful, comprehensive primary health care for all residents in our region, regardless of their ability to pay. We offer quality health care services to everyone. In the spirit of community, we make efforts to reach out and welcome those who need health services, but may have insufficient means to access them. We commit ourselves 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.[1]

[1] Source: https://www.littlerivers.org/about.

4) One of our guiding principles for patient care is that Little Rivers provides holistic care that takes the patients' social, emotional and situational needs into consideration to support them in managing their health.

5) Little Rivers provides patient care services covering a wide variety of specialties, including Family Medicine, Pediatrics, Obstetrics, Behavioral Health and Oral Health Care.

6) Little Rivers is certified by the United States Department of Health and Human Services as a Federally Qualified Health Center ("FQHC").

7) FQHCs are providers of primary care services that must comply with certain federal requirements, including being operated by a Board of Directors that is comprised of at least 51% of individuals who are active patients of the clinic and who represent the individuals served by the health center in terms of such factors as race, ethnicity, and gender. FQHCs provide health care services regardless of a patient's ability to pay, and charge for services on a sliding fee scale according to the patient's financial resources. Little Rivers complies with all requirements to be certified as an FQHC.

8) In 2019, Little Rivers provided services to 5,561 patients. Approximately 15.46% of these patients were under the age of 18 and 25.68% were 65 years of age or older.[2]

9) In 2019, Little Rivers patients included 93 agricultural workers and families, 46 homeless individuals, 265 veterans, 261 uninsured and 37 prenatal patients.[3]

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[2] Source: Health Resources and Services Administration, Bureau of Primary Care: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId

[3] Source: Little Rivers 2019 Annual Report, p. 10 (available at littlerivers.org).

10) In 2019, Little Rivers provided mental health services to 519 patients and Little Rivers conducted 4,304 behavioral health visits.[4]

11) In 2019, Little Rivers served 475 children in its dental health program, many of whom would not have received preventative care services had Little Rivers not provided it. Little Rivers also held fluoride varnish days in our Bradford and Wells River clinics, where medical providers offered screenings and fluoride treatments to children free of charge.[5]

12) Little Rivers operates a chronic care management program to assist patients with chronic diseases. Patients in the chronic care management program receive individualized education and assistance from a registered nurse to help the patient manage their chronic conditions. Registered nurses also visit patients in their homes between health care visits at a Little Rivers facility. In 2019, 105 patients were enrolled in the Little Rivers' chronic care management program.[6]

13) Little Rivers works with Willing Hands, a non-profit, charitable organization with a mission to receive and distribute donations of fresh food that otherwise might go to waste in order to improve health and provide reliable access to nutritious food for community members in need. A Little Rivers employee coordinates with Willing Hands to distribute fresh produce and dairy to Little Rivers' clinics for care coordinators to deliver to patients in need.[7]

14) Little Rivers offers behavioral health services at local public schools that include counseling for students and families. At some public schools, Little Rivers provides

[4] Source: Little Rivers 2019 Annual Report, p. 6 and 10 (available at littlerivers.org).
[5] Source: Little Rivers 2019 Annual Report, p. 7 (available at littlerivers.org).
[6] Source: Little Rivers 2019 Annual Report, p. 9 (available at littlerivers.org).
[7] Source: Little Rivers 2019 Annual Report, p. 14 (available at littlerivers.org).

extensive training and education for faculty and staff regarding resiliency, classroom behaviors, and trauma-informed approaches.[8] (Trauma-informed care recognizes the presence of trauma symptoms and the role that trauma may play in an individual's life.)

15) Little Rivers operates a Medication Assisted Treatment ("MAT") program, which provides services to individuals who are on a drug regimen to treat addiction.

16) A critical component of the health care that Little Rivers provides is its care coordination services. Little Rivers employs six care coordinators, including at least one care coordinator who specializes in behavioral health issues and works with patients to "improve their overall social-emotional wellbeing. Care coordinators provide assistance with transportation, insurance enrollment, sliding fee discount eligibility, linkage to affordable housing, food access, and patient care advocacy."[9]

17) Based on my 40 years of experience as a registered nurse, care coordination is a vital factor in helping our patients to stay well and manage their health care conditions. Without care coordinators, many of Little Rivers' patients would not be able to access the health care that they need or obtain affordable housing or food. These services are critical in preventing our patients' health from deteriorating. Care coordination is particularly important for homeless and indigent individuals, who require additional support services to ensure that they continue to receive necessary health care services.

18) Little Rivers offers a sliding fee scale to patients whose incomes are under 200% of the Federal Poverty Level. This discount includes access to prescription drugs through our 340B program when they receive a prescription as the result of health care services provided by Little Rivers. If a patient's income is at or below 100% of the federal

[8] Source: Little Rivers 2019 Annual Report, p. 6 (available at littlerivers.org).
[9] Source: Little Rivers 2019 Annual Report, p. 7 (available at littlerivers.org).

poverty level, and the patient does not have insurance coverage for retail prescription drugs, Little Rivers pays 100% of that patient's drug costs. For patients whose income is between 100% and 200% of the federal poverty level, Little Rivers pays a percentage of the cost of the drug (25%, 50% or 75%, depending on the patient's income level). Most of our patients in the sliding fee program qualify for the 100% discount.

19) Little Rivers does not operate an in-house retail pharmacy. It relies exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients.

20) Little Rivers has four contract pharmacies arrangements registered with the 340B program and listed on the Office of Pharmacy Affairs ("OPA") database. Little Rivers has registered three Wal-Mart locations. Two of those locations (Texas and Florida), however, are for repackaging drugs for sale at retail pharmacies, including repacking for distribution by the Wal-Mart retail pharmacy in New Hampshire, which is the third Wal-Mart registration. Stated differently, only two of the contract pharmacies registered by Little Rivers on the OPA database dispense 340B drugs directly to Little Rivers' patients.

21) The savings from Little Rivers' contract pharmacy arrangements allow it to: 1) pay for drugs needed by its patients who cannot afford to pay for the drugs; and 2) pay for support services for its patients that are not covered by insurance or paid for through grant funding.

22) All of the services described above are provided to patients without insurance and to patients whose insurance does not cover the services. In addition, the costs of these services are not covered, or not fully covered, by grant funding.

23) Based on its calculations of the 340B savings that Little Rivers has historically achieved through filling prescriptions for drugs manufactured by Defendant, Little Rivers will lose

approximately $36,070 annually in 340B savings as a result of the decision by Defendant not to honor contract pharmacy arrangements. This calculation was based on data from the period October 1, 2020 to January 31, 2021 and extrapolated to an annual calculation.

24) In 2018 and 2019, Little Rivers operated at a loss. In 2019, Little Rivers' expenses exceeded its revenues by $188,451. In 2018, Little Rivers' expenses exceeded its revenues by $289,380.[10]

25) The COVID-19 public health emergency (PHE) has had a detrimental impact on Little Rivers' finances because patients have been reluctant to schedule in-person appointments for health care services. Despite government aid to Little Rivers, its monthly revenue has decreased by approximately 10% since the start of the PHE.

26) Currently, Little Rivers has lost some employees by attrition but has not filled those positions due to financial constraints.

27) Little Rivers will have to cut or eliminate some of the services that it provides, or make salary cuts to current employees, if Little Rivers loses $36,070 annually as the result of the actions of Defendant.

28) Cutting or eliminating services to Little Rivers' patients will be detrimental to the patients' health and well-being. As one example, if Little Rivers has to reduce or eliminate its chronic care management program which educates patients about preventative care, the health care condition of the patients in that program is likely to deteriorate. Similarly, if Little Rivers has to reduce or eliminate its care coordination services, patients will be at risk of not being connected to necessary health care services,

[10] Source: Little Rivers 2019 Annual Report, p. 13 (available at littlerivers.org).

affordable housing opportunities, or access to low-cost food. Cutting staff salaries will decrease morale and potentially result in valuable staff seeking employment elsewhere.

29) If Little Rivers' patients do not receive the full range of support services that Little Rivers currently provides, their health is likely to decline and they are more likely to require additional and more extensive and expensive health care visits at Little Rivers and at hospitals and specialists. The cost of providing additional health care visits not previously accounted for will cause a strain on Little Rivers' resources.

30) In order to continue to provide at least some of the services that Little Rivers currently offers to its patients, Little Rivers will have to seek other funding sources, either through increased donations or additional grant funding.

31) The mission of Little Rivers, which is to provide "comprehensive primary health care" and "to improve the health and quality of life of those for whom we care" will be compromised if Little Rivers is not able to provide the full range of support services that it currently provides due to the unavailability of 340B discounts on drugs manufactured by Defendant. We will be hampered in our goal to provide for our patients with the affordable, comprehensive, and holistic care they need and deserve.

32) Little Rivers will not be able to provide low-cost drugs through its drug discount program if Little Rivers cannot purchase drugs at 340B prices and instead will have to pay undiscounted prices for those drugs.

33) The loss of $36,070 annually in 340B savings as the result of the actions of Defendant will have a severe financial impact on Little Rivers. Little Rivers strives to keep three months' operating expenses in reserves, which is consistent with sound business practices and guidance from the Bureau of Primary Care within the Health Resources and Services

Administration, the federal agency that administers the FQHC program. Little Rivers often struggles to meet this goal and the loss of $36,070 annually will exacerbate the problem and impose undue operational and financial burdens on Little Rivers.

34) I am concerned that other drug manufacturers will follow the lead of Defendant and decide to no longer provide 340B pricing through contract pharmacies. Eli Lilly Company and Sanofi-Aventis US LLC, and their corporate affiliates, have already restricted access to 340B pricing at contract pharmacies under policies similar to Defendants' policy. If Little Rivers lost access to 340B pricing for all retail drugs, it would be devastating to Little Rivers' operations and the patients it serves.

35) Bevespi Aerosphere® is an inhaler produced by Defendant to treat chronic obstructive pulmonary disorder (COPD), and for which no generic substitute is available. I requested information from Hudson Headwaters, which assists Little Rivers in processing 340B contract pharmacy claims, to provide pricing on the 340B price and non-340B price of Bevespi Aerosphere®. Hudson Headwaters provided this information:

NDC	Average Wholesale Price	Wholesale Acquisition Cost	340B Cost
0310460012- 12 PKG	$474.13	$395.11	$90.30
0310460039 28 PKG	$261.44	$217.81	$49.79

36) Some of Little Rivers' financially need patients are prescribed Bevespi Aerosphere® and Little Rivers will no longer be able to offer the inhaler at the 340B discounted pricing to those patients.

37) Because Little Rivers has operated at a loss for the last two fiscal years, it does not have the financial resources to bear the additional cost of these drugs for our financially needy

patients. The increased costs to Little Rivers to pay for the drugs under its drug discount program will exacerbate its already precarious financial position.

38) The U.S. Department of Health and Human Services ("HHS") has implemented a statutorily mandated Administrative Dispute Resolution ("ADR") process for 340B covered entities and manufacturers to resolve certain 340B program disputes. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.20–10.24. On February 4, 2021, Little Rivers filed an ADR petition against AstraZeneca. The Little Rivers ADR petition contends that AstraZeneca has violated the 340B statute by declining to ship 340B discounted drugs to Little Rivers' contract pharmacies. On February 4, 2021, Little Rivers' counsel sent the ADR petition to AstraZeneca via certified mail. See 42 C.F.R. § 10.21(a). Little Rivers' counsel received confirmation that AstraZeneca received the petition via certified mail on February 8, 2021. A 340B ADR regulation provides that "[u]pon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition." 42 C.F.R. § 10.21(f). AstraZeneca has not responded to the Little Rivers ADR petition.

[*Signature on next page*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 3rd day of May 2021.

Respectfully submitted,

Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N.
Chief Executive Officer
Little Rivers Health Care, Inc.

Exhibit C

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Donald A. Simila

I, Donald A. Simila, declare as follows:

1. I am Chief Executive Officer at Upper Great Lakes Family Health Center, Inc. ("Upper Great Lakes"), and I have held this role since on or about October 1, 2009. As Chief Executive Officer, I am responsible for oversight of all services, including pharmacy services. To fulfill my job duties, I have access to all pharmacy-related transactions generated by prescriptions written by our physicians. Additionally, Upper Great Lakes has a dedicated analyst and 340B/pharmacy committee that reviews program activity, and educates me, as well as the board, staff, and patients, on the program. To prepare this declaration, I reviewed wholesaler invoices, pharmacy contracts, and pharmacy invoices.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Upper Great Lakes is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide primary health care and related services across a 10,000 square mile service area at 11 distinct and dispersed clinic sites, 20 congregate care facilities, and various school-based clinics.

4. Upper Great Lakes has been in business as an FQHC since approximately May 2010, and is a member of the National Association of Community Health Centers.

5. On an annual basis, Upper Great Lakes provides approximately 25,000 unique patients with 80,000 clinical visits for comprehensive primary care, OB/GYN, Behavioral Health including Medication Assisted Treatment for Opioid Use Disorder, and preventative and restorative dental services. As a rural community, Upper Great Lakes' target population is significantly underserved, aging, and impoverished. Sixty percent of Upper Great Lakes patients are either on Michigan Medicaid or on Medicare. Seventy percent of our patients

are at or below 200% of the federal poverty level ("FPL"), and 25% are at or below 100% of the FPL.

6. Upper Great Lakes is a "covered entity" for purposes of the 340B Drug Program ("340B Program). As a covered entity, Upper Great Lakes can purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

7. Upper Great Lakes has been a covered entity since in or around 2010 and, as required, annually recertifies its locations as 340B eligible sites with the Health Resources and Services Administration ("HRSA").

8. As a covered entity, Upper Great Lakes is permitted to choose how it will deliver pharmacy services to its patients. Upper Great Lakes—across its 10,000-mile service area—maintains contractual arrangements with local retail pharmacies to support its patients by ensuring local access to reduced price medications for those who meet federal poverty guidelines.

9. Upper Great Lakes requests HRSA approval for each of its contracted pharmacy partners. Once approved, Upper Great Lakes enters into a contractual relationship with the individual pharmacy's wholesaler under which Upper Great Lakes purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to the contract pharmacy. The health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible Upper Great Lakes patients.

10. When an Upper Great Lakes provider writes a prescription, it is electronically transmitted to a local pharmacy where the prescription is filled by the retail pharmacist; a third-party application identifies patients who qualify to purchase medications at 340B pricing, as well as claims that are submitted to insurance plans.

11. The "virtual inventory" owned by Upper Great Lakes is tracked by an Upper Great Lakes 340B analyst through real-time data reporting from third-party administrator software. Reconciliations occur each month.

12. Upper Great Lakes carves in a select few pharmacies that bill a single managed Medicaid plan for most claims; as required, Medicaid is not billed for outpatient medications. The retail pharmacy directly submits claims to Medicaid for medications purchased at retail pricing from non-340B inventory.

13. Upper Great Lakes passes its 340B savings directly to eligible patients who meet federal poverty guidelines.

14. Savings generated through claims made to commercial insurance and other third-party payers ensure that Upper Great Lakes can continue to provide essential health care services to its underserved rural community.

15. With its 340B savings, Upper Great Lakes is able to provide its vulnerable patient population access to a board-certified addiction medicine physician for treatment of Opioid

Use Disorder—the only Addiction Medicine Specialist in the entire Upper Peninsula of Michigan, which encompasses 15 counties and approximately 17,000 square miles—and is able to support the training of an additional 4 physicians to meet DEA licensing requirements for Medication Assisted Treatment. The approximate annual cost to support the addiction services above and beyond reimbursement is $200,000.

16. Additionally, as the only dental provider that accepts Medicaid in large volumes in the service area, Upper Great Lakes is able, due in part to 340B savings, to maintain a dental service at two locations with combined annual operating losses of approximately $450,000.

17. 340B savings also support OB/GYN services in a 4-county area with a population of approximately 45,000. The approximate annual operating loss of this service for the community exceeds $225,000 annually. Without this service, women in our service area and target population would be required to travel more than 100 miles one-way for access to OB/GYN care.

18. Clinic locations in rural counties such as Ontonagon, Iron, and Menominee all carry annual operating losses as the cost of employing physicians and operating a clinic exceed reimbursement from Medicaid, Medicare, and private insurance. In total, clinic services for these counties add up to an annual operating loss of more than $600,000.

19. Federal grant money falls far short of covering the operating losses outlined in the preceding paragraphs. 340B savings help to fill these gaps.

20. Finally, as an organization, Upper Great Lakes has completed over 10,000 COVID-19 tests in local communities through mobile services and walk-up or drive-up testing. Funds from 340B savings have supported the costs associated with standing up testing teams, purchasing test kits, and underwriting coordination of this service. Our health center has been the only source of community testing in most communities we serve. In addition, Upper Great Lakes has been instrumental at two local Universities commencing face-to-face instruction; at those institutions, we conduct random COVID-19 surveillance testing for students and employees daily, providing approximately 600 tests per week. This service enabled the Universities to bring 6,700 students back to campus. Without the safe integration of students into these communities, the economic impact to the greater community would be dire.

21. Upper Great Lakes follows HRSA requirements and the 340B statute to ensure all contract pharmacies are engaged in a binding contractual agreement with the Health Center. Each pharmacy has executed a contract with Upper Great Lakes prior to registering and obtaining approval for including the pharmacy in Upper Great Lakes' approved network.

22. Upper Great Lakes designed its contract pharmacy network to ensure that all patients across the 10,000-mile, 11-county rural service area have access to discount medications. In addition to being located in the communities we serve, most contract pharmacies have expansive hours of operation that many of our patients need.

23. Our annual operating margin is approximately 1-2% on a budget of $22 million. The average salary for a primary care physician in this region is approximately $240,000 plus benefits of about $50,000. Without 340B savings, all our primary care practices lose money. On an annual basis, across all 11 locations, Upper Great Lakes' drug sales through the 340B Program at all contract pharmacies amounts to approximately $6 million dollars. After administrative fees, ingredients costs, and dispensing fees, the health center nets approximately $250,000 to $300,000 per month (or approximately $3 million to $3.6 million annually).

24. Beginning on or about September 1, 2020, I became aware that certain drug manufacturers, including Eli Lilly, Sanofi, and AstraZeneca would cease providing outpatient prescription drugs at 340B prices to Upper Great Lakes' contract pharmacies.

25. Because of these actions by the drug manufacturers, health center patients, staff, and the community Upper Great Lakes serves will be significantly and irreparably harmed both clinically and economically.

26. Although Eli Lilly at least appeared to offer us the option of selecting one single contract pharmacy through which 340B-priced medications could be dispensed to eligible patients, a single pharmacy for all our patients would severely limit our patients' access to life saving medications.

27. The travel distance between our northern most and southern most clinical delivery sites is 200 miles. The Upper Peninsula of Michigan is a roughly 17,000 square mile region that is sparsely populated with approximately 300,000 individuals. Only one 90-mile stretch of interstate highway exists in the region, running north and south on the Peninsula's extreme eastern edge. Most of the population is served by two-lane state and county highways. As a region, the Peninsula will receive annual snowfalls in excess of 200 inches. Some areas receive more than 300 inches annually. Given the geographic and weather realities here, travel is hampered nine months of any given year.

28. The drug manufacturers' decisions were seemingly made without regard for the narrow margins on which safety net providers like Upper Great Lakes operate, or for the immediate and unplanned-for financial losses that result from these actions. Since September 1, 2020, and on a monthly basis, Upper Great Lakes has lost and will lose anticipated revenues in excess of approximately $50,000 from Eli Lilly's actions alone. Annualized, this amounts to approximately $600,000 from Eli Lilly alone.

29. As a result of this loss, we are currently planning major reductions in services, which will include closure of access points/service delivery sites, termination of employees, reductions in health center providers, and likely closure of OB/GYN (for which we have already reduced staffing), dental, and mental health services.

30. The ultimate result of the manufacturers' actions will be a significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community with chronic health conditions that require ongoing care.

31. Additionally, as a major employer in the region with a monthly payroll in excess of approximately $1.2 million, a likely necessary staff reduction of about 50% will have a direct economic impact on our communities of approximately $7.2 million annually.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/03/2020

By Donald A. Simila, MSW, FACHE

Donald A. Simila
Chief Executive Officer, Upper Great Lakes Health Center, Inc.

Exhibit D

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Lee Francis, MD, MPH

I, Lee Francis, MD, MPH, declare as follows:

1. I am the President and CEO of Erie Family Health Center, Inc. ("Erie"), located in and around Chicago, Illinois. I joined Erie in 1991 and have held the role of President and CEO since 2007. As President and CEO, I am charged with enacting Erie's strategic vision of serving as a national leader in the provision of community-based health care. I am responsible for the overall health of the organization, including financial stability, operational success, and clinical quality.

2. Regarding the 340B Drug Pricing Program ("340B Program"), as President and CEO, I have regular access to 340B financial and operational updates. I also receive regular updates on the 340B Program from Erie's Chief Financial Officer, who serves as the federal OPAIS Authorizing Official. As part of my regular duties, I am also made aware of provider and staff feedback related to 340B successes and barriers. Additionally, in my role as an Internal Medicine physician at Erie, I am keenly aware of the benefit the 340B Program offers for my own patients. To prepare this declaration, I have reviewed 340B Program metrics and feedback from providers and staff.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. Erie is a Federally-qualified health center, and a member of the National Association of Community Health Centers. The health center receives federal funding under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population residing across over 185 zip codes in the Chicagoland region.

5. Erie is an approximately 63-year-old primary healthcare provider that delivers integrated and affordable medical, dental, and behavioral health care for patients of all ages. We also encourage good health in our underserved patient population through ongoing health education, case/care management, strong hospital partnerships, and community outreach.

6. Motivated by our belief that high-quality health care is a human right, Erie serves more than 80,000 patients per year at 12 locations throughout Chicago and the surrounding suburbs, regardless of patient insurance status, immigration status, or ability to pay for Erie's services. Almost all of Erie's patients are low income, and approximately 27% of Erie's patients are uninsured. Approximately 71% of patients are Hispanic and about 44% are best served in a language other than English.

7. Erie is a "covered entity" for purposes of the 340B Program. Erie has been registered with the Health Resources and Services Administration ("HRSA") as a 340B covered entity since on or about January 1, 1997. As required, we maintain accurate management of our clinic registrations within HRSA's OPAIS database. We recertify our 340B covered entity status annually, and most recently recertified for all twelve of our participating 340B locations on or about February 18, 2020. A list of our covered entity locations, downloaded from HRSA's 340B OPAIS database on October 7, 2020, is attached as Exhibit A.

8. The 340B Program allows Erie to purchase significantly discounted outpatient prescription drugs for pharmacy dispensing and as clinic-administered drugs. We acquire 340B discounted drugs for pharmacy dispensing through wholesaler AmerisourceBergen; we are also in the process of adding Cardinal Health as another 340B wholesaler account. For clinic-administered medications, we have 340B drug purchasing accounts with Allergan, Henry Schein, Paragard Direct, Theracom, and R&S Northeast, LLC.

9. Erie's participation in the 340B Program allows us to help our low-income uninsured and underinsured patients afford their medications. Without 340B discounts, critical medications—including, among many others, insulin, asthma inhalers, blood pressure medications, Pre-Exposure Prophylaxis (PrEP) for HIV, Suboxone and Narcan to treat opioid use disorder—would be unaffordable and inaccessible for these patients. 340B contract pharmacies enable our patients to access, and many other medications.

10. As required by federal law and regulations, and in keeping with our mission, we reinvest 100% of 340B savings and revenue from third-party reimbursement into expanding access for our underserved patients. For example, this money is used to cover costs associated with comprehensive care, a Medication-Assisted Treatment Program for opioid use disorder, and telemedicine and electronic population health tools, which enable Erie to serve patients at greatest risk for missing health screenings or services.

11. Many Erie patients have chronic conditions exacerbated by social challenges. Improving health outcomes depends on Erie providing: 1:1 Care Management, Maternal and Child Case Management, HIV/AIDS Case Management, Health Coaching, Referrals support,

Care Coordination and Outreach, Public Benefits navigation, Resource navigation, and PrEP navigation services. Because robust comprehensive care and case management are not usually reimbursed by third-party payers, Erie would not be able to offer these services without 340B savings.

12. As a covered entity, Erie is permitted to choose how it will deliver pharmacy services to its patients. While we use drugs purchased at 340B pricing for a select portion of our in-clinic medication supply, Erie contracts with local pharmacies to dispense all other 340B medications to its patients. We do not own or operate our own pharmacies. We currently contract with many local Walgreens pharmacy stores and one independent community pharmacy, Allcare Discount Pharmacy, which is co-located within one of our clinic sites.

13. Erie has a written agreement with Walgreens to dispense the 340B drugs we purchase to eligible Erie patients. We first contracted with Walgreens in or around 2011 and received HRSA approval for our first Walgreens contract pharmacy location on or about August 22, 2011. In the intervening years—following guidance from HRSA and Apexus—we have registered additional Walgreens locations. Our current Pharmacy Services Agreement with Walgreens—which applies to of all our active Walgreens pharmacy locations and all of our active covered entity locations, as registered in HRSA's 340B OPAIS database—was executed on or about April 4, 2017.

14. Erie likewise has a written agreement with Allcare Discount Pharmacy to dispense 340B drugs to eligible patients. We first contracted with Allcare Discount Pharmacy in or around September 2010; HRSA approved the pharmacy arrangement on or about May 23, 2011. Our current Pharmacy Services Agreement with Allcare Discount Pharmacy was executed on or about August 7, 2019.

15. As described in our Pharmacy Services Agreements, Erie purchases 340B drugs from wholesalers and directs those drugs to be shipped to the contract pharmacy as part of a "bill-to, ship-to" arrangement. Under this arrangement, Erie maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services to our eligible patients. Some of our contract pharmacies use a precise accumulation software to dispense a retail pharmacy product to patients and perform a careful 340B eligibility assessment; if the dispense meets all eligibility criteria, the accumulator will be replenished with an Erie-purchased 340B drug for that dispense.

16. Understanding that 340B compliance falls squarely on Erie, we have multiple compliance safeguards in place and perform extensive auditing, including an audit of all contract pharmacy 340B dispenses for patient and provider eligibility and audits to verify that Medicaid Fee-For-Service was not billed for any contract pharmacy 340B claim (to avoid prohibited duplicate discounts). All audits are completed on a monthly basis and reported out quarterly to our 340B Compliance Committee. We also commission an annual external 340B audit. Our most recent external audit, in January 2020, yielded positive feedback on Erie meeting HRSA 340B compliance standards.

17. Our contract pharmacies dispense over 115,000 340B discounted prescriptions annually to our eligible patients. On average, Erie spends approximately $470,000 on 340B drug products monthly for dispensing through our contract pharmacies.

18. The critical benefit the 340B drug discount to patient outcomes is illustrated in an email from an Erie pediatrician attached as Exhibit B. In the email, the pediatrician explains how one of her patients benefited from access to affordable insulin through the 340B Program. The patient turned 18 this year, moved out to live independently, started working, and lost his Medicaid coverage. Previously, the patient's Type 1 diabetes had been managed by providers at the local children's hospital. During this transition to adulthood, he was unable to stay with his care team and could no longer afford the insulin he was prescribed. The Erie pediatrician was able to work collaboratively with the patient's previous provider to assume care for his diabetic condition and prescribed an affordable Lantus pen (a Sanofi product) through the 340B Program. Aligning the patient with access to the affordable 340B drug helped to keep his sugars under control, keep him out of diabetic ketoacidosis, and keep him out of the hospital until he was able to get his insurance reinstated. The 340B Program helped this young adult access life-saving medicine and avoid hospitalization.

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.

20. Our contracts with local pharmacies to dispense 340B medications allow our patients to receive their critical 340B medication at a pharmacy close to their home. Erie patients generally experience multiple barriers to accessing care, including significant transportation barriers. Even though Erie has twelve clinic locations, some Erie patients still have significant travel times to attend their visit at the health center. The trip for some patients requires multiple segments on public transportation, as well as walking. Providing medication access near a patient's home supports that patient's ability to take their medication regularly, without potentially dangerous gaps around refills.

21. Many of our patients are hourly wage-earners, essential workers, work long hours, hold multiple jobs, or have care-giving responsibilities during the business day, and most will not get paid to take time away from work to obtain medications. Our contract pharmacy partners include 24-hour pharmacies and those with home delivery capabilities, providing crucial access to our patients, both day-to-day and in times of crisis.

22. Beginning on or about July 7, 2020, I became aware that certain drug manufacturers—starting first with Eli Lilly and its Cialis products and now including Eli Lilly, Sanofi, and AstraZeneca, Merck, and Novartis—had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Erie's contract pharmacies.

23. Eli Lilly's notification affecting all products made or distributed by the company was implemented without advance notice on September 1, 2020, which did not allow Erie adequate time to respond to protect our patients' access to Lilly medication. Sanofi, Merck, and Novartis, for their parts, have requested that covered entities enroll in an unsanctioned and burdensome data collection platform called 340B ESP. Erie will not be participating in this data collection; our patients have thus lost access to Sanofi products. To date, Novartis has not yet followed through on threats to block 340B price access at contract pharmacies.

24. Because of these actions, our ability to provide patients with affordable medications has been dramatically reduced—Erie patients who were regularly receiving a 340B drug made by Eli Lilly, Sanofi, or AstraZeneca no longer have access to that medication at the discounted 340B price. Without the 340B discount, these medications are inaccessible for an Erie patient paying out-of-pocket. The following table provides Erie's average annual 340B prescription volumes prior to the manufacturers' actions:

Medication Impacted	**Medication Type**	**Average number of Erie 340B prescription fills annually at contract pharmacies, prior to recent manufacturer limitations**
Eli Lilly		
Basaglar	Insulin (diabetes)	840
Humalog	Insulin (diabetes)	1080
Humulin	Insulin (diabetes)	240
Trulicity	GLP-1 Agonist (diabetes)	120
Sanofi		
Admelog	Insulin (diabetes)	300
Lantus	Insulin (diabetes)	2400
AstraZeneca		
Brilinta	Antiplatelet (heart, circulation)	120
Bydureon	GLP-1 Agonist (diabetes)	240
Byetta	GLP-1 Agonist (diabetes)	480
Farxiga	SGLT2 Inhibitor (diabetes)	180
Symbicort	Inhaler (LABA+ICS) (asthma)	840

25. Erie is in communication with AstraZeneca regarding designating one exception contract pharmacy. This process is not finalized, and at present, our contract pharmacies are unable to purchase 340B priced AstraZeneca drugs. Even if the AstraZeneca exception process comes to fruition, it would only allow 340B access at one of our contract

pharmacies. To provide just one example of how unworkable this will be for our patients, patients of our Erie HealthReach Waukegan clinic would need to travel nearly three hours one-way on public transportation to arrive at our one remaining contract pharmacy in the Humboldt Park neighborhood of Chicago.

26. Erie is actively assessing opportunities to switch patients to affordable alternative medications. But I know as a medical provider that it is neither easy nor seamless to switch patients from one product to another. Many medication alternatives require a medical provider to review the patient chart, consider comorbidities, and assess appropriate dosing for the substitute medication. Several of the impacted diabetic treatments have very different dosing—for example daily versus weekly dosing—which requires extensive patient education and provider troubleshooting.

27. Language barriers add another layer of difficulty for patients who proceed to the pharmacy to pick-up their 340B refill and are told the price will potentially be hundreds of dollars more than it was last month. Forty-four percent of Erie patients are best served in a language other than English, and in 2019 Erie, through our interpretation service, provided care in 77 unique languages.

28. Erie has teams of Diabetes Educators who help teach patients how to use their insulin, diabetes medications, and glucose monitoring systems. As an Erie clinician, I directly see how important it is for my patients to thoroughly understand how to use their medication as directed. Frequent and/or rushed switching between medication formulations increases the opportunity for medication errors.

29. The loss of 340B savings and revenue—100% of which is reinvested into expanding access for our underserved patients—threatens Erie's ability to (1) provide comprehensive care to existing patients and (2) expand services to reach more individuals in its underserved target population. During the COVID-19 pandemic especially, 340B savings have been critical to our ability to continue serving patients and to maintain capacity to provide future services.

30. We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue. Erie is proud of the work of our care managers, case managers, health educators, and patient navigators, who provide personalized services that address social determinants of health and help Erie patients navigate their chronic health conditions. Without 340B savings, we would not have the capacity to fund these unreimbursed comprehensive care programs.

31. Erie is exploring all available options, but there is no action we can take to promptly remedy the drug manufacturers' refusal to provide 340B discount pricing. Erie has always used contract pharmacy partnerships to provide 340B medication access to patients. We do not have the pharmacy infrastructure to participate in the 340B program as an in-house pharmacy, and creating that infrastructure would involve a lengthy and expensive endeavor. Our patients cannot wait, they need access to affordable medications now.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: _____

By: _____ December 2, 2020
Lee Francis, MD, MPH, President and CEO
Erie Family Health Center, Inc.

Exhibit E

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
Plaintiff,	)	
	)	Civil Action No. 1:20-cv-03032
v.	)	
ALEX M. AZAR II, et. al	)	

Declaration of Kimberly Christine Chen

I, Kimberly Christine Chen, declare as follows:

1. I am the Director of Pharmacy at North Country HealthCare, Inc. ("NCHC") in Flagstaff, Arizona and have held this role since July 2012. As the Director of Pharmacy, I am responsible for oversight of our 340B compliance program, our in-house pharmacy programs, our contract pharmacy partnerships, and our clinical pharmacy services. I am also part of our management team, and to fulfill my job duties have access to financial and strategic planning information, including information related to the application of pharmacy revenue to other areas of the organization. My role reports directly to the Chief Financial Officer (CFO), who in turn reports to the Chief Executive Officer (CEO).

2. To prepare this declaration, I met with my pharmacy management team—which includes the pharmacy manager, pharmacy business manager, and clinical pharmacist representative—met with our CEO and CFO, and reviewed relevant internal data and reporting. I also met with my clinical pharmacists to discuss general patient impact and specific patient cases in which recent changes to our access to 340B discount pricing have impacted patient care.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. NCHC, a member of the National Association of Community Health Centers, is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. NCHC has its historical roots in a free health clinic model that transitioned to FQHC status upon community health center funding in 1996. The center has approximately 500 employees, approximately 85 of whom are medical providers.

5. Our primary clinic site and administrative hub is located in Flagstaff, Arizona, a population center with Medically Underserved Population (MUP) designation.

6. We also provide primary care services at behavioral health centers and homeless shelters, and operate satellite clinics targeting uninsured patients in Seligman, Winslow, Holbrook, Round Valley, Show Low, Williams, Grand Canyon, Dolan Springs/Kingman, Bullhead City, Lake Havasu City, and Payson communities. All, excluding Lake Havasu City, are designated Medically Underserved Areas (MUA's) and Health Professional Shortage Areas (HPSA's). These communities vary in distance from Flagstaff, primarily across the Interstate 40 corridor of Northern Arizona. The table below indicates the approximate distance and direction of these communities from our Flagstaff location.

Site (PCA)	Distance from Flagstaff (miles)	Direction from Flagstaff
Seligman	70	W
Winslow	60	E
Holbrook	90	E
Round Valley	180	SE
Show Low	140	E
Williams-Grand Canyon	35	NE
Dolan Springs/Kingman	143	W
Bullhead City	184	W
Lake Havasu City	208	W
Payson	115	SE

7. NCHC's services include diagnosis, treatment and referral for all illnesses, chronic disease management, prenatal/perinatal and delivery care, well woman checks, well child services/immunizations, pharmacy, laboratory and radiology services, preventive care/health education, oral health services, and integrated behavioral health. We also provide significant health promotion/disease prevention and enabling programs.

8. The Center has grown rapidly over the past twenty-five years, providing approximately 164,000 patient visits in calendar year ending December 31, 2019 to approximately 52,000 unduplicated users who call NCHC their "medical home."

9. The current payer mix from our most recent financials show that approximately: 7.2% of our patients are uninsured; 38% are Medicaid; 19.1% are Medicare; and 32.8% are commercially insured. The Medicare user population is expected to continue growing as few local providers accept new Medicare assignment.

10. According to the three Medicaid Managed Care plans in our service areas, diabetes, hypertension, and cardiovascular issues are the top three medical issues among that population. NCHC sees these issues similarly reflected in their patient population regardless of payer type.

11. NCHC has three in-house pharmacies situated within our Flagstaff, Grand Canyon, and Kingman locations. Our Grand Canyon and Kingman pharmacies are tele-pharmacies, staffed by pharmacy technicians (with Flagstaff-based pharmacists performing all

pharmacist's duties, oversight, and counseling). These tele-pharmacies were the first in Arizona—approved by special waiver from the Arizona Board of Pharmacy in 2010—and represent two of only a handful across the state. Tele-pharmacies help address the critical and unique needs in rural health care.

12. NCHC is a "covered entity" for purposes of the 340B Drug Program ("340B Program") and has been registered as such with the Health Resources and Services Administration (HRSA) since July 1, 1998. As required, NCHC recertifies all its eligible locations annually with HRSA. A current covered entity listing pulled from HRSA's Office of Pharmacy Affairs Information System (OPAIS) 340B database is attached as Exhibit A.

13. The 340B Program allows NCHC to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

14. NCHC uses a combination of both in-house and contract pharmacies to meet our patients' pharmaceutical needs. In addition to NCHC's three in-house pharmacies, NCHC utilizes 52 contract pharmacies in 12 different communities. Specific contract pharmacies, contract dates, HRSA OPA registration dates, and active dates are included as Exhibit B.

15. NCHC works with both McKesson and Cardinal distributors in a "bill-to/ship-to" replenishment model for providing 340B medications to eligible patients. The 340B medications are purchased after the prescription has been filled at a contract pharmacy and it has been confirmed that the prescription is (1) eligible for the 340B Program and (2) is not a Medicaid claim.

16. Our claims are managed by a third-party administrator (TPA) and audited by NCHC compliance staff. The TPA matches the prescriptions to patient, provider and encounter files to "carve in" those claims as 340B eligible. Depending on the TPA, there are also additional mechanisms to ensure accuracy, such as embedded coding in electronic prescriptions from our electronic medical record and bar coding on printed prescriptions. Once the TPA has "carved in" a prescription, a record of that eleven-digit national drug code (NDC) is recorded. When the TPA identifies that a full package of a medication (11-digit NDC match required) has been dispensed to eligible patients, an order is generated for that medication. The drug is purchased by NCHC (aka "bill-to") and provided to the contract pharmacy where the medication was originally filled (aka "ship-to"). At no point in this process can the contract pharmacy order 340B medications directly or see the 340B drug pricing.

17. All claims the TPA "carves in" are communicated to NCHC and audited to ensure compliance. No such claims are billed to Medicaid—the TPA is provided with all Bank Identification Numbers (BIN) and Processor Controller Number (PCN) listed on Arizona's Medicaid Exclusion File and NCHC audits all carved in claims to additionally ensure that all prescriptions were eligible and that none were billed to Medicaid.

18. NCHC also achieves compliance through (1) ongoing internal and external audits of both in-house pharmacy and contract pharmacy claims; and (2) extensive staff training.

19. NCHC providers prescribe roughly 280,000 prescriptions annually. Of those prescriptions, only about 13.97% were filled by NCHC's in-house pharmacy; approximately 65.33% were filled by NCHC contract pharmacies. However, of the prescriptions sent to the contract pharmacies, only about 26% were ultimately applied to the 340B Program. The other 74% were either Medicaid or otherwise not eligible for the 340B Program.

20. Contract pharmacy agreements are critical to provide our most vulnerable patients access to affordable medications for several reasons.

21. First, NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel (one-way trip), to reach the closest of NCHC's in-house pharmacies:

Service Areas	Pharmacy Locations		
	Flagstaff Pharmacy	Kingman Pharmacy	Grand Canyon Pharmacy
Seligman	70	74	
Lake Havasu		60	
Bullhead City		37	
Williams	35		59
Winslow	50		
Payson	115		
Holbrook	90		
Show Low	140		
Round Valley	180		

22. Traveling such tremendous distances to access affordable medications is not feasible for our patients, especially in northern Arizona where inclement weather is a significant factor during the winter months.

23. Our contract pharmacy agreements provide our patients access to affordable medications within their communities.

24. Second, our contract pharmacies, unlike our in-house pharmacies, are open on nights, weekends, and holidays. Even in the communities where we have an in-house pharmacy, contract pharmacies are critical to provide medication access outside regular business hours.

25. Finally, our homeless populations are best served by community pharmacies near where they are located to increase their adherence and reduce their significant barriers to care.

26. NCHC's participation in the 340B Program allows us to provide our uninsured and underinsured patients—including low-income workers and homeless individuals—access to affordable or no-cost medications. All our contract pharmacies provide a modified sliding fee scale pricing to our patients who are 200% or more below the federal poverty level.

27. Additionally, revenue from prescriptions filled for our insured patients is used in furtherance of our mission and federal grant project.

28. For example, 340B Program proceeds support our clinical pharmacy program, in which pharmacists work in the clinics as members of interdisciplinary care teams to optimize medication regimens, promote adherence, generate medication alternatives and provide both group and individual patient education. Clinical pharmacists are critical on teams that provide chronic disease management, anticoagulation services, and pain management. Clinical pharmacy services expand patient access to care, improve patient outcomes, decrease medical providers' workloads, and improve provider satisfaction. This service is not reimbursable by CMS or commercial insurance, and would not be possible without the 340B Program.

29. Revenue generated from the 340B contract pharmacy environment is also used to support our most rural clinics. Without this subsidy, these clinics, which have lower patient volumes, would not be sustainable. Without this funding source, NCHC may be forced to close as many as six of our locations and lay off approximately 100 staff and providers.

30. Beginning in or around June 2020, I became aware that certain drug manufacturers, including Merck (notified June 29, 2020), Sanofi (notified July 31, 2020), AstraZeneca (notified August 20, 2020; position since modified to permit limited use of contract pharmacies) and Eli Lilly (notified September 1, 2020) had unilaterally decided, without government approval, to cease providing most or all outpatient prescription drugs at 340B prices to most or all of NCHC's contract pharmacies.

31. These actions significantly and negatively impact our patients.

32. Without contract pharmacies, only three of the twelve communities NCHC serves would have access to pharmacy.

33. Without contract pharmacies, patients will not be able to afford their medications at commercial pricing and most will not be able to travel the great distances required to procure their medication from our in-house pharmacies.

34. For example, Symbicort, made by AstraZeneca, is the only approved first line medication in the treatment of asthma according to the 2020 guidelines by Global Initiative for Asthma (GINA). NCHC has multiple patients who are homeless who were tried and failed on other alternative treatments. The clinical pharmacist was able to switch them to Symbicort and the patients experienced marked improvement in their asthma, decrease in their exacerbations, and quality of life due the medication change. Many of these patients can no longer use a contract pharmacy for Symbicort and instead must find a way to access the medication through an NCHC in-house pharmacy. Although NCHC identified and implemented workarounds for these patients, there is a limit to what we can do, and inevitably patients' health outcomes will be negatively impacted by limits on medication access.

35. An uninsured, Type 1 diabetic patient of our Show Low clinic, which is located approximately 280 miles from our closest in-house pharmacy, was taking Novartis-produced Novolin N, an insulin medication, but was experiencing frequent hypoglycemia (low blood sugar). Our clinical pharmacy staff worked with this patient to switch him to Sanofi-produced Lantus, on which he was able to keep his blood sugars stable. On or about October 1, his Lantus was no longer available through the contract pharmacy. Additionally, even if he could tolerate being switched back to Novolin N, the product and its comparable product made by Eli Lilly (Humulin N) are also not available at 340B pricing.

36. This patient's body is unable to make insulin. Without it he will die. Insulin is not a choice. Type 1 diabetes is not a choice.

37. I would also add that with the loss of contract pharmacy revenue, the clinical pharmacist who was able to get this patient on a stable, healthy insulin regimen targeted to his particular needs is potentially in jeopardy of losing their job, leaving this patient and all the others like him struggling to manage chronic diseases and navigate access to affordable mediations.

38. While this is just one patient story, all our diabetic patients face similar terrible outcomes. In the short term, switching insulins on stable patients can increase weight gain, reduce adherence due to formulations that require more frequent dosing throughout the day, and increase the risk of hypoglycemia, which can lead to seizures, coma, and even death. Insulin changes are difficult to titrate and require frequent contact with a clinical pharmacist, whose jobs are hanging in the balance. In the long term, these patients face higher risk for renal damage, retinopathy and blindness, and cardiovascular events.

39. Our patients are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications. Our providers are being forced to deviate from the standards of care based on a patient's payer type.

40. These changes have caused immediate harm and will cause additional harm the longer this is allowed to continue. Due to our geographical barriers, NCHC has had to scramble to get couriers in place at our various clinics and establish other workarounds for access to affordable care. We have also placed additional staffing burdens on our pharmacy team to identify those patients most impacted by these manufacturer's actions and to determine what treatment options may be available that the patient can both afford and access. Our pharmacy team has also had to create and support new processes for these deliveries and solutions for managing the influx of changed prescriptions. Our clinic staff has scrambled to navigate processes to allow patients to pick up medications in our clinics, a process that many front office clinic staff have never had to do before.

41. These additional burdens come at a time when health care across the nation is trying to adapt to the global pandemic.

42. If these actions continue, NCHC will have to make crucial decisions on what will need to be cut to compensate for the reduction in program income derived from our participation in the

340B Program. We will likely have eliminate our clinical pharmacists and determine which rural clinic location would need to be the first of possibly multiple clinic closures.

43. Last fiscal year, NCHC's in-house pharmacy wrote off more than $3.2 million in direct patient medication costs. As an FQHC, NCHC does not have the capacity to continue to provide the scope and depth of our services to patients if these attacks on the 340B Program continue.

44. NCHC has done its best to protect our patients during this crisis, but our solutions fall short.

45. For example, the courier deliveries we have established occur weekly and cannot address acute patient needs. If a patient realizes that they will run out of their insulin after the courier has left the clinic, they will not be able to access their medications for another week, putting the patient in danger of significant medical emergency that may require hospitalization or even result in death. Additionally, in northern Arizona, where severe snowstorms can occur on short notice during the winter months, it is common for couriers to have to cancel deliveries. The resulting delays in therapy are detrimental for patients and pose significant costs and burdens to the healthcare system.

46. Mailing prescriptions to patients poses challenges as well. Many of our patients do not have consistent addresses, our homeless patients have no addresses at which they can receive mail, our insurance contracts prohibit mailing beyond individual patient exceptions, and even if we were to secure mail-order status, all mail in our region is routed through Phoenix, where summer heat exceeds manufacturer recommendations for safe medication storage. Safely and legally mailing medications would involve significant expense and would still fail to help many of our most vulnerable patients.

47. A longer-term solution to consider is expanding our tele-pharmacy program. These pharmacies are very expensive to maintain, and the Arizona Board of Pharmacy requirements state that the pharmacy technician that staffs these locations must have a minimum of 1,000 hours of technician experience prior to working in tele-pharmacy. This is a huge barrier due to the rural nature of these locations. Staffing in these locations by skilled, credentialed team members is an ongoing issue and this would also be the problem for tele-pharmacy. Additionally, due to the parameters of operation, these pharmacies do not demonstrate a high capture rate of prescriptions for those patients who have insurance, making the model not financially sustainable without outside funding.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: December 3, 2020

By: Kimberly Chen

Kimberly Christine Chen
Director of Pharmacy
North Country HealthCare, Inc.

Exhibit F

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Ludwig M. Spinelli

I, Ludwig M. Spinelli declare as follows:

1. I am the Chief Executive Officer at Optimus Health Care Inc ("Optimus"), which serves approximately 50,000 patients in the Bridgeport and Stamford regions of Connecticut. In this position, which I have held since in or around September 1983, I am ultimately responsible to the Board of Directors for health center performance and patient care.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Optimus is a Federally-qualified health center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. Optimus is a member of the National Association of Community Health Centers.

4. Optimus has been in operation since approximately December 1976, and presently offers some 210,000 annual visits to approximately 50,000 unduplicated patients at our 35 service locations. Our target population is low-income residents in our southwestern Connecticut service area that ranges from western New Haven county to the New York border.

5. Approximately 22% of our patients have no insurance and are thus placed on a sliding fee scale based on their income. Some 60% of our patients qualify for Medicaid and approximately 8% for Medicare.

6. We have around 7,000 patients with diabetes, hypertension, and asthma, and we provide comprehensive support to approximately 500 HIV positive patients.

7. Optimus is a covered entity for purposes of the 340B Drug Pricing Program ("340 Program") and has been for some 10 years. Optimus recertifies its covered entity status

annually with the Health Resources and Services Administration (HRSA) in keeping with HRSA's Office of Pharmacy Affairs guidelines and directives.

8. The 340B Program allows Optimus to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. Optimus purchases drugs at 340B pricing from two main wholesalers: Cardinal Health and McKesson. We purchase approximately $1.4 million in prescription medications from our 340B wholesalers every year.

9. Optimus dispenses the drugs it purchases at 340B pricing to eligible patients via contracted pharmacy partners. These contracted pharmacies include Walgreens, CVS, Walmart, Rite Aid, and three local pharmacies in our service area: Slavins, Cornerstone, and Bridgeport Pharmacy.

10. From a patient perspective, these pharmacies are accessible and conveniently located. Many also have home delivery options, which help out patients to obtain their medications and remain compliant with medication regimens.

11. Optimus has written agreements with each contract pharmacy that detail how the program works. In compliance with 340B rules, each of these pharmacies was registered with and approved by HRSA, before any 340B medications were dispensed to any of our patients. The approximate date of approval for each pharmacy is as follows:

    - Walgreens Pharmacies executed on 8/24/2011
    - Rite Aid Pharmacies executed on 7/1/2014
    - Slavins-Hancock Pharmacy executed on 1/1/2013
    - Cornerstone Pharmacy executed on 9/18/2013
    - Bridgeport Pharmacy executed on 4/4/2019
    - Wal-Mart Pharmacy (Stratford CT) executed on 4/1/2019
    - CVS Pharmacies executed on 7/22/2019

12. With the exception of Walgreens, our 340B operations are managed by our Third-Party Administrators ("TPAs") CaptureRx and Wellpartner. Through the services provided by the TPAs, we ensure 340B Program compliance including:

    - Patient, prescriber and covered entity eligibility
    - Exclusion of Medicaid prescriptions to prevent duplicate discounts
    - Purchasing and tracking inventory
    - Reports for auditing

13. Although the TPAs assist us in fulfilling these responsibilities, we know that Optimus is ultimately accountable for adherence with 340B Program requirements. Our Finance Department tracks the activity overseen by our in-house pharmacist, who helps to manage the program and is a resource to the contract pharmacies and the patients. Our 340B Committee and our Compliance Department are actively involved in ensuring that we meet all relevant HRSA and program requirements.

14. At the pharmacy level, each prescription is verified for eligibility in accordance with 340B rules. Patient eligibility, covered entity and prescriber eligibility, and all other 340B criteria must be met. We achieve this through our TPA's, CaptureRx, WellPartner, and Walgreens. If a prescription does not meet any of the qualifying criteria, it is excluded from our 340B Program. This applies to both insured and uninsured patients.

15. Optimus' participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Uninsured patients get 100% of the savings at our partner (contract) pharmacies, as explicitly spelled out in our agreements with these pharmacies, and pharmacists do not mark-up our 340B medications. In addition to the 340B cost of the medication, a reasonable, pre-negotiated dispensing fee is charged to patients who can afford it. For our patients who cannot afford the dispensing fee, we cover the entire cost of their prescription.

16. Any net revenue we derive from the 340B Program also goes directly to our patients. Our Dental, Podiatry, and Clinical Nutrition departments are excellent examples of how we provide enhanced patient care with 340B dollars. In our geographical area, we are one of the only sites to offer dentures and other procedures at deep discounts.

17. Similar to dentistry, our Podiatry and Clinical Nutrition Departments are supported by 340B dollars. These departments reach some of our most needy patients, including those with diabetes, for whom podiatry and clinical nutrition services can be crucial to overall wellbeing.

18. Optimus has a robust 340B Program with approximately 3,200 unique patients participating. Of these, about 1,500 patients have no prescription insurance. The remaining 1,700 some odd patients have prescription insurance; however, they may still need additional assistance affording their medications. Through our partnerships with contract pharmacies, our patients receive approximately 17,000 prescriptions every year.

19. At Optimus, pharmacy services are an integral part of comprehensive health care. In addition to 340B dispensing services, our community pharmacy partners provide pharmacy-based health care to our patients and support to our clinical staff. Some of these services include chronic disease state monitoring, medication adherence programs, medication therapy management services, and timely feedback to our clinicians. The strong communication link between our providers and pharmacists allows for easy communication and delivery of patient care.

20. Convenient locations and service hours, coupled with culturally competent staff, make our 340B partner pharmacies the best choice for our patients. To accommodate patient care priorities, we do not require patients to change pharmacies for 340B pricing. Instead, we expand 340B access to the patients' pharmacies of choice.

21. Beginning on or about July 23, I became aware that certain drug manufacturers, including Eli Lilly, AstraZeneca, and Sanofi had unilaterally decided, without government approval,

to cease providing outpatient prescription drugs at 340B prices to most or all of Optimus' contract pharmacies. These restrictions have impacted our uninsured patients' ability to acquire life-saving and life-improving medications. We have determined the impact from these three manufacturers alone to be as follows:

- Uninsured patients will lose access to approximately 773 affordable prescription medications for their chronic health conditions. Our records show that before COVID-19, annually 1,610 unique (unduplicated) patients received one or more medications made by one of these three manufacturers. The need for affordable medications in underserved communities has been amplified by the pandemic and the economic fall-out that resulted. Access to insulin, asthma controllers, and other essential medications are cut off when people need them the most. Patients that were paying about $12 to $15 for three months' supply of these medications will now have to pay about $300 to $600 per month to continue their treatment.

- Our health center will lose over $560,000 a year in 340B revenue, this does not include the impact from Merck and other manufacturers who have also announced plans to restrict access to 340B pricing but have not implemented their plans to date. If the current trend is allowed to continue, we believe this figure will be much higher. 340B is a vital revenue stream that allows us to expand primary care to patients who need it the most. As a result, vital programs like Dental, Podiatry, Clinical Nutrition, and others will be at risk of losing their funding. Without 340B revenue, our expanded dental services would become an expense we could not afford to cover.

- To limit the loss to our patients, we are actively searching for suitable alternatives for medications made by Eli Lilly, AstraZeneca, and Sanofi. Please see the attached list of recommendations developed by our Clinical Pharmacist to help support our providers and patients.

22. There is significant harm done to our patients due to the sudden discontinuation of 340B pricing of maintenance medications. As pharmaceutical companies continue to exclude more medications from the 340B Program, we are quickly running out of options for our patients.

    - The sudden discontinuation of 340B pricing did not allow time to notify patients and work out an effective strategy.

    - Providers are forced to change medication therapies without adequate time to evaluate the health outcome of new therapies to their patients.

    - In the case of the "one contract pharmacy only" requirement imposed by certain manufacturers, providers are put in the uncomfortable (and sometimes inappropriate) position of telling patients which pharmacy they can go to for their medications.

23. Patients who rely on our 340B Program for their medications have been harmed directly. Mrs. P. is an uninsured patient. Since 2017 her diabetes has been controlled on insulin

made by Eli Lilly, for which she paid $15 a month. On September 4, 2020, she went to the pharmacy and she was asked to pay $270. Without any prior notice or a reasonable alternative, she was left without her medication. To complicate matters more, Mrs. P. is a visually impaired patient who does not speak English. She depended on the 340B Program to access her medication at a local pharmacy that accommodates her needs. She has been let down.

24. Mrs. A. has a similar story. She is followed in our ob-gyn practice in Stamford for gestational diabetes. While her pregnancy is high risk, she has been managed well on an insulin product made by Eli Lilly. However, 27 weeks into her pregnancy, she was asked to pay full price for her insulin, $320 which she could not afford. Like many of our patients, Mrs. A. is not eligible for discount programs sponsored by pharmaceutical companies due to her undocumented immigrant status.

25. Many of our asthmatic patients are also affected by Astrazeneca's restriction on 340B priced medications. Mr. O. can be cited as an example. He suffers from severe asthma. While his illness has been difficult to control, he and his doctor have worked closely together to manage his condition and stabilize him on the right medication. Mr. O. paid $15 a month and visited the local pharmacy frequently since 2014. In October 2020, his medication therapy was interrupted due to Astrazeneca's policy change. Mr. O. could not afford to pay $315 a month for his inhaler. He is now starting treatment on a new medication, uncertain how well it will control his asthma. Even more uncertain of what might happen to him if more pharmaceutical companies block access to the 340B Program.

26. These patient experiences demonstrate the challenges uninsured individuals face to pay for their medications. The pandemic has worsened the problem with additional health problems and a lack of jobs to pay for these medications. At a time of dire need, access to 340B priced medications is being restricted by some pharmaceutical companies.

27. The harms listed above are in addition to the financial burden levied on Optimus to continue to provide comprehensive health services, without the vital dollars to reach more patients. To fill the gap created by the 340B loss, Optimus anticipates a $1.5 million budget reduction. At risk are our patients who receive free and reduced-cost care, many of the same patients who lost their 340B savings at the pharmacy.

28. Optimus is coming out of the last fiscal year with an overall loss caused by COVID-19. We did participate in the Payroll Protection Program, but our revenue remains below that of the pre-COVID period. Our visits are down approximately 20%, and many patients are reluctant to visit Optimus for routine care due to recent COVID-19 positive spikes in the population.

29. We are working with some drug manufacturers that will ship our drug purchases to one contract pharmacy, but our service area is approximately 25 miles wide. It is impossible to expect all of our patients to travel to one single pharmacy given the significant practical barriers that stand in the way such as time and transportation availability.

30. Additionally, many patients are hesitant to use mail order pharmacies, and those pharmacies are not part of our 340B Program. Thus, this option does not improve access to needed medications.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12/8/20

By: Ludwig M Spinelli

Ludwig M. Spinelli
Chief Executive Officer
Optimus Health Care Inc

Exhibit G

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of David Steven Taylor

I, David Steven Taylor, declare as follows:

1. I am the Director of Pharmacy Operations for Appalachian Mountain Community Health Centers (Appalachian Mountain) in western North Carolina, and have held this position since September 2018. As Director of Pharmacy Operations, I am responsible, among other duties, for overseeing Appalachian Mountain's 340B program participation, our Hepatitis Treatment program, and many aspects of our Outpatient Based Opioid Therapy.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Appalachian Mountain, a member of the National Association of Community Health Centers, is a Federally-qualified health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in a mixed urban and rural six-county area of roughly 2,916 square miles, much of which is deep in the Appalachian Mountains. As required, we provide our care and services regardless of patient insurance status or ability to pay.

4. In 2019, we served over 12,000 unduplicated patients at our six clinic locations.

5. Our overall uninsured patient count tops 2,000, or about 20% of our patient population, depending on the month. We treat over 1,000 patients with some form of substance use disorder, and this patient population is growing rapidly. Our more urban clinics currently serve just under 1,000 homeless and completely indigent patients.

6. Appalachian Mountain is a "covered entity" for purposes of the 340B Program.

7. The 340B Program allows Appalachian Mountain to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

8. As a covered entity, Appalachian Mountain is permitted to choose how it will deliver pharmacy services to its patients. We have a single in-house pharmacy located in Robbinsville, North Carolina, which, due to its size, is only able to service the patients of that particular clinic.

9. Additionally, we use a network of over 20 community partner pharmacies to provide care for Appalachian Mountain patients seen at our other five clinics. Each one of these partnerships was created with the execution of a unique contract that lays out the terms agreed upon by both parties, including the manner in which the avoidance of duplicate discounts and diversion will be accomplished (as required by statute). Each contract is also certified and enrolled via the Health Resources and Services Administration (HRSA) OPAIS web portal.

10. Our contract pharmacy relationships are absolutely necessary to our patients. It would be highly unreasonable to ask our patients in Asheville or those who are homeless to drive to our in-house pharmacy roughly two hours away to retrieve their medications. It would be equally unreasonable to force single parents working two jobs to find the time to come to a 9-to-5 pharmacy when they could use a Walgreens that is open 24 hours.

11. We currently purchase drugs to be dispensed by our contract pharmacies from three wholesalers: Amerisource Bergen, McKesson, and Smith Drug. The primary drive for determining which wholesaler to use is the established relationship of the contract pharmacy in question. By using the pharmacy's primary wholesaler, we ensure cohesiveness between all parties.

12. These relationships are managed with the utmost attention to detail and always keeping in mind the intended goal of expanding care. Our wholesalers create separate 340B accounts for each pharmacy and establish individual "ship-to, bill-to" arrangements under which medications sent to each pharmacy are owned by Appalachian Mountain and are audited every two weeks to ensure that 340B medications have only been used for eligible patients and prescriptions, and that the medications have been dispensed in a way that avoids duplicate Medicaid discounts. The contracted pharmacy provides these medications to our patients often at a highly discounted rate—sometimes at only 1–2% of the medication's wholesale value—while only charging a nominal dispensing fee.

13. Appalachian Mountain's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Through participation in the 340B program, we have established avenues through which our patients can get ultra-low cost and even free medications.

14. We have also used our 340B savings to expand numerous services within our community: we have hired staff for community outreach who build bridges to access for care; provided a fleet to take homeless patients to and from appointments and to pick up their medications; hired behavioral health staff and embedded them in each of our clinics; expanded access to Outpatient Based Opioid Treatment to each of our clinics; and overall created a place where those less fortunate in our community can come to get care that is equal to or better than the care provided by anyone else.

15. Appalachian Mountain processes over 38,000 out-patient medications a year under the 340B Program, many of which would not be affordable to our patients were it not for the discount pricing that is extended to us under the statute. These include, but are not limited to, medications necessary to treat hepatitis, diabetes, behavioral health diagnoses, and cardiac conditions, as well as addiction treatment medicines.

16. Appalachian Mountain currently purchases over $100,000 a month in 340B medications, which results in over $250,000 in net 340B savings at a margin of between 64% and 70%. Just under half of these purchases are dispensed to patients through our contract pharmacy relationships. We do our best to utilize our in-house services when possible, but we should not be required to do so at the expense of our patient's care.

17. Beginning on or about August 15, 2020, I became aware that certain drug manufacturers, including AstraZeneca, Eli Lilly, and Sanofi, would no longer provide outpatient prescription drugs at 340B prices to most or all of Appalachian Mountain's contract pharmacies.

18. After only a few short weeks, I saw first-hand the extent to which the actions taken by these drug manufacturers caused irreparable harm to our patient population. For example:

    - Numerous patients who live miles away from our offices have already gone without insulin because when they arrived at the pharmacy, instead of a $20 out of pocket cost they were met with a $285 cost.
    - Individuals who were on Farxiga, an AstraZeneca drug used in the treatment of diabetes, cannot always be switched to Invokana (a similar medication produced by Janssen Pharmaceuticals, Inc.) due to certain comorbidities, so they are forced to take an inferior class of medication altogether.
    - Patients who were taking Lantus, a Sanofi insulin medication used in the treatment of diabetes, are having to be switched to the only remaining affordable, long-acting insulin, Levemir, which is an inferior molecule and requires 2 shots a day versus just one with Lantus. With such a switch, not only is the patient inconvenienced with twice as many shots per day, he or she now also must purchase twice as many lancets for use.
    - Having to travel long distances for medications that are needed acutely puts an unneeded strain on a population that already struggles to simply afford medication, let alone transportation costs.

19. Our attempts to switch patients to alternate medications create an ethical (as well as practical/logistical) dilemma. Our providers want our patients to be on the drug that is best-suited to treat their current disease state, not on whatever medication is left over after multibillion-dollar companies disassemble the 340B statute.

20. Since its initial announcement, AstraZeneca has walked back its position, allowing some health centers to designate one contract pharmacy location for each health center site that does not already have an in-house pharmacy. Appalachian Mountain applied for this exception on or about November 11, 2020, using an AstraZeneca form. This process was not straightforward—AstraZeneca was not clear about which covered entities or sites would qualify—but Appalachian Mountain received notice on or about November 17, 2020 that AstraZeneca had approved its application retroactive to October 1, 2020. On or about

November 24, 2020 pricing for the contract pharmacies selected was updated within our wholesaler ordering platform. Although this is an improvement, it does not restore access to all of our contract pharmacies.

21. The actions taken by these drug manufacturers have caused and will continue to cause irreparable harm to our health center, which in turn harms our patients. Between September 1, 2020 and October 1, 2020, we lost just under 4% of our 340B savings due to Eli Lilly's actions alone. After reviewing September and October data, we project that because of the drug manufacturers' actions, we will lose approximately 7–8% of 340B revenue, or approximately $250,000 over the next year. That figure assumes that no additional manufacturers limit our access to 340B pricing.

22. The money we have lost and will lose has been used to fill gaps in programs for our most vulnerable patients. As described above, among other patient-focused uses, this money is used to provide transportation to individuals without vehicles and to pay for medications for those without sufficient income.

23. Additionally, finding a way to fit scores of patients into a full schedule for additional visits to consult on medication alterations without being able to bill for those visits is a near impossibility.

24. If the actions taken by drug manufacturers are not reversed, our ability to be the safety net provider in our community—our very mission and the reason we receive federal grant funds—will be diminished. I am concerned we will be reduced to nothing more than an Urgent Care facility, and that we will lose our ability to provide affordable medications to patient who need them.

25. Our efforts to mitigate the harm done by these manufacturers unfortunately have fallen, and will continue to fall, short of the mark. We could establish a mail order pharmacy, but this would take almost a year to set up and we would still be left with no solution for highly indigent Appalachian Mountain patients and those experiencing homelessness.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12 - 3 - 2020

By: _____
David Steven Taylor
Director of Pharmacy Operations,
Appalachian Mountain Community Health Centers

Exhibit H

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. 1:20-cv-03032
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of J.R. Richards

I, J.R. Richards, declare as follows:

1. I am the CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus ("MAP") and have held this role since in or around January 2015. As CEO, I am responsible for overall operations and implementation of the policies of the Board of Directors. I supervise a senior leadership team consisting of the Chief Operations Officer, the Chief Financial and Business Development Officer, the Chief Medical Officer, the Chief Information Officer, the Chief Compliance Officer, and the Satellite Operations Administrator. I am also responsible for oversight of all departments within the organization, including the Pharmacy Department, whose members have regular access as part of their job duties to all information related to pharmacy operations. To prepare this declaration, I consulted with all members of the senior management team, as well as our Director of Pharmacy Operations, and reviewed relevant data and information.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. MAP is a Federally Qualified Health Center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in Augusta, Georgia and surrounding areas, including in Richmond, Burke, and Jefferson counties. MAP has served this patient population regardless of patient insurance status or ability to pay since in or around 1997.

4. MAP estimates it will serve over 25,000 patients in 2020, over 5,000 of whom are uninsured and below 200% of the federal poverty level. MAP currently provides primary care, woman's health, dental, pediatrics, behavioral health, diabetes management, pharmacy, endocrinology, pulmonary, dermatology, infusion therapy, and infectious disease services for our patients and community.

5. In 2019 alone, MAP provided over $8,000,000 in uncompensated care to patients who could not, either through insurance or independently, cover some or all the costs for their care.

6. MAP is a "covered entity" for purposes of the 340B Drug Pricing Program ("340B Program") and first received Health Resources and Services Administration (HRSA) approval to participate in the 340B Program in or around 2008. MAP recertifies its status annually with HRSA to maintain that approval.

7. The 340B Program allows MAP to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. MAP purchases these discounted medications for dispensing at its in-house pharmacies, clinics, and contract pharmacies from several wholesalers, including Cardinal, McKesson, Henry Schein, and other independent companies. MAP currently spends an estimated $410,000 per month—close to $5 million per year—in 340B drugs for its patients.

8. MAP uses a combination of in-house pharmacy and contract pharmacy arrangements to provide all-inclusive access to its patients for their prescription needs. Due to several patient-related factors, MAP is only able to serve about 40% of its patients through in-house pharmacies. Most of MAP's patients thus rely on our contract pharmacy network to fulfill their prescription needs. All contract pharmacy arrangements are memorialized in written agreements between MAP and the pharmacy. Dispensing is available through contract pharmacies only after an agreement is finalized and approved by HRSA's Office of Pharmacy Affairs (OPA).

9. Our contract pharmacy network expands our ability to offer 340B savings and reach more of our vulnerable patients to fulfill their pharmacy needs. Because of 340B, MAP is able to provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all.

10. Six of our eleven sites do not have an in-house pharmacy and MAP's patients who rely on these sites for care strictly rely on contract pharmacies to meet their prescription needs at affordable prices. Additionally, because our in-house pharmacies are only open during clinic hours—weekdays from 8AM to 5PM—our contract pharmacy network allows our patients to access 340B discounted drugs outside of these hours. A lack of available time during the traditional workday is a significant barrier for our patient population.

11. An optimized network of contract pharmacies also allows MAP to generate additional revenue by increasing its "capture rate," which in turn enables MAP to retain more 340B savings and therefore support more services for its patients. As required, we reinvest all 340B savings and revenue in services that expand access for its medically underserved patient population.

12. Our participation in the 340B Program further allows us to provide services to vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families.

13. MAP does not—and legally cannot—refuse to see an individual based on his or her inability to pay for services. We offer all our services on a sliding fee scale for those that are 200% below the poverty level, and many patients receive services for free. This means that a patient can see a provider for a primary care medical visit valued at $175 including lab work, for as little as $25, or for free depending on their family's income and size.

14. MAP also uses 340B Program savings and revenue to provide patient services that could not be offered without these funds. These services include behavioral health, dental, mobile van services, a patient assistance program, and free prescription delivery services, which annually entail an estimated 6,000 free prescription deliveries to our underserved community to overcome major transportation barriers to care.

15. Across all pharmacies, MAP currently fills an average of approximately 7,500 prescriptions per month, and approximately 90,000 prescriptions per year.

16. All our contract pharmacies operate on a virtual inventory model, which means pharmacies dispense medications from their retail stock, identify qualified 340B claims, and replenish their stock with 340B medications. The claim matching process is handled by Third-party Administrators (TPAs) and goes through several filters before a claim is deemed eligible for 340B pricing. MAP pays a fee to the contract pharmacies (for providing dispensing services) and TPAs (for qualifying claims and ordering medications).

17. As required by HRSA, MAP does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount. MAP views compliance of contract pharmacies very seriously and has hired a pharmacist who is a 340B Apexus Certified Expert (340BACE) to audit and reconcile inventories on all contract pharmacy claims. In or around July 2020, MAP underwent a 340B HRSA Audit where there were no findings.

18. Beginning on or about July 22, 2020, I became aware that certain drug manufacturers including Eli Lilly, Sanofi, and AstraZeneca had unilaterally decided to cease providing outpatient prescription drugs at 340B prices to MAP's contract pharmacies.

19. Because of this action, many of MAP's patients can no longer fill their prescriptions for life-saving and life-sustaining medications through MAP's contract pharmacy network.

20. MAP currently has no access to Eli Lilly or Sanofi medications at 340B pricing to be dispensed through its contract pharmacies.

21. MAP likewise has no access to AstraZeneca drugs at 340B pricing at most of its contract pharmacies. After its initial announcement, AstraZeneca indicated it would ship drugs purchased at 340B prices to certain contract pharmacies. On or about October 14, 2020, MAP requested that AstraZeneca approve six of its contract pharmacies for this exception. MAP received notice on or about November 30, 2020, that AstraZeneca would continue to ship drugs at 340B pricing to three of the six requested pharmacies. MAP is currently working with its TPA to implement 340B purchases and dispensing for these pharmacies.

22. We have been working to switch patients to alternate medications and to convince our patients, where possible, to fill their prescriptions at our own, in-house pharmacies where they will still have access to discount pricing.

23. Both efforts have challenges. Even for patients who don't face significant barriers to filling their prescriptions at one of MAP's in-house pharmacies, many are reticent to switch because of familiarity and comfort. Switching patients to alternate formulations to avoid paying full price for these medications may cause patients to become unstable and potentially cause adverse health consequences. For example, a patient whose diabetes was fully controlled by Humalog (an Eli Lilly insulin) may be forced to switch to Novolog (a Novo Nordisk insulin) since Eli Lilly has banned or restricted shipments of its products at 340B pricing to our contract pharmacies. This patient's diabetes may become uncontrolled or the patient may experience adverse effects from switching. In 2019, approximately 19% of MAP's patients were diabetics compared to the State and National averages of 12% and 9%, respectively.

24. Additionally, MAP estimates we will lose up to approximately $350,000 in annual net revenue as a result of these manufacturer's actions. MAP receives grant dollars to help serve its patients, but these grants only cover about 28% of MAPs total expenses, and MAP depends on its 340B Program savings and revenue to help support approximately 41% of the remaining expenses, which include underfunded and unfunded programs and services such as behavioral health and dental services.

25. This significant financial loss, if not prevented or recovered, will also result in reduction in other clinical and/or patient services, increased work for clinicians, and increases in costs where MAP is covering costs for its uninsured patients and/or patients who are unable to pay.

26. MAP has actively tried to find ways to mitigate the negative financial consequences of the manufacturers' actions. We have considered eliminating or charging a fee for our current free prescription delivery program, increasing per-provider patient volume, and making reductions in some clinical services. Each of these options, however, ultimately negatively impacts patient care and still falls short of an adequate remedy.

27. These restrictions from manufacturers, and MAP's inability to access an administrative remedy through HRSA, will drastically impact our health center's operations and could severely alter our ability to provide access to low-cost services to our underserved community, which is the premise of the FQHC program.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: DECEMBER 9, 2020

By: _____
J.R. Richards, MPA
Chief Executive Officer

Exhibit I

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of Heather Rickertsen

I, Heather Rickertsen, PharmD, declare as follows:

1. I am Director of Clinical Pharmacy Services at Crescent Community Health Center (Crescent) in Dubuque, Iowa. I began working with Crescent in or around the spring of 2006, just prior to the clinic's official opening. I have served as Crescent's Director of Clinical Pharmacy Services since in or around August 2016. As director I have developed our pharmacy services to better serve our patients' health through improved medication access and compliance.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Crescent is a Federally-qualified health center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act. Crescent opened in or around the fall of 2006. Our health center serves approximately 6,500 patients annually; a third of the patients identify as racial or ethnic minority, 92% are 200% below poverty level, and 50% are uninsured. Compared to other health centers, we have slightly higher rate of hypertension at 29% of patients and diabetes at 17%, whereas within Iowa the average rates for hypertension is 26% and diabetes is 15%.

4. The cornerstone of Crescent's pharmacy services is patient access to necessary medications. In addition to providing our patients discounted medications, we cover the entire cost of medications for patients who cannot afford even discounted drugs. We also cover the cost of medication compliance packaging to assist those individuals with complex medication regimens.

5. Further refining pharmacy services, we provide pharmacists embedded within Crescent's medical and behavioral health clinic. These pharmacists provide a variety of services from medication reviews, anticoagulation, diabetes, and hypertension management, as well as support to providers for prior authorizations and pharmaceutical education.

6. Crescent is a "covered entity" for purposes of the 340B Drug Pricing Program (the "340B Program"). We have been eligible for 340B since in or around January 2008 and added a second contract pharmacy in or around January 2020. We maintain a physical inventory at each pharmacy and review reports, inventory, and eligibility on a monthly basis.

7. The 340B Program allows Crescent to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

8. As a covered entity, Crescent is permitted to choose how it will deliver pharmacy services to its patients. We use Cardinal Health as our wholesaler. Reorder points are set at the pharmacy, once prescriptions are dispensed and the inventory falls below order point, the pharmacy will generate replenishment to maintain physical inventory to allow a three-month supply of medication to be dispensed.

9. We contract with two pharmacies, both within walking distance of Crescent. The first contract is with Mercy Family Pharmacy (Mercy One Elm) at 1920 Elm Street. This was approved by the Office of Pharmacy Affairs (OPA) on January 1, 2008. The second contract pharmacy is Infocus Pharmacy Services, at 1690 Elm Street Suite 200. This was approved by the OPA on January 1, 2020. Our pharmacy model is 'physical on hand inventory' where prescriptions are dispensed to the patient at 340B acquisition cost of the drug plus a $9.50 dispensing fee. When patients are unable to afford the cost of drugs, Crescent covers the total cost for them.

10. Crescent retains all savings from each contract pharmacy model and does not utilize a third-party administrator ("TPA"). Crescent reimburses each pharmacy approximately $20 per prescription for dispensing fee, which we believe is in alignment with national and regional averages.

11. Both contract pharmacies offer a variety of services for patients including same day or next day delivery services within the city and free mail out services for our rural patients. Both pharmacies provide medication compliance packaging. Mercy One Elm offers additional transitions of care services for patients being discharged from their health systems and Infocus provides transitions of care services through their connection with Midwest Medical Center in Galena, Illinois. Both pharmacies offer flexibility to meet patients' needs, providing additional care coordination and leveraging referral-based prescriptions; the leveraging of additional funds allows medications to be affordable and guidance on regimens to meet patients' needs.

12. Both of our pharmacies maintain a physical inventory, reorder points are routinely set to allow for a three-month supply of a prescription to be dispensed, however as a result of the COVID-19 pandemic, and ongoing threats to the 340B Program, we have increased inventory to a 6 to 12 month supply. The pharmacies report when inventory falls below that threshold, and orders are directly uploaded to inventory. Additionally, for those items that are above acquisition cost of $100, the pharmacy has an inventory on demand and can order the medication for next day, rather than having physical inventory. Each contract pharmacy then provides a monthly report to the health center on prescription medications dispensed,

and a variety of detail on transaction and community benefit services offered, as well as specific therapeutic class and demographic information. These reports are reviewed and collated monthly for compliance to 340B policy, patient eligibility, and referral data. Additionally, report out on financial and volume data is reviewed and compiled for monthly reports to quality improvement, financial and board.

13. Annual prescription purchases in the 2020 fiscal year include over 2,300 unique National Drug Codes (NDCs) and current 340B purchase prices of approximately $350,000, 50% of which is directly tied to treatment of diabetes, hypertension, and mental health.

14. In the past 5 years, we have seen our annual prescription volume grow from about 10,000 to about 20,000, with approximately half of prescriptions for uninsured patients. Of the medications dispensed, the largest percentage of therapeutic classes include 17% to treat diabetes, 15% for hypertension, and 14% for mental health, these three categories represent nearly 50% of overall prescriptions dispensed.

15. Approximately 20% of our patients access prescriptions through the community health center. If out-of-pocket expense becomes a barrier for a patient, Crescent pays for the entire cost of the medication.

16. Our 340B Program participation also helps us to provide pharmacy services at no cost to patients, including medication management, anticoagulation management, diabetes education and management, and hypertension management.

17. Crescent's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Federal law and regulations, as well as Crescent's mission, require that every penny of 340B savings be invested in services that expand access for its medically underserved patient population.

18. In addition to various prescription medications—including insulin—Crescent also currently provides the following at no cost to any patient who is unable to afford a copay: blood pressure cuffs, diabetic testing supplies, and wound care supplies. This service is available to all patients who report being unable to afford medication, all patients on medication compliance services, and all Pacific Islander patients. We are able to do this for our most vulnerable patients because of the savings and revenue we generate through the 340B Program.

19. Furthermore, with 340B savings, we cover the cost of medication compliance packaging for patients with complex medication regimens that can make compliance a challenge.

20. 340B savings and revenue support our non-revenue generating Pacific Islander programs, which serve the unique needs of pocket populations of individuals from Marshall Islands and Federated State of Micronesia located in Dubuque and surrounding counties. These individual's may legally live and work in the area but may not rely on Medicaid or Medicare. Many of these patients are uninsured, food insecure, and in poor health.

Additionally, many were exposed to radiation during routine nuclear testing on these islands and suffer direct and ancillary health consequences. These unique patients are frequently found to have poorly controlled diabetes, higher rates of cancer, and heart disease.

21. The COVID-19 pandemic has exacerbated the situation for these patients, many of whom work in meat packing plants and reside in overcrowded living arrangements, both of which are ideal environments for rapid virus spread. To help meet the needs of this population, Crescent has implemented our Pacific Islander Health Project, which provides dedicated community health workers, as well as language interpreters and translators, social workers, and nursing staff. Participation in this program provides monthly group classes, free access to all medication, and frequent outreach.

22. Crescent's other non-revenue generating activities aimed at its general population include social services, community health workers, offsets to wellness center costs, and care coordination.

23. In early April 2020, we became aware of Bausch Health reducing distribution to one limited wholesaler in "direct distribution model" for 340B medication via a phone call by the new wholesaler appointed by Bausch Health. We did not receive direct notice of this change. This contact came on the heels of the COVID-19 outbreak, particularly devastating to a subset of Pacific Islander population, as well as having little prescription volume for our program. As seen as a limited threat, I choose not to register with a new wholesaler due to timing, limited use, and uncertainty surrounding COVID-19.

24. Additionally, on June 29, 2020, Merck notified us that it would only continue shipment of drugs we purchase to contract pharmacies, if we registered with 340B ESP to report data on prescriptions. We did initially register and attempted to submit data for July, but we were hampered by technical issues; we were able to upload and report data for August and September, but changes in terms and conditions on part of 340B ESP effective October 1, 2020 have made it impossible for us to upload data.

25. On or about August 17, 2020, we received notices from drug manufacturers Sanofi and Novartis, also requiring us to report data via 340B ESP.

26. Additionally, Astra Zeneca has informed health centers that they will only ship drugs to in-house pharmacies or, if a health center lacks that capacity, to a single contract pharmacy. Limiting shipment to a single contract pharmacy choice would severely limit patients' access as well as create inconsistent pharmacy services for patients.

27. Finally, on or about September 2, Eli Lilly indicated to the media that while it had ceased shipping covered entity-purchased drugs to contract pharmacies, it might be willing to ship insulin products to a single contract pharmacy per health center if the health center and pharmacy agreed to (1) dispense insulin at 340B purchase price and (2) to not leverage reimbursement from patients' private insurers.

28. Because of the actions by Bausch Health, Merck, Eli Lilly, AstraZeneca and Novartis, we face the possibility of losing 340B savings and revenue. Without these funds, we would no longer be able to cover patient copays, Pacific Islander programing, or our wellness center. We will also need to consider limiting patient access to dentures due to our loss of savings and the increasing cost of goods sold.

29. Beginning in or around July 2020, as changes began to develop with the 340B Program, we not only looked closely at revenue and expense specifically supporting the 340B Program, but also prepared a drug utilization review of distribution of medications based on manufactures and therapeutic classes.

30. We have determined that based on the manufacturers' actions, many patients will lose access to medications to treat diabetes, hypertension, asthma/COPD, and heart disease. Approximately thirty-two uninsured patients will no longer be able to afford their Asthma/COPD medications including rescue inhaler albuterol, 76 diabetic patients will lose access to critical oral medications to treat diabetes, an additional 51 patients will lose access to their insulin, an additional 40 patients will no longer have access to the medication to treat both acute and chronic health conditions. We would anticipate in response that patients will start to ration medications, and we will see an accompanying chronic decline in diabetes control over a period of 3 to 6 months; specifically for diabetic patients this will cause an uninsured hospital expense due to untreated diabetes including diabetic ketoacidosis, infections, heart disease, and renal disease.

31. For many patients on maintenance medication regimens, there are alternative drugs on the market; however, the appropriateness of a medication change is complicated by differing medication potencies, renal dosing, insurance formularies, and challenges in medication adherence posed by a new routine.

32. I have approximately nine patients who currently take Humulin U-500 from Eli Lilly, this medication has no alternative and patients who require this medication take insulin dosing well outside of dosing ranges in typical insulin products on market. Due to these patients' high insulin dosing requirements, we would expect a more rapid decline in diabetes control and rapid increase in negative patient outcomes.

33. The cost of medication for our patients is expected to rise from an average of approximately $180 annually, to approximately $5,000 for patients with large chronic disease burden.

34. Starting our new budget year in November 2020, our health center anticipates an annual reduction of $1,000,000 in lost revenue, and $500,000 in increased costs of goods sold. However, some cost projections are upwards of $2,000,000 cost increase of goods sold just in the top 100 drugs dispensed.

35. We are also now having to consider costs associated with opening an in-house pharmacy, which are estimated to be an additional $250,000 annually.

36. As we shift expenses, we would no longer be able to cover patient copays. We will also need to decrease our clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health project.

37. We have increased inventory levels to attempt to weather the storm, increasing monthly cost of goods sold from $30,000 to approximately $50,000. Unfortunately, our inventory will only last 3 to 6 months, and if this destruction of 340B structure continues, in a year we would no longer be able to provide access to medications or clinical pharmacy services.

38. Our number one goal in navigating these unfortunate circumstances will be to continue to provide our patients access to life-saving and life-sustaining medications. If needed will move to patient assistance programs and samples; however, this is known to increase patient burden and decrease patient compliance and is not a sustainable long-term solution.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/9/2020 (Date) Signature Marcelle Reed

Exhibit J

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Ryan White Clinics for 340B Access, et al., Plaintiffs, v. Alex M. Azar, Secretary U.S. Department of Health and Human Services, et al., Defendants.	Case Number: 1:20-cv-02906 KBJ

AFFIDAVIT

I, Terri S. Dickerson, hereby attest and state as follows:

1) I am the Chief Financial Officer ("CFO") of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare").

2) As CFO of FamilyCare, I am responsible for overseeing the accuracy of its financial statements and reports. I am knowledgeable about all of FamilyCare's sources of funding and its expenses.

3) The net revenues from FamilyCare's contract pharmacy arrangements allow it to: 1) pay for drugs needed by its patients who cannot afford to pay for the drugs; and 2) pay for support services for its patients that are not covered by insurance or paid for through grant funding.

4) Based on data from January 1 to June 30, 2020 and extrapolated to twelve months, FamilyCare realizes approximately $ 2,115,422 in net revenues annually through its

contract pharmacy agreements with contract pharmacies other than Walgreen's. (FamilyCare was not able to obtain data from Walgreen's at the time that this Affidavit was required.)

5) In comparison, FamilyCare received approximately $4.3 million in FQHC grant funding in the fiscal year ended June 30, 2020. FamilyCare's FQHC grant funding in 2020 was greater than in prior years because of additional federal funding that provided to health care providers that were treating COVID-19 patients and testing for COVID-19.

6) Based on data from January 1 through June 30, 2020 and extrapolated to twelve months, FamilyCare achieves approximately $449,178 annually in 340B net revenue for drugs manufactured by Eli Lilly Company ("Lilly"), Zeneca Pharmaceuticals, L.P. ("AstraZeneca"), and Sanofi-Aventis US LLC ("Sanofi"), and their corporate affiliates and filled through contract pharmacy arrangements other than the one with Walgreen's.

7) In 2018, FamilyCare's revenues exceeded its expenses by only $168,469. In 2019, FamilyCare's revenues exceed its expenses by only $298,258.[1]

8) FamilyCare will have to cut or scale back some of the services that it provides if FamilyCare loses over $449,178 annually as the result of the actions of Lilly, AstraZeneca, and Sanofi.

9) In order to continue providing at least some of the services that FamilyCare currently offers to its patients, FamilyCare will have to seek other funding sources, and there is no certainty that FamilyCare would be able to obtain additional funding.

10) The mission of FamilyCare, which is to make "making high-quality, whole-person care available to every member of the family and every member of the community" will be

[1] https://familycarewv.org/wp-content/uploads/2020/05/FamilyCare_AnnualReport2019.pdf , p.5.

compromised if FamilyCare is not able to provide the full range of support services that it

31) I am concerned that other drug manufacturers will follow the lead of Lilly, AstraZeneca, and Sanofi and decide to no longer provide 340B pricing through contract pharmacies. If FamilyCare lost access to all 340B drugs at its contract pharmacies, it would be devastating to FamilyCare's operations and the patients it serves.

[*Signature on next page*]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 23 day of November 2020.

Respectfully submitted,

Terri S. Dickerson
Chief Financial Officer
WomenCare, Inc., dba FamilyCare Health Center

Exhibit K

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. _____
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Kiame Jackson Mahaniah

I, Kiame Jackson Mahaniah, declare as follows:

1. I am CEO at Lynn Community Health Center ("LCHC") in Lynn, Massachusetts and have held this role since October 2017. As CEO, I am responsible for overall compliance and adherence to all HRSA requirements, including requirements related to our participation in the 340B Program. To prepare this declaration, I reviewed relevant internal patient and prescribing data with Kim Macleod, our CFO, and discussed the current situation and its challenges in depth with my executive team, the Board of Directors, and most of our external stakeholders.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. LCHC is a nonprofit community health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide healthcare and related services to a medically underserved population in the city of Lynn, Massachusetts regardless of patient insurance status or ability pay. We have been designated as a federally qualified health center (FQHC) since 1993.

4. Since 1971, LCHC that has served as the primary source of healthcare services in Lynn, Massachusetts, a dense, urban community with high rates of poverty. In 2019, LCHC provided approximately 286,980 medical, behavioral health, vision, and dental visits to approximately 41,115 patients.

5. Over 94% of our patients live at or below 200% of the federal poverty level, over 83% are racial/ethnic minorities, and about 59% are best served in a language other than English. Close to 60% of LCHC patients are on Medicaid, 9% are on Medicare, and 12% are uninsured.

6. The COVID-19 emergency is having a severe impact on Lynn and our patients. As of November 30, 2020, Lynn had 7,537 cases and 134 deaths in a city with 94,655 residents.

7. Lynn Community Health Center is a "covered entity" for purposes of the 340B Program. Our participation in the 340B Program, which provides us discount pricing on outpatient prescription drugs, began in or around 1999. We certify our covered entity status annually with the Health Resources and Services Administration (HRSA).

8. LCHC has contracted with pharmacies—principally Walgreens and CVS—to provide dispensing services to our eligible patients. We purchase drugs at 340B pricing from wholesalers McKesson, Cardinal, and AmeriSource Bergen and direct those drugs to be shipped to our contract pharmacies on a replenishment basis. LCHC maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies. LCHC's contract pharmacies undergo an annual certification process with HRSA's Office of Pharmacy Affairs.

9. One of the consistent barriers our patients face to accessing healthcare, including filling prescriptions, is transportation. In addition, we have a growing number of elderly patients for whom ambulation is also difficult. Contracting with pharmacies close to where our patients resides ensures convenient access, increases medication adherence, and provides opportunities for education within established patient-pharmacist relationships. Although always difficult to measure, this type of preventative and community-oriented care ultimately benefits total cost of care.

10. LCHC's average number of monthly 340B prescriptions is 14,000. Although that number is astounding, LCHC has one of the lowest ER use rates of any outpatient institution in Massachusetts.

11. Our annual purchases of pharmaceuticals at 340B pricing is approximately $4 million.

12. We ensure 340B Program compliance—including compliance with prohibitions on diversion and duplicate discounts—through a monthly reviews and independent third-party compliance testing.

13. LCHC's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients.

14. We are a national leader in integration of behavioral health (BH), Substance Use Disorder (SUD) treatment, and primary care. BH in particular does not have payment parity: providing psychopharmacologic services for children would simply be impossible without the margin provided by 340B discount pricing.

15. Support services, though vital to our patients, are generally not reimbursed. We use 340B savings and revenue to fund:
    - foreign language interpretation/translation services, which are currently provided in 30+ languages, with the top five languages accounting for 85% of our patients;

- social services, including assiduous screening for social determinants of health and a referral system through which we coordinate access to various services in the area (such as housing services coordinated through our relationship with the Massachusetts Coalition for the Homeless);
- recovery coaches and case management for our highest risk tier of patients, which includes patients suffering from homelessness, serious mental illness, and social isolation.

16. We respond to the needs of our most vulnerable constituents. Although we maximize our efficiency through lean management practices, we have limited flexibility given that we cannot choose our market, but instead simply answer identified community needs.

17. Without 340B discount pricing, we could not cover the cost of the programming listed above. With our care and services, there is a way forward for the most vulnerable in our underserved patient population. Our patients' needs will not disappear in the absence of such services, they will instead be pushed onto law enforcement, the schools, and/or the courts.

18. In September 2020, I became aware that certain drug manufacturers, including Eli Lilly and Sanofi, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of LCHC's contract pharmacies.

19. Because of this action, we estimate an approximate loss of $6 million from our roughly $8 million budget.

20. As a result of this loss, we are preparing for the permanent layoff of about 5% of our employees, or about 35 people. This includes all data management capabilities (3 FTE) that allow us to use our funding in the most efficient way possible; a dramatic scaling back of our mental health team, particularly in the psychopharmacology realm, to include our recovery coaches and most of our case managers.

21. We will also have to cut services, most of which are exactly those that heighten our efficiency and our ability to deliver targeted services: case management for vulnerable patients, programs targeting mentally ill folks suffering from homelessness, and therapy provided in our patients' native languages.

22. As a health center, we are used to operating very close to bare bone. Two years ago, for the first time in decades, we were ecstatic to realize a margin above 2%. A good month is one in which we clear $200,000. We normally have 4 good months a year.

23. LCHC would simply cease to exist as we now know it without our ability to purchase prescription drugs for our patients at 340B discount pricing. We would retrench to very basic care.

24. Crucially, our most vulnerable and marginalized patients would suffer the most. These patients will suffer untreated mental illness, lack of access to substance use disorder/addiction treatment, and lack of support services. I fear that the gains we have made in tackling some of the most profound problems in our community will be lost.

25. There are no good strategies we could employ to mitigate the drug manufacturers' actions. We could certainly develop a mail-in pharmacy program, yet we already have a 20% mail rejection rate. Trusting life-sustaining medication to this process seems unwise. Could we act as a wholesaler? Perhaps, but we currently don't have our own pharmacy and to expand in that way would require the development of a complex process that clearly lies outside our current services. It would take precious funds and bandwidth away from areas that cannot afford to spare either money, time, or expertise. There is no reasonable alternative to the 340B Program in its current iteration.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12/3/2020

By: 

Dr. Kiame Jackson Mahaniah
CEO
Lynn Community Health Center