OBERMAYER REBMANN MAXWELL & HIPPEL LLP
By: Steven A. Haber, Esquire
1120 Route 73, Suite 420
Mount Laurel, NJ 08054-5108
Phone: (856) 795-3300
Email: steven.haber@obermayer.com

Attorneys for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

CONSENT MOTION TO FILE BRIEF AS AMICI CURIAE IN SUPPORT OF DEFENDANTS BY RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER

Ryan White Clinics for 340B Access ("RWC-340B"), Little Rivers Health Care, Inc. ("Little Rivers"), and WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare") (collectively the "Amici"), by and through undersigned counsel, respectfully request to file a brief as amici curiae in the above captioned case. The Amici support the Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction. ECF No. 29. Amici have conferred with the parties, and counsel for all parties have consented to the filing of the attached amicus curiae brief. Amici's motion should be granted for several reasons: 1) Amici have a special interest in this case through pending 340B administrative dispute resolution ("ADR") petitions; 2) no party represents the interests of covered entities that participate in the 340B program, such as Amici;

3) Amici can provide the Court with the useful and unique perspective of small, community based 340B covered entities. The Amici focus on one topic in the attached brief: the harms that a preliminary injunction will cause to small, community based 340B covered entities and their vulnerable patients.

RWC-340B is a national, not-for-profit association of clinics that receive funding under the Ryan White Comprehensive AIDS Resources Emergency Act ("Ryan White CARE Act"), Pub. L. No. 101-381, 104 Stat. 576 (codified at 42 U.S.C. §§ 300ff–300ff-140), to provide health care and related support services to individuals living with human immunodeficiency virus/acquired immunodeficiency syndrome ("HIV/AIDS"). Receipt of this funding qualifies the members of RWC-340B to participate in the 340B program as "covered entities." Clinics funded under the Ryan White CARE Act provide primary medical care, medications, and support services to over half a million underserved and uninsured individuals living with HIV/AIDS. RWC-340B has members in all regions of the United States, including members that operate at least nine clinics throughout New Jersey. RWC-340B's members are typically small, nonprofit organizations that do not have the financial resources to operate in-house pharmacies and participate in the 340B program by ordering drugs for shipment to contract pharmacies, which dispense the drugs to the members' patients.

Little Rivers is a not-for-profit health care provider with facilities located in Wells River, Bradford, and East Corinth, Vermont. Little Rivers' mission is to provide respectful, comprehensive primary health care for all residents in its region, regardless of ability to pay. Little Rivers is certified by the United States Department of Health and Human Services ("HHS") as a federally qualified health center ("FQHC"), which qualifies Little Rivers to participate as a covered entity in the 340B program. Little Rivers has been registered as a

covered entity in the 340B program since 2006. Statistics from the Health Resources and Services Administration ("HRSA"), the division of HHS that administers FQHC grants, show that Little Rivers served more than 5,500 patients in 2019 and that, of those patients with known incomes, 61.2% had income at or below 200% of the Federal Poverty Level ("FPL"), including 19.48% with income at or below 100% of the FPL. HRSA, *Health Center Program Data for Little Rivers, Patient Characteristics*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 26, 2021). In 2019, approximately 50% of Little Rivers' patients were either Medicaid or Medicare recipients and approximately 5% of its patients were uninsured. *Id.* Little Rivers does not operate an in-house pharmacy and participates in the 340B program by using contract pharmacy relationships. Little Rivers filed an ADR petition on February 4, 2021, to contest a drug company's action to cease shipping 340B drugs to Little Rivers' contract pharmacies.

FamilyCare is a not-for-profit health care provider with several facilities in West Virginia, including three mobile units and clinics at local schools. FamilyCare's mission is to make high-quality, whole-person care available to every member of the family and every member of the community. FamilyCare is an FQHC and is eligible to participate as a covered entity in the 340B program by virtue of that designation. FamilyCare has been registered as a covered entity in the 340B program since 2000. According to HRSA statistics, FamilyCare served 32,353 patients in 2019, and of those patients with known incomes, 99.53% have annual incomes at or below 200% of the FPL, including 50.43% with annual incomes at or below 100% of the FPL. HRSA, *Health Center Program Data for WomenCare, Patient Statistics*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS00827 (last visited Feb. 26, 2021). In 2019, approximately 63% of FamilyCare's patients were either Medicaid or

Medicare recipients and 7.46% of its patients were uninsured. *Id.* FamilyCare does not operate an in-house pharmacy and participates in the 340B program by using contract pharmacy relationships. FamilyCare filed an ADR petition on February 12, 2021, to contest a drug company's action to cease shipping 340B drugs to FamilyCare's contract pharmacies.

Neither the Federal Rules of Civil Procedure nor the Local Rules of this Court address amicus briefs. Therefore, this Court has "broad discretion" to determine the "extent, if any, to which an amicus curiae should be permitted to participate in a pending action." *Bryant v. N.J. Dep't of Transp.*, 987 F. Supp. 343, 346 n. 3 (D.N.J. 1998) (rev'd on other grounds); *see also Yip v. Pagano*, 606 F. Supp. 1566, 1568 (D.N.J. 1985), aff'd, 782 F.2d 1033 (3d Cir. 1986). District courts have granted amicus curiae status where (1) the amicus has a "special interest" in the particular case; (2) the amicus' interest is not represented adequately or at all in the case; and (3) the proffered information is timely and useful.[1] *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002). The Amici meet all three standards.

First, the Amici have a "special interest" in this case. *Alkaabi*, 223 F. Supp. 2d at 592. All three Amici are plaintiffs in a lawsuit against several of the Defendants that concerns the ADR regulations that the Plaintiff seeks to enjoin. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21 (stayed Jan. 13, 2021). Moreover, two of the Amici (Little Rivers and Family Care) have filed petitions under the ADR process that Plaintiff seeks to enjoin.

[1] The *Alkaabi* court also examined whether the amicus was partial to a particular outcome in the case, *Alkaabi*, 223 F. Supp. 2d at 592, but this factor is not controlling. The Third Circuit has held that a party seeking to file an amicus brief does not need to be impartial and may have an interest in the outcome of the case. *Neonatology Associates, P.A. v. C.I.R.*, 293 F.3d 128, 131 (3d Cir. 2002) ("Thus, an amicus who makes a strong but responsible presentation in support of a party can truly serve as the court's friend."). Additionally, the New Jersey District Court has granted motions to file amicus briefs when the amicus was interested in the outcome of the case. *See Acra Turf Club, LLC v. Zanzuccki*, No. 12–2775, 2014 WL 5465870, at *6 (D.N.J. 2014).

Plaintiff Sanofi Aventis U.S., LLC, ("Sanofi") has stopped shipping 340B discounted drugs to Little Rivers' and Family Care's contract pharmacies. When Sanofi adopted this policy, Amici's options to vindicate their rights were limited in important ways. First, covered entities are precluded from bringing an action directly against a drug manufacturer to enforce the 340B statute. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011). Second, Congress had ordered HHS to implement an ADR process to resolve disputes between covered entities and drug companies, but HHS had not yet adopted the final ADR regulations. Therefore, the Amici's only recourse was to file suit against several of the Defendants to seek an order directing them to promulgate ADR regulations or to otherwise remedy the drug companies' actions. HHS subsequently issued the ADR regulations that are the subject of plaintiff's motion for preliminary injunction. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020).

On the same date that the ADR regulations became effective, the parties in *RWC-340B v. Azar* agreed to stay the case to allow Amici to pursue ADR claims against drug manufacturers. Joint Mot. to Stay, *RWC-340B v. Azar,* No. 1:20-cv-02906 (D.D.C. Jan. 13, 2021), ECF No. 58. Significantly, the parties in *RWC-340B v. Azar* recently notified the United States District Court for the District of Columbia of the instant action and agreed to file a further status report the earlier of April 19, 2021, or within five business days of any an injunction of the ADR regulations. Joint Status Report, *RWC-340B v. Azar,* No. 1:20-cv-02906 (D.D.C. Feb. 16, 2021), ECF No. 59. Amici Little Rivers and FamilyCare have already filed ADR Petitions and amicus RWC-340B is evaluating whether to file an ADR petition.[2] In addition, the United States

[2] Little Rivers and FamilyCare have filed ADR petitions against another manufacturer that has, like Plaintiff, also refused to provide 340B discounts through contract pharmacies. Decisions issued through the ADR process are precedential. 42 C.F.R. § 10.20, 10.24(d). Therefore, this Court's decision will undoubtedly have an impact on the ADR proceedings for Little Rivers and

District Court for the Northern District of California recently ruled that that the 340B statute requires that disputes between covered entities and manufacturers must first be adjudicated through the ADR process. *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.,* No. 4:20-CV-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021), ECF No. 91. The Amici, therefore, have a significant interest in whether this Court enjoins the ADR regulations because those regulations implement a process that may be the only way Amici, and other 340B covered entities, can obtain a remedy against the Plaintiff. The Court should grant Amici's motion because the Amici have a direct interest in both their own lawsuit as well as their pending ADR petitions, and the decision on Plaintiff's motion for preliminary injunction will materially affect those interests. Access to the ADR process is essential because Sanofi's unlawful contract pharmacy policy deprives discounts to disadvantaged patients and prevents covered entities from funding necessary health care services.

Second, the Amici are not represented adequately in this case. *Alkaabi*, 223 F. Supp. 2d at 592. Clearly, Plaintiff does not represent Amici's interests because Plaintiff refuses to ship 340B discounted drugs to Amici's contract pharmacies and is now seeking to enjoin the ADR procedures that Amici are already using. The Defendants also do not adequately represent Amici's interest. The Defendants administer the 340B program and the ADR process but are not covered entities on the front lines of furnishing health care to the disadvantaged. While Amici support the Defendants' opposition to the Plaintiff's motion for preliminary injunction, and generally the arguments in Defendants' opposition brief, Amici are currently plaintiffs in a lawsuit against several of the Defendants concerning both the ADR regulations and the contract pharmacy program. Amended Compl., *RWC-340B v Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23,

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FamilyCare.

2020), ECF No. 21, (stayed Jan. 13, 2021). In addition, the proposed intervenors in the instant action, if granted intervention, would not adequately represent the interests of Amici because the proposed intervenors do not seek to intervene regarding the ADR regulation at issue in Plaintiff's motion for preliminary injunction. Mem. Law Supp. Mot. to Intervene 7, ECF No. 34.

Third, the Amici can provide the Court with useful and unique information in the instant case, and that information is timely. *Alkaabi*, 223 F. Supp. 2d at 592. Congress intended the 340B program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also Cares Cmty Health v. U.S. Dep't of Health & Human Servs.*, 944 F.3d 950, 955 (D.C. Cir. 2019) (340B savings "help safety-net providers fund the uncompensated care they supply and expand the services they offer."). Neither the Plaintiff nor the Defendants in this case are 340B covered entities. The Amici can, therefore, provide the Court with the perspective of the entities that the 340B program was intended to benefit, a perspective that neither the Plaintiff nor the Defendants can possibly have because they are not 340B covered entities. This motion and the attached amicus curiae brief are also timely. Because the Federal Rules of Civil Procedure and the Local Rules of this Court do not address amicus briefs, Rule 29 of the Federal Rules of Appellate Procedure is instructive. Rule 29(a)(6) provides that an amicus brief and motion are timely if filed no later than seven days after the principal brief of the party supported. Fed. R. App. P. 29(a)(6). The Amici are supporting Defendants' opposition to the Plaintiff's motion for preliminary injunction, which Defendants filed on February 25, 2021, and the Amici filed this motion with attached amicus curiae brief within seven days.

Therefore, the Amici respectfully move the Court for leave to file the attached amicus

curiae brief and accompanying exhibits.

Respectfully submitted,

/s/ Steven A. Haber
Steven A. Haber (I.D. #03946-1988)
OBERMAYER REBMANN MAXWELL & HIPPEL LLP
1120 Route 73, Suite 420
Mt. Laurel, NJ 08054
Tel. (856) 857-1422
Fax (856) 482-0504
Steven.Haber@Obermayer.com

/s/ Ronald S. Connelly
Ronald S. Connelly
D.C. Bar No. 488298 (pro hac vice application pending)
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 466-6550
Fax (202) 785-1756
Ron.Connelly@PowersLaw.com

Attorneys for Amici Curiae

Dated: March 4, 2021

OBERMAYER REBMANN MAXWELL & HIPPEL LLP
By: Steven A. Haber, Esquire
1120 Route 73, Suite 420
Mount Laurel, NJ 08054-5108
Phone: (856) 795-3300
Email: steven.haber@obermayer.com

Attorneys for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center

SANOFI-AVENTIS U.S., LLC,

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

[PROPOSED] ORDER GRANTING MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF

Ryan White Clinics for 340B Access ("RWC-340B"), Little Rivers Health Care, Inc. ("Little Rivers"), and WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare") (collectively the "Amici"), have moved to file an Amicus Curiae brief in support of Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction. Being duly advised, the Court now GRANTS Amici's request.

IT IS THEREFORE ORDERED that Amici's motion to file an Amicus Curiae brief in support of Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction is granted, and the Amicus Curiae brief attached to Amici's motion is hereby deemed filed with the Court in this case.

DATED:

The Honorable Freda L. Wolfson
Chief Judge, U.S.D.C.N.J.

OBERMAYER REBMANN MAXWELL & HIPPEL LLP
By: Steven A. Haber, Esquire
1120 Route 73, Suite 420
Mount Laurel, NJ 08054-5108
Phone: (856) 795-3300
Email: steven.haber@obermayer.com

Attorneys for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

BRIEF OF AMICI CURIAE RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND FAMILYCARE HEALTH CENTER IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Ronald S. Connelly
(pro hac vice application pending)
Powers Pyles Sutter and Verville, PC
1501 M Street, Northwest, 7th Floor
Washington, DC 20005
(202) 872-6762

Steven A. Haber
Obermayer Rebmann Maxwell & Hippel LLP
1120 Route 73, Suite 420
Mt. Laurel, NJ 08054
(856) 857-1422
Counsel to Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and FamilyCare Health Center

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INTERESTS OF AMICI CURIAE

Amici Curiae are two "covered entities" that participate in the 340B program and a trade association representing certain covered entities (collectively, the "Amici"). Amici Little Rivers Health Care, Inc. ("Little Rivers") and FamilyCare Health Center ("FamilyCare") have filed petitions for 340B Administrative Dispute Resolution ("ADR"), which are currently pending. All three Amici have sued several of the federal Defendants in this case for failing to promulgate 340B ADR regulations. *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Oct. 9, 2020) (stayed Jan. 13, 2021). After the Amici filed their lawsuit, the Department of Health and Human Services ("HHS") issued ADR regulations that enabled Little Rivers and FamilyCare to pursue their ADR claims. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule"). Plaintiff Sanofi-Aventis U.S., LLC, ("Sanofi") now asks this Court to enjoin those same regulations. The Amici therefore have a significant interest in the outcome of this case, and the Amici can provide the Court with a unique perspective because neither party in the instant case is a "covered entity," which is the category of health care provider that Congress intended to benefit through the 340B program. The Amici will therefore focus on the harms that a preliminary injunction will cause to 340B covered entities and their vulnerable patients, which Sanofi has wholly ignored in its motion, and which far outweigh any harms that Sanofi has alleged it will incur.

I. Little Rivers

Little Rivers is a not-for-profit health care provider with facilities located in Wells River, Bradford, and East Corinth, Vermont. Little Rivers is certified by HHS as a federally-qualified health center ("FQHC") and is eligible to participate as a covered entity in the 340B program by

virtue of that designation.[1] Little Rivers provides family medicine, pediatrics, obstetrics, behavioral health, and oral health care. Little Rivers' mission is to provide respectful, comprehensive primary health care for all residents in its region, regardless of their ability to pay. Little Rivers Health Care, *About*, https://www.littlerivers.org/about (last visited Feb. 25, 2021). Statistics from the Health Resources and Services Administration ("HRSA") Health Center Program, the division of HHS that administers FQHC grants, show that Little Rivers served more than 5,500 patients in 2019 and that, of those patients with known incomes, 61.2% had income at or below 200% of the Federal Poverty Level ("FPL"), including 19.48% with income at or below 100% of the FPL. HRSA, *Health Center Program Data for Little Rivers, Patient Characteristics*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 25, 2021). In 2019, more than 25% of Little Rivers' patients were Medicaid recipients, and approximately 5% of its patients were uninsured. *Id.* Approximately 15.46% of Little Rivers' patients were under the age of 18 and 25.68% were 65 years of age or older. *Id.*

Little Rivers has been registered as a covered entity in the 340B program since 2006. Little Rivers does not operate an in-house pharmacy. Auclair Aff. ¶ 19.[2] Little Rivers relies

[1] An FQHC is a community-based health care provider that receives federal grant funding and "provide[s] primary care services in underserved areas." HRSA, *Federally Qualified Health Centers*, https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last reviewed May 2018).

[2] The following declarations, which are attached to this brief, were originally submitted as exhibits in the Amici's lawsuit against HHS, 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 Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Inc. (Ex. A, "Auclair Aff."); Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (Ex. B, "Glover Aff."); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (Ex. G, "Dickerson Aff."); Declaration of James D. Duck, Owner of The Corner Drug Store, (Ex. H, "Duck Aff.").

exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients. *Id.* Little Rivers filed an ADR petition on February 4, 2021, to contest a manufacturer's action to cease shipping 340B drugs to Little Rivers' contract pharmacies.

II. FamilyCare

FamilyCare is a not-for-profit health care provider with several facilities in West Virginia, including three mobile units and facilities at local schools. FamilyCare is certified by HHS as an FQHC and is eligible to participate as a covered entity in the 340B program by virtue of that designation. FamilyCare's service area is very large, and some patients drive for an hour to reach one of its locations. 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. FamilyCare's mission is to "make high-quality, whole-person care available to every member of the family and every member of the community." FamilyCare Health Centers, *About*, https://familycarewv.org/about/ (last visited Feb. 25, 2021). FamilyCare provides patient care services covering a wide variety of specialties, which include adult health care, pediatric health care, a 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. According to HRSA statistics, FamilyCare served 32,353 patients in 2019, and of those patients with known incomes, 99.53% had annual incomes at or below 200% of the FPL, including 50.43% with annual incomes at or below 100% of the FPL. HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Feb. 25, 2021).

FamilyCare has been registered as a covered entity in the 340B program since 2000. FamilyCare does not operate an in-house pharmacy. Glover Aff. ¶ 4. FamilyCare relies exclusively on contract pharmacy arrangements to dispense 340B retail drugs to its patients. *Id.* FamilyCare filed an ADR petition on February 12, 2021, to contest a manufacturer's action to cease shipping 340B drugs to FamilyCare's contract pharmacies.

III. RWC-340B

RWC-340B is a national association of human immunodeficiency virus ("HIV")/acquired immunodeficiency syndrome ("AIDS") health care clinics and service providers that receive funding under the federal Ryan White Comprehensive AIDS Resources Emergency Act ("Ryan White CARE Act"), 42 U.S.C. § 300ff-11, et seq., either through a primary grant or subgrant, and participate as covered entities in the 340B program by virtue of receiving this funding. Entities that receive grants or subgrants under the Ryan White CARE Act are commonly referred to as "Ryan White clinics." RWC-340B, *Ryan White Clinics For 340B Access*, https://www.rwc340b.org/ (last visited Feb. 25, 2021); 42 U.S.C. § 256b(a)(4)(D). Three of RWC-340B's members operate nine clinics in Hackensack, Jersey City, Newark, New Brunswick, Paterson, Plainfield, and Trenton, New Jersey.

Approximately 1.2 million people are currently living with HIV/AIDS in the United States. HIV.gov, *HIV Basics: Overview: Data & Trends: U.S. Statistics*.[3] Ryan White clinics provide critical support to this vulnerable population, serving over half a million individuals by furnishing "HIV primary medical care, medications, and support services for underserved and

[3] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (last visited Feb. 25, 2021).

uninsured" people living with HIV/AIDS. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2-3 (Oct. 2020).[4]

Patients of Ryan White clinics are particularly vulnerable. They are "more likely to have less than a high school education, live in poverty, and be homeless" than people living with HIV/AIDS who are not treated in Ryan White clinics. *Id*. at 6. Patients at Ryan White clinics, however, achieve better overall outcomes than patients in other settings of care. Patients at Ryan White clinics are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id*. at 4. Viral load suppression can result in an undetectable level of HIV in a patient's blood, reducing the risk of transmission. *Id*. Ryan White clinics increased the rate of viral suppression from 69.5% in 2010 to 87.1% in 2018, which is far higher than the 62.7% suppression in all people living with HIV/AIDS. *Id*. at 4-5. The success of Ryan White clinics is due, in part, to the higher rates of mental health, substance abuse, and case management services that Ryan White clinics provide. *Id*. at 6-7.

Although Sanofi recently modified its policy to permit Ryan White grantees to order discounted drugs for shipment to contract pharmacies, other manufacturers, including Eli Lilly & Co., have not. The coordinated attack by Sanofi and other drug companies on the 340B contract pharmacy program constitutes an existential threat to the 340B program and RWC-340B's members. The Defendants' database of 340B providers shows that 75% of Ryan White clinics have contract pharmacy arrangements. *See* HRSA, *Welcome to 340B OPAIS*, https://340bopais.hrsa.gov/ (last visited Feb. 25, 2021). For many Ryan White clinics, contract pharmacy arrangements are the primary, or even sole, path to 340B discounts and revenue. Loss

[4] https://www.rwc340b.org/wp-content/uploads/2020/10/20200921-RWC340B-White-Paper-FINAL.pdf.

of these discounts or revenue would jeopardize services provided by Ryan White clinics and irreparably harm the very vulnerable patients they serve.

SUMMARY OF ARGUMENT

Covered entities have only one way to take direct action against drug companies that violate 340B requirements: ADR. Covered entities cannot sue drug companies for these violations. *Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011) ("*Astra*"). They can only take their disputes to a congressionally mandated ADR panel established through regulations issued by HHS. Congress directed HHS to promulgate regulations to establish ADR ten years ago, but HHS finalized the regulations only recently. The lack of ADR became critically important last summer when Sanofi and other drug companies started a campaign to undermine the 340B program by cutting off discounts on drugs shipped to contract pharmacies, which for many covered entities is the only way to access 340B discounted drugs. Enjoining ADR will irreparably harm covered entities by leaving them at the mercy of Sanofi and other manufacturers that have adopted similar policies. Covered entities will inevitably have to cut services that are supported by 340B discounts. Patients will lose access to low-cost medications, and some may have to forgo their prescriptions altogether. The Amici therefore support the Defendants' opposition to Sanofi's motion for preliminary injunction and urge the Court to deny Sanofi's motion. Mot. for Prelim. Inj., *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, No. 3:21-cv-634 (D.N.J. Feb. 2, 2021), ECF No. 19-1 ("Motion for PI").

STATEMENT OF THE CASE

I. The 340B Drug Discount Program

The 340B program provides significant discounts on drugs to safety-net healthcare providers *at no cost to the federal government* because the discounts are provided by drug manufacturers. Many covered entities do not have the resources to operate their own pharmacies

and can only participate in the program by purchasing the drugs for shipment to contract pharmacies, where they are dispensed to the covered entities' patients.

The 340B statute (along with provisions of the Medicaid statute) requires the Secretary of Health and Human Services ("Secretary") to execute Pharmaceutical Pricing Agreements ("PPAs") with manufacturers as a condition of their participation in the Medicaid and Medicare Part B insurance programs. 42 U.S.C. §§ 256b(a)(1), 1396r–8(a)(1). The PPAs "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1). The "ceiling price" is set by a statutory formula. *Id.* § 256b(a)(1)-(2). The Secretary has delegated authority to administer the 340B program to HRSA.

Health care providers that participate in the 340B program serve as the nation's healthcare "safety net," providing health care to the neediest individuals, regardless of ability to pay. The 340B statute limits participation in the program to certain defined health care providers, referred to as "covered entities." 42 U.S.C. § 256b(a)(4). Each category of covered entity receives some form of federal assistance to treat the nation's most vulnerable patients. Congress intended the 340B program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Stated differently, by spending less on medications, covered entities can devote more of their precious resources to patient care. The program is a vital and indispensable tool to help offset the costs to healthcare providers of providing uncompensated and under-compensated care. Without the 340B program, taxpayers would have to absorb the costs of uncompensated care or covered entities would be forced to restrict access to services or even cease operations.

The 340B program is designed to permit covered entities to determine how best to use the discounts. Many covered entities choose to pass the discounts on to their most needy patients, particularly the uninsured. For patients with health insurance, covered entities are typically paid for the drugs by the health insurer at a rate set by the insurer. The difference between the insurer's rate and the discounted price is income to the covered entity to supplement federal funds, thus stretching scarce federal resources as far as possible and enabling the covered entity to reach more eligible patients and provide more comprehensive services. *Id.* This is exactly how Congress intended the program to function.

II. Contract Pharmacies Have Been a Critical Component of the 340B Program Since 1996

Sanofi mischaracterizes the 340B contract pharmacy program as a massive giveaway to large, for-profit contract pharmacies. Motion for PI at 5-7. Nothing could be further from the truth. A contract pharmacy is simply a dispensing agent for the 340B covered entity, which is the purchaser of the 340B drugs. The contract pharmacy dispenses the drugs to the covered entity's patients and relinquishes any third-party payments and/or patient co-payments that the contract pharmacy receives for the drugs. These payments are used by the covered entity to support its safety-net missions, including providing necessary health care services for disadvantaged patients. Contract pharmacies are paid a dispensing fee by the covered entity, which is typical in all contract pharmacy arrangements, including those arrangements that do not involve the 340B program. Payment of dispensing fees is also common in agreements between health care insurers and pharmacies. HHS, through HRSA, has recognized contract pharmacy arrangements since 1996 and has consistently interpreted the 340B statute to require drug companies to sell discounted drugs to covered entities for shipment to contract pharmacies that receive and dispense the drugs to the covered entities' patients. Notice Regarding Section 602 of

the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ("Contract Pharmacy Notice").

In 1996, after considering comments submitted in response to a November 1, 1995, notice, HRSA published "final guidelines" in the Federal Register regarding contract pharmacy services under the 340B statute. *Id*. "Contract pharmacy services," as HRSA's 1996 guidance described it, means 340B covered entities' ability to contract with pharmacies as the covered entities' agents to dispense 340B drugs to the covered entities' patients. *Id*. at 43,550. Under such arrangements, a covered entity purchases 340B drugs from a manufacturer and directs the manufacturer to ship the 340B drugs to the contract pharmacy.

In its 1996 guidance, 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.

Id. at 43,549. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id*. at 43,555.

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

> The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.

> It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance.

Id. at 43,549-50. HRSA was clear that it was interpreting the statute and that its contract pharmacy "guidelines create no new law and create no new rights or duties." *Id*. at 43,550; *see also* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (HRSA's contract pharmacy guidance "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. . . . Contract pharmacy service guidelines have been considered by HRSA to be 'interpretative rules and statements of policy' exempt from notice and comment rulemaking under the APA.").

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." Contract Pharmacy Notice, 61 Fed. Reg. at 43,550. Thus, for over twenty-four years, HHS has recognized that the program can only function effectively if certain covered entities purchase 340B discounted drugs to be dispensed by contracted third-party pharmacies. *Id.*

Contract pharmacy arrangements are not unique to the 340B program. These arrangements are a well-settled aspect of the drug distribution system of non-profit healthcare entities. In 2010, the Federal Trade Commission ("FTC") formally recognized the right of certain non-profit organizations to contract with for-profit retail pharmacies for purposes of dispensing 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").[5] Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).[6] Absent an exemption like the NPIA, the resale of discounted drugs purchased by a non-profit hospital to its patients would be subject to challenge as a violation of the antitrust law. In the favorable opinion, the FTC examined the exact same contract pharmacy model 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.* Importantly, both the 340B statute and the 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).

Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, four of 700 manufacturers participating in the 340B program announced that they would either refuse to honor contract pharmacy arrangements or impose onerous conditions on contract pharmacy arrangements. Eli Lilly and Co. ("Lilly") was the first manufacturer to publicize its new, restrictive contract pharmacy policy. HRSA, *Manufacturer Notices to Covered Entities*

[5] In 1936, Congress enacted the Robinson-Patman Antidiscrimination Act to protect small businesses from larger businesses using their size advantages to obtain more favorable prices and terms from suppliers. 15 U.S.C. §§ 13–13b. The Act is primarily designed to prohibit, among other things, discrimination in the sale of fungible products, including drugs, to different buyers. *See id.* Congress then passed the NPIA, which added an additional exception to the Robinson-Patman Act's price discrimination rules. 15 U.S.C. § 13c. The NPIA created an avenue for manufacturers to sell discounted medical supplies, including pharmaceuticals, to non-profit entities that met certain criteria. Specifically, the NPIA exempts "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. *Id.* As a result, eligible non-profit entities may purchase—and vendors may sell to them—pharmaceutical products and other supplies at reduced prices for the non-profit entity's "own use," without violating the Robinson-Patman Act's prohibitions against price discrimination. *Id.*

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

(July 2020)[7]; *see also* Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020).[8]

Less than one-month later, Sanofi issued letters to 340B covered entities announcing that it would no longer honor contract pharmacy arrangements for covered entities that refuse to provide all of their claims data for 340B drugs purchased through contract pharmacies to a system called the 340B ESP program. Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020).[9] Sanofi has since partially retreated and recently announced that it will provide 340B drugs through contract pharmacy arrangements for all grantees other than FQHCs (and other Consolidated Health Centers Programs covered entities), and for Children's and Cancer hospitals. Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (Feb. 2021). Because the Amici Little Rivers and FamilyCare are FQHCs, they do not benefit from Sanofi's partial concession.

AstraZeneca LP ("AstraZeneca") and Novartis Pharmaceuticals Corp. ("Novartis") quickly followed suit in announcing their own policies limiting contract pharmacies. Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca LP (Aug. 17, 2020)[10]; Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020).[11] More recently, Novo Nordisk, Inc. ("Novo Nordisk")

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[7] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.
[8] https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf.
[9] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.
[10] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.
[11] Novartis has since retreated, in part. By letter dated October 30, 2020, Novartis informed covered entities that "all federal grantees, including Ryan White Clinics and Community Health

and United Therapeutics Corporation have announced limitations on providing 340B drugs through contract pharmacies. Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020)[12]; Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[13] Hundreds of other drug companies that participate in the 340B program continue to ship to contract pharmacies. Sanofi, Lilly, AstraZeneca, Novartis, United Therapeutics Corporation, and Novo Nordisk are outliers, but their actions nonetheless significantly impact the Amici.

III. 340B Administrative Dispute Resolution

The Patient Protection and Affordable Care Act ("ACA") was signed into law on March 23, 2010, and mandated 340B ADR regulations within 180 days:

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

ACA, Pub. L. No. 111-148, § 7102(a), 124 Stat. 823 (2010) (codified at 42 U.S.C. § 256b(d)(3)). The Secretary's 180-day deadline to promulgate regulations for an ADR process fell on September 19, 2010.

Centers, will continue to receive 340B discounts" at contract pharmacies. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020). The letter also stated that, effective November 16, 2020, Novartis will honor contract pharmacy arrangements with 340B hospitals if the contract pharmacy is located within a 40-mile radius of the main hospital facility. *Id*.

[12] https://bit.ly/2NQlzpc.

[13] https://bit.ly/3pNrfgZ.

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

Shortly after the ACA was enacted, the Supreme Court held that 340B covered entities cannot sue drug companies for violating 340B requirements. *Astra USA v. County of Santa Clara*, 563 U.S. 110 (2011) ("*Astra*"). The Court's holding in *Astra* leaves covered entities with no means to bring a dispute directly against a pharmaceutical manufacturer other than ADR.

More than six years after the expiration of the 180-day deadline to promulgate ADR regulations, the Secretary finally proposed regulations. 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016). More than four years later, the Secretary had not finalized those ADR regulations. Faced with the refusal by Sanofi and other drug companies to provide 340B discounted drugs through contract pharmacies, the Amici filed suit in the U.S. District Court for the District of Columbia to compel the Secretary to issue final ADR regulations. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21 (stayed Jan. 13, 2021). Other covered entities and associations filed similar actions. *Nat'l Ass'n of Cmt. Health Cts. v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020) (stayed Jan. 7, 2021); *Am. Hosp. Ass'n v. Azar,* 4:20-cv-08806-YGR, (N.D. Cal. dismissed Feb. 17, 2021).

Shortly after the Amici filed their lawsuit, HRSA issued final regulations to implement the ADR process. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule"). As a result, the Amici's lawsuit is stayed so they may pursue ADR claims against manufacturers for refusing to sell drugs at 340B discounts for delivery to contract pharmacies. Joint Mot.'s for Stay, *RWC-340B v. Azar*, No. 1:20-cv-02906, ECF No. 58 (D.D.C. Jan. 13, 2021); Status Report, *RWC-340B v. Azar*, No. 1:20-cv-02906, ECF No. 59 (D.D.C. Feb. 16, 2021).

The ADR Rule allows covered entities to file petitions against drug companies to challenge overcharges for drugs purchased under the 340B Program. ADR Rule, 85 Fed. Reg. at 80,637. The ADR Rule also permits manufacturers to file petitions against covered entities for alleged violations of certain 340B prohibitions after the manufacturer has conducted a formal audit of the covered entity. *Id.* at 80,638. The ADR Rule creates an ADR Board, from which an ADR Panel is selected to review the petitions and issue final decisions. *Id.* at 80,634. The ADR Rule became effective on January 13, 2021. *Id.* at 80,632.

The ADR process consists of the following procedures: (1) initiation of an action; (2) request for additional information; (3) proceedings or hearings; and a (4) final agency decision, which is subject to judicial review. A covered entity or manufacturer initiates an action by filing a petition with HRSA along with sufficient documentation to support the claim within three years of the alleged violation, and the petition must allege damages that exceed $25,000. 42 C.F.R. § 10.21(a)-(b). Next, the ADR Panel may allow a covered entity to request additional information from a manufacturer. *Id.* § 10.22(b). The ADR Panel may also request additional information from either party. *Id.* Federal rules applicable to court proceedings and evidentiary matters apply to ADR proceedings unless the parties agree, or the ADR Panel dictates otherwise.

Id. § 10.23(a)-(c). Once the ADR Panel issues a decision, the outcome of the 340B ADR process is binding and precedential and subject to judicial review. *Id*. § 10.24(d).

THE BALANCE OF HARMS WEIGHS IN FAVOR OF DENYING THE PRELIMINARY INJUNCTION BECAUSE AN INJUNCTION WILL DEPRIVE COVERED ENTITES AND THEIR VULNERABLE PATIENTS OF REDRESS AGAINST SANOFI AND OTHER MANUFACTURERS

Sanofi contends that "enforcing the ADR Rule will serve no public interest." Motion for PI at 32. Sanofi's only reasoning for its assertion is that "the public interest is not served by the enforcement of an unconstitutional law" and devotes no time to addressing the harm that a preliminary injunction will cause 340B covered entities and their patients. Motion for PI at 32. In this case, the public interest includes the Amici, other covered entities, and the vulnerable patients that they serve. Currently, many covered entities do not have access to 340B discounts via their contract pharmacies due to Sanofi's policy and similar policies of other manufacturers. Covered entities have waited ten years for the ADR Rule, which has now become vital so that covered entities may challenge the unilateral policy of Sanofi and other manufacturers to limit or deny the provision of 340B discounted drugs at contract pharmacies. The harms that the Amici and their patients will suffer if the ADR Rule is enjoined far outweigh any harm that allowing the process to continue would cause Sanofi. This Court should, therefore, deny Sanofi's motion for preliminary injunction.

A party seeking a preliminary injunction must hurdle a high bar: "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc*., 555 U.S. 7, 20 (2008). The Third Circuit has recognized that a preliminary injunction is an "extraordinary remedy, which should be granted only in limited circumstances." *Frank's GMC*

Truck Ctr., Inc. v. General Motors Corp., 847 F.2d 100, 102 (3d Cir.1988). The party requesting a preliminary injunction must show that the following:

> (1) the party seeking a preliminary injunction has shown a reasonable probability of success on the merits; (2) the party will be irreparably injured by the denial of the relief; (3) granting preliminary relief will result in even greater harm to the nonmoving party; and (4) granting the preliminary relief will be in the public interest.

LCN Enterprises, Inc. v. City of Asbury Park, 197 F. Supp. 2d 141, 145 (D.N.J. 2002), as amended (Apr. 5, 2002). A preliminary injunction should only be granted if there is "evidence sufficient to convince the district court that all four factors favor preliminary relief." *Id*. (quoting *AT&T Co. v. Winback & Conserve Program, Inc*., 42 F.3d 1421, 1427 (3d Cir. 1994)). In considering the effect on the public interest, this Court must consider "possible harm to interested third parties." *LCN Enterprises, Inc.*, 197 F. Supp. 2d at 145.

I. The Balance of Harms Weighs in Favor of Denying the Preliminary Injunction Because the ADR Regulations Were Ten Years in the Making and Are Critical for Amici and Other Covered Entities to Vindicate Their Rights to Obtain 340B Discounted Drugs Through Contract Pharmacies

Covered entities cannot sue drug companies in federal court for violating 340B program requirements. *Astra*, 563 U.S. at 113-14. Instead, Congress provided for an ADR process to allow covered entities to resolve disputes with drug companies. Covered entities waited ten years for the final ADR Rule, even though Congress set a September 19, 2010, deadline for those regulations. 42 U.S.C. § 256b(d)(3)(A). As the Amici explained in their lawsuit in the United States District Court for the District of Columbia, this delay raises very serious due process concerns. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21, (stayed Jan. 13, 2021); *see Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). Enjoining the ADR Rule will further delay the ADR process by months or even years.

Significantly, the United States District Court for the Northern District of California recently ruled that the 340B statute requires that disputes between covered entities and manufacturers must first be adjudicated through the ADR process. Order Granting Mot. to Dismiss, *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.,* No. 4:20-CV-08806-YGR, 2021 WL 616323 (N.D. Cal. Feb. 17, 2021), ECF No. 91.

Sanofi asserts that its constitutional rights will be violated through the ADR process. Motion for PI at 28-31. Defendants have already provided the Court with arguments as to why Sanofi's assertions are groundless. Defs.' Opp'n to Pl's. Mot. for Prelim. Inj., *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs*., No. 3:21-cv-634, 30-32 (D.N.J. Feb. 25, 2021), ECF No. 29. The Court should also weigh any constitutional claim by Sanofi against the Amici's loss of due process rights if they are denied the ability to bring a claim against drug manufacturers to assert their rights to 340B discounted drugs. The balance of harms weighs in favor of denying Sanofi's motion for preliminary injunction so that Amici and other covered entities may assert their due process rights through the ADR process.

II. The Balance of Harms Weighs in Favor of Denying the Preliminary Injunction Because Covered Entities and Their Patients Will Suffer Irreparable Harms

The balance of harms between the parties and the effect of granting a preliminary injunction on the "public interest," *LCN Enterprises, Inc.*, 197 F. Supp. 2d at 145, weighs against enjoining the ADR regulations because the Amici and other 340B covered entities will suffer significant, irreparable harms. Congress authorized the ADR Rule so that covered entities could bring actions against drug manufacturers for violating the 340B statute. Access to the ADR process is vitally importantly currently because Sanofi's unlawful contract pharmacy policy deprives discounts to disadvantaged patients and prevents covered entities from funding necessary health care services. Enjoining the ADR Rule will give Sanofi, and possibly other

drug companies, a free pass to continue flouting 340B program requirements, depriving covered entities of statutory discounts to support health care services during a pandemic. The Amici are on the front lines of caring for our nation's low-income and most vulnerable patients and support the broad goals of increasing access to care and improving health outcomes. The public interest cuts strongly against a preliminary injunction enjoining the ADR Rule because if the Amici are not able to access savings generated from the 340B program, the health of our nation's most vulnerable patients will be harmed. Patients will continue to lose access to inexpensive medications that they need to address chronic conditions and even survive. The Amici are losing discounts that support many of their key health care programs. Some covered entities may even become insolvent. These financial losses will not be recoverable in the ordinary course of litigation. These outcomes would be tragic at any time, but in the midst of the COVID-19 pandemic, they are unconscionable.

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

The Amici offer discounts on drugs to financially needy patients through contract pharmacy arrangements, and these programs are premised on the Amici being able to purchase the drugs at 340B discounted prices. For example, FamilyCare operates a drug discount program for financially disadvantaged patients in which FamilyCare charges only the amount that it pays for the drug. Glover Aff. ¶ 17. Because the 340B discounted prices, however, are significantly lower than non-340B prices, patients that relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30.

Similarly, Little Rivers operates a drug discount program that subsidizes the costs of drugs for their financially needy patients. Under this program, the patient does not incur any cost

for the drugs, or pays a percentage of the cost of the drug, depending on the patient's income level. Auclair Aff. ¶ 18. Little Rivers, and other covered entities that offer similar programs, are now bearing the increased cost of drugs produced by Sanofi and filled at contract pharmacies. Auclair Aff. ¶¶ 21, 30. Little Rivers, however, will struggle financially if it is forced to continue to incur these increased costs. Auclair Aff. ¶¶ 31-34. The increased costs to Little Rivers to pay for the drugs under its drug discount program will severely worsen its already precarious financial position.

Through contract pharmacy arrangements, patients of 340B covered entities who do not have insurance or are underinsured are able to fill their prescriptions at convenient locations, often at no cost or a greatly discounted cost. Without the availability of contract pharmacies, many patients of the covered entities would have no access to lifesaving medications, either because the covered entity does not have a pharmacy or because the covered entity is located too far away. Contract pharmacies provide 340B covered entities' patients with access to no-cost or low-cost medications that have been purchased by the covered entity through the 340B program and ensure that patients throughout the covered entity's service area are able to access those discounted drugs. This access to pharmaceutical care provided through 340B contract pharmacy arrangements is consistent with the congressional intent of the 340B statute.

Sanofi has made a tiny concession to allow certain covered entities to designate one pharmacy as a contract pharmacy if they do not operate their own retail, in-house pharmacies, but Sanofi's policy still means that many financially needy patients are left without 340B drugs. Designating only one contract pharmacy is not practical for FamilyCare because it serves a very large area in rural West Virginia and has made contract pharmacy arrangements across its service area. Glover Aff. ¶ 19. Multiple contract pharmacy arrangements enable FamilyCare to provide

covered outpatient drugs to patients that qualify for its Prescription Savings Program at the patient's local pharmacy. Glover Aff. ¶ 19. For covered entities in remote or rural parts of a state, it is important that patients are able to access affordable medications at a pharmacy that is convenient for them. *See* Simila Aff. ¶ 27 ("[t]he travel distance between our northern most and southern most clinical delivery sites is 200 miles.")[14]; 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-house pharmacies").

The owner of The Corner Drug Store submitted an affidavit in Amici's lawsuit against Defendants. Duck Aff. The Corner Drug Store is a contract pharmacy for Amici's co-plaintiff, Springhill Medical Center ("Springhill"). In the affidavit, The Corner Drug Store explains how it assists with implementation of Springhill's "Cash Savings Program," which helps uninsured individuals or individuals who must meet a high deductible with paying for their prescription

[14] Sanofi has submitted with its motion for preliminary injunction an ADR petition that was filed against it. Motion for PI, Ex. 6, ECF No. 19-7; Motion for PI, Ex. 7, ECF No. 19-8; *Nat'l Ass'n of Cmty. Health Ctr.s v. Eli Lilly and Co*., *et al.*, ADR Pet. No. 210112-2 (Jan. 13, 2021). Sanofi, however, omitted declarations from covered entities that were submitted as exhibits to that ADR petition, which demonstrate how Sanofi is harming covered entities. The following declarations were submitted as exhibits to ADR petition No. 210112-2: Declaration of Donald A. Simila, CEO of Upper Great Lakes Health Center, Inc. (Ex. C, "Simila Aff."); Declaration of Lee Francis, President and CEO of Erie Family Health Center (Ex. D, "Francis Aff."); Declaration of Kimberly Christine Chen, Director of Pharmacy at North County HealthCare, Inc. ("NCHC") (Ex. E, "Chen Aff."); Declaration of Ludwig M. Spinelli, CEO of Optimus Health Care Inc., (Ex. F, "Spinelli Aff."); Declaration of J.R. Richards, CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus (Ex. I, "Richards Aff."); David Steven Taylor, Director of Pharmacy Operations for Appalachian Mountain Community Health Centers (Ex. J, "Taylor Aff."). Amici have attached these declarations to this brief for the Court's reference.

drugs. Duck Aff. ¶ 3. Springhill only charges the 340B price and a dispensing fee to patients who qualify for Springhill's Cash Savings Program. Duck Aff. ¶ 3. The Corner Drug Store stated that several patients were no longer able to afford Sanofi's insulin product, Lantus, because Sanofi no longer allowed the drug to be purchased with 340B discounts. Duck Aff. ¶¶ 4-12. At least two patients who had been paying a 340B price of $17.30 for Lantus were charged $1,360.57 because Sanofi had cut off Springhill's access to 340B pricing for drugs shipped to The Corner Drug Store. Duck Aff. ¶¶ 8, 11. Because of the significant price increase, these patients left the pharmacy without purchasing Lantus.[15] Duck Aff. ¶¶ 4-12.

The CEO of Optimus Health Care Inc. ("Optimus") submitted an affidavit in an ADR petition separate from the Amici's. Spinelli Aff. Optimus describes how Sanofi and other drug manufacturer actions will cause its uninsured patients to lose access to approximately 773 affordable prescriptions. Spinelli Aff. ¶ 21. This includes access to insulins, asthma controllers, and other essential medications, all of which are vital to the patient population that is at the highest risk during the COVID-19 pandemic. Spinelli Aff. ¶ 21. As a result of Sanofi and other drug manufacturers' actions, Optimus estimates that patients who were previously "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." Spinelli Aff. ¶ 21.

These are just a few examples that highlight the plight of thousands of patients nationwide who can no longer afford medications due to Sanofi's restrictive policy. Without the ADR process, covered entities have limited recourse to fight for their right to access 340B prices

[15] The Corner Drug Store also notes that "[d]iabetic patients often must try several insulin products in order to find one that is effective at stabilizing their blood sugar levels" and that "[a] diabetic cannot simply switch from one product to another without working closely with a physician to find the right dosage of insulin," which "often requires numerous visits to a physician and blood sugar tests." Duck Aff. ¶ 5.

at contract pharmacies, which allows them to pass savings on to the patients who rely on the 340B program to afford their medications.

B. Covered Entities Rely on Revenue from Payments for 340B Drugs to Pay for Necessary Health and Related Services

340B covered entities use the revenues from payments for 340B drugs to subsidize the cost of important and life-saving health care and support programs for their patients. For patients with prescription insurance, covered entities benefit from the difference between the 340B price and the reimbursement received from the insurance company. Covered entities may use these funds to supplement their federal grants and other revenues, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992).

For covered entities that are federal grantees, examples of these services include case management services to assist patients with transportation, insurance enrollment, linkage to affordable housing, food access, patient care advocacy, in-home support, education for chronic health care conditions, and food pantries. Auclair Aff. ¶¶ 12-16, 22; Glover Aff. ¶¶ 11, 14-15. Without care coordinators, many patients will not be able to access the health care that they need or obtain affordable housing or food. These services are critical for preventing 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. Auclair Aff. ¶ 17; Glover Aff. ¶ 26. Education and in-home assistance for patients with chronic health conditions is also vitally important to manage the patients' diseases and prevent the need for more costly care. Glover Aff. ¶¶ 15, 27. 340B revenues also enable the Amici to provide health, behavioral, and dental services to local school children. Auclair Aff. ¶¶ 10-11; Glover Aff. ¶¶ 11, 25. Covered entities operate medication

assisted treatment programs and offer additional treatment services for opioid use disorder to financially needy individuals. Auclair Aff. ¶ 15; Glover ¶ 14; Simila Aff. ¶ 15-16; Francis Aff. ¶ 9-10.

Little Rivers provides the following services that are not funded, or are only partially funded, through grants and private insurance:

- a chronic care management program to assist patients with chronic diseases;
- working with Willing Hands, a non-profit, charitable organization, to distribute fresh produce and dairy to Little Rivers' clinics for care coordinators to deliver to patients in need;
- behavioral health services at local public schools that include counseling for students and families; and
- a Medication Assisted Treatment ("MAT") program that provides services to individuals who are on a drug regimen to treat addiction.

Auclair Aff. ¶¶ 12-15.

Most of the above services are not paid by insurance or through grant funds. Auclair Aff. ¶ 22; Glover Aff. ¶ 15; Richards ¶ 24; Simila Aff. ¶ 19. Covered entities use the revenue from their 340B contract pharmacy arrangements to pay for these services, and this revenue is significant for covered entities. Little Rivers realizes approximately $200,000 annually by purchasing products through contract pharmacy arrangements from Sanofi and the other drug companies that have refused to honor such arrangements. Auclair Aff. ¶ 23.

Based on data from January 1, 2020, through June 30, 2020, and extrapolated to twelve months, FamilyCare estimates that purchases shipped to contract pharmacies result in approximately $449,178 annually in savings from 340B drugs that are filled through contract

pharmacies, including drugs that are manufactured by Sanofi and the other drug companies that have cut off contract pharmacy arrangements. Glover Aff. ¶ 22; Dickerson Aff. ¶ 6. FamilyCare would have to scale back dramatically the services that it provides to its patients if FamilyCare loses over $449,178 annually as the result of the actions of these drug companies. Glover Aff. ¶ 24; Dickerson Aff. ¶ 8.

Loss of 340B discounts will force the Amici and other covered entities to curtail or even terminate the additional services that they provide. Auclair Aff. ¶ 25; Glover Aff. ¶ 24; Dickerson Aff. ¶ 8; Simila Aff. ¶ 29. If the Amici's patients do not have access to the additional services described above, which focus on preventive care and ensuring that the patient obtains needed health care and related support services, the patients' health will undoubtedly decline. As a result, they will require additional, more extensive and expensive health care visits at the Amici's locations, as well as more expensive care from hospitals and specialists. Auclair Aff. ¶¶ 26-27; Glover Aff. ¶¶ 26-27. The cost of providing additional health care visits will cause an additional strain on the resources of covered entities.

The Amici will also have to divert staff to seek out and apply for additional federal grants or other sources of funding to make up for the lost 340B savings. Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9. Expending already scarce financial and human resources will further burden budgets that are already severely strained and cause irreparable harm in the form of additional operational expense. Of course, the Amici have no assurances that they will be able to obtain additional funding. Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9.

In 2018 and 2019, Little Rivers operated at a loss. Based on 340B savings that it has historically achieved, Little Rivers calculates that it will lose approximately $200,000 in annual 340B savings and revenue as a result of the actions of Sanofi and other drug companies that now

condition or refuse to offer 340B pricing on drugs that are purchased by Little Rivers and shipped to its contract pharmacies. Auclair Aff. ¶¶ 23, 25. Little Rivers will have to cut or eliminate some of those services if it loses $200,000 annually as the result of the drug companies' actions. Auclair Aff. ¶ 25. Cutting or eliminating services to Little Rivers' patients will be detrimental to their health and well-being.

In response to Sanofi's actions, covered entities have been working to switch patients' medications. Richards Aff. ¶¶ 22-23; Francis Aff. ¶ 26; Chen Aff. ¶ 35; Taylor Aff. ¶ 18. Many patients may wish to stay on the medications they are familiar with or may be fearful of the negative health impact of switching to new medications. Richards Aff. ¶¶ 22-23; Francis Aff. ¶ 26; Chen Aff. ¶ 35. 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." Francis Aff. ¶ 26.

The Director of Pharmacy of North Country HealthCare, Inc. ("NCHC") describes how an uninsured patient with Type 1 diabetes and stable on Lantus (produced by Sanofi) could no longer access the drug through NCHC's contract pharmacy. Chen Aff. ¶ 35. When an individual has Type 1 diabetes, the body cannot produce its own insulin and is therefore reliant on manufactured insulin to survive. Chef. Aff. ¶ 36. Once Sanofi's restrictive policy went into place, Lantus was no longer available at 340B pricing through NCHC's contract pharmacy and the patient was located "approximately 280 miles from [NCHC's] closest in-house pharmacy". Chen Aff. ¶ 35. The patient had adverse side-effects to another insulin so switching medications was not an option. Chen Aff. ¶ 35-36. The Director of Pharmacy Operations for Appalachian Mountain Community Health Centers ("Appalachian Mountain") describes how, when Sanofi's

policy went into place, diabetic patients who were taking Lantus were "having to be switched to the only remaining affordable, long-acting insulin, which is an inferior molecule and requires 2 shots a day versus just one with Lantus." Taylor Aff. ¶ 18. Not only are these patients now forced to bear the burden of twice as many shots per day, but they are also required to purchase twice as many of the lancets used to test their blood sugar. Taylor Aff. ¶ 18.

C. 340B Covered Entities Rely on Revenue From the 340B Program to Continue to Operate

The Amici rely entirely on contract pharmacies to dispense self-administered drugs purchased with 340B discounts to their patients. Auclair Aff. ¶ 19; Glover Aff. ¶ 18. For some covered entities, the revenue from the 340B program 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 income that it receives from its grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5. The loss of all 340B savings to the Amici would be even more "devastating" to the Amici's operations and the patients they serve. Auclair Aff. ¶ 31; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11.

Little Rivers currently operates at a loss and FamilyCare's operating expenses barely exceeds its revenue. Auclair Aff. ¶ 24; Dickerson Aff. ¶ 7. Data from the HRSA webpage shows that, in 2019, Little Rivers' average cost per patient was $1,270.64 and FamilyCare's average cost per patient was $764.39. HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 25, 2021). The cost per patient will increase dramatically if these providers are burdened with the obligation of covering the full price of drugs manufactured by Sanofi. The Amici do not have the financial resources necessary to bear the additional costs of drugs for financially needy patients. Auclair Aff. ¶ 34.

D. Amici's Financial Harms Are Not Recoverable in the Ordinary Course of Litigation

Enjoining the ADR regulations will result in economic losses to the Amici that will not be recoverable. A final decision on the merits of Sanofi's ADR claims will not provide relief to the Amici and other covered entities and, therefore, are not recoverable through "'compensatory or other corrective relief . . . at a later date, in the ordinary course of litigation.'" *Bakery Drivers & Salesmen Local 194, IBT v. Harrison Baking Grp., Inc*., 869 F. Supp. 1168, 1177 (D.N.J. 1994) (quoting *Sampson v. Murray*, 415 U.S. 61, 90 (1974)); *see also Instant Air Freight Co. v. C.F. Air Freight, Inc.,* 882 F.2d 797, 801 (3d Cir. 1989).

Furthermore, Amici's losses would not be recoverable in any other forum because covered entities cannot bring a suit against Sanofi for violating 340B requirements. *Astra*, 563 U.S. 110, 113-14. The economic losses to the Amici from Sanofi's contract pharmacy policy will be "devastating" and could cause Amici to have to cease operations. Auclair Aff. ¶¶ 32, 34; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11; *see Doran v. Salem Inn*, 422 U.S. 922, 932 (1975) (finding irreparable harm where movant's business "would suffer a substantial loss of business and perhaps even bankruptcy" absent injunctive relief). Thus, the Amici cannot recover lost 340B savings through "the ordinary course of litigation" and must therefore rely on the ADR regulations to remedy the harm suffered from Sanofi's and other manufacturers' actions. *Bakery Drivers & Salesmen Local 194*, 869 F. Supp. at 1177.

III. The Losses to Amici and 340B Covered Entities Far Outweigh Any Losses to Sanofi

Sanofi contends that it "cannot recover a dime from the government" as a result of the damages that it would incur in defending itself before the ADR panel. Motion for PI at 31. However, any losses that Sanofi would suffer in defending itself against the government pale in comparison to the current and ongoing harms to the Amici and other covered entities. Sanofi's

financial status in 2020 was quite robust. On February 5, 2021, Sanofi reported that its fourth-quarter sales in the United States increased 5.3% from its third-quarter sales. Sanofi-Aventis U.S. LLC, *Press Release* (Feb. 5, 2021).[16] Moreover, Sanofi reported that its U.S. annual sales increased from approximately $14.159 billion in 2019 to approximately $16.023 billion in 2020 at the current exchange rate for those periods. Sanofi-Aventis U.S. LLC, *Press Release* (Feb. 6, 2020)[17]

Sanofi's increased sales are in sharp contrast to the financial plight of Amici and other covered entities, particularly in the midst of the COVID-19 pandemic. An HHS official recently noted that halting contract pharmacy shipments is "at the very least, insensitive to the recent state of the economy." Letter from Robert P. Charrow, General Counsel, U.S. Department of Health and Human Services, to Anat Hakim, Senior VP and General Counsel, Eli Lilly Company (Sept. 21, 2020).[18] HHS also noted that "most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance." *Id*.; Francis Aff. ¶ 29 ("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.").

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[16] https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2021_02_05_Results_PR_EN.pdf?la=en&hash=DF27EDA00E7444D1973BF599FBE765E5.

[17] https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2019_Q4_Press_Release_v2_EN.pdf?la=en&hash=85C666D993F5B4ECC1A9CF7C27A2EDD0; *see also* Sanofi-Aventis U.S. LLC, *Press Release* (Feb. 5, 2021), https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2021_02_05_Results_PR_EN.pdf?la=en&hash=DF27EDA00E7444D1973BF599FBE765E5.

[18] Available at https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

The financial harms befalling Amici and other covered entities due to Sanofi's policy are devastating to Amici and covered entities and far outweigh any expense that Sanofi may incur in defending itself before the ADR Panel. The balance of harms weighs in favor of denying Sanofi's motion for preliminary injunction.

CONCLUSION

The public interest cuts strongly against a preliminary injunction enjoining the ADR Rule because if the Amici are not able to access savings generated from the 340B program, our nation's most vulnerable patients will be harmed. HHS has long recognized the importance of the 340B contract pharmacy program and the vital role that it plays for covered entities and their vulnerable patients. Many 340B program participants rely on these contract pharmacy arrangements because they are the only way of serving patients. The ADR Rule provides covered entities with the administrative proceeding they need to remedy the harms from the statutory violations of Sanofi and other drug companies. Amici therefore respectfully request that the Court deny Sanofi's motion for preliminary injunction and permit the ADR regulations to remain in effect.

Respectfully submitted,

/s/ Steven A. Haber
Steven A. Haber
New Jersey Bar No. 03946-1988
OBERMAYER REBMANN MAXWELL & HIPPEL LLP
1120 Route 73, Suite 420
Mt. Laurel, NJ 08054
Tel. (856) 857-1422
Fax (856) 482-0504
Steven.Haber@Obermayer.com

/s/ Ronald S. Connelly
Ronald S. Connelly
D.C. Bar No. 488298 (pro hac vice application pending)
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 466-6550
Fax (202) 785-1756
Ron.Connelly@PowersLaw.com

Attorneys for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center

Dated: March 4, 2021

OBERMAYER REBMANN MAXWELL & HIPPEL LLP
By: Steven A. Haber, Esquire
1120 Route 73, Suite 420
Mount Laurel, NJ 08054-5108
Phone: (856) 795-3300
Email: steven.haber@obermayer.com

Attorneys for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

INDEX OF EXHIBITS TO BRIEF OF AMICI CURIAE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION[1]

Exhibit A	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 B	Declaration of Craig Glover, MBA, MA, FACHE, CMPE, CEO of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare").
Exhibit C	Declaration of Donald A. Simila, CEO of Upper Great Lakes Health Center, Inc.

[1] All prior ECF stamps have been redacted so that the ECF stamps for the United States District Court for the District of New Jersey are legible. Exhibits A and B were submitted with the plaintiffs' motion for temporary restraining order and preliminary injunction in *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24. Exhibits C, D, E, F, I, and J were submitted as part of Exhibit D to Eli Lilly and Company's motion for preliminary injunction in *Eli Lilly and Co. v. Azar*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 12, 2021), ECF No. 19-5.

Exhibit D	Declaration of Lee Francis, President and CEO of Erie Family Health Center.
Exhibit E	Declaration of Kimberly Christine Chen, Director of Pharmacy at North County HealthCare, Inc. ("NCHC").
Exhibit F	Declaration of Ludwig M. Spinelli, CEO of Optimus Health Care Inc.
Exhibit G	Declaration of Terri S. Dickerson, CFO, FamilyCare.
Exhibit H	Declaration of James D. Duck, owner of The Corner Drug Store.
Exhibit I	Declaration of J.R. Richards, CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus.
Exhibit J	David Steven Taylor, Director of Pharmacy Operations for Appalachian Mountain Community Health Centers.

OBERMAYER REBMANN MAXWELL & HIPPEL LLP
By: Steven A. Haber, Esquire
1120 Route 73, Suite 420
Mount Laurel, NJ 08054-5108
Phone: (856) 795-3300
Email: steven.haber@obermayer.com

Attorneys for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil Action No. 3:21-cv-634-FLW-LHG

CERTIFICATE OF SERVICE

I, Steven A. Haber, Esquire, hereby certify that I electronically filed Consent Motion to file *Amici Curiae*'s Brief with the Clerk of Court, using the CM/ECF filing system, which will send notification of the filing to all counsel of record.

Dated: March 4, 2021

s/ Steven A. Haber
Steven A. Haber

EXHIBIT A

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, 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]

[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 Eli Lilly Company ("Lilly"),

Zeneca Pharmaceuticals, L.P. ("AstraZeneca"), and Sanofi-Aventis US LLC ("Sanofi"), and their corporate affiliates, Little Rivers will lose approximately $200,000 annually in 340B savings as a result of the decision by these manufacturers not to honor contract pharmacy arrangements. (Little Rivers has not recently purchased 340B drugs manufactured by Novartis Pharmaceuticals.)

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) Little Rivers will have to cut or eliminate some of the services that it provides if Little Rivers loses $200,000 annually as the result of the actions of Lilly, AstraZeneca and Sanofi.

26) 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, affordable housing opportunities, or access to low-cost food.

27) 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

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

hospitals and specialists. The cost of providing additional health care visits not previously accounted for will cause a strain on Little Rivers' resources.

28) 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.

29) 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 Lilly, AstraZeneca, and Sanofi. We will be hampered in our goal to provide for our patients with the affordable, comprehensive, and holistic care they need and deserve.

30) 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. As one example, behavioral health drugs are an expensive category of drugs. In my experience as a nurse, there are important societal reasons, such as controlling unemployment, family strife and crime, for ensuring that behavioral health patients have access to their medications.

31) The loss of $200,000 annually in 340B savings as the result of the actions of Lilly, AstraZeneca and Sanofi 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 $200,000

annually will exacerbate the problem and impose undue operational and financial burdens on Little Rivers.

32) 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 Little Rivers lost access to 340B pricing for all retail drugs, it would be devastating to Little Rivers' operations and the patients it serves.

33) I compared the 340B price and non-340B price of two drugs that some of our financially needy patients are prescribed. I found that the cost of a 30 day supply of Humulin®, an insulin product manufactured by Lilly for which no biosimilar is available, increased from $117.24 to $450.17. I 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 $198.42 to $1910.13.

34) 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.

[*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,

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

EXHIBIT B

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

[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.

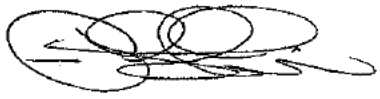
30) FamilyCare's Prescription Savings Program is offered for drugs that are purchased with 340B discounts. If FamilyCare cannot purchase drugs manufactured by Lilly, AstraZeneca, and Lilly with 340B discounts, those drugs will no longer be part of its program. FamilyCare does not have funds allocated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

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 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
Chief Executive Officer, Upper
Great Lakes Health Center, Inc.

EXHIBIT D

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 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

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 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

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

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 H

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, James Daniel Duck hereby attest and state as follows:

1) I am the owner of The Corner Drug Store, located in Springhill, Louisiana. I have had an ownership interest in The Corner Drug Store since 2011.

2) The Corner Drug Store acts as a contract pharmacy to Springhill Medical Center ("Springhill"), whose main facility is located approximately two (2) miles from The Corner Drug Store. This contract pharmacy arrangement is the only contract pharmacy arrangement that The Corner Drug Store has entered into

3) As part of the contract pharmacy arrangement, The Corner Drug Store assists with implementation of Springhill's "Cash Savings Program". The Cash Savings Program assists uninsured individuals or individuals who must meet a high deductible. If an individual qualifies for the Cash Savings Program, the patient pays Springhill's 340B price for the drug plus a dispensing fee to The Corner Drug Store.

4) Lantus® is a long-acting insulin product manufactured by Sanofi-Aventis U.S. LLC ("Sanofi"). Many diabetic patients are better able to stabilize their blood sugar levels using Lantus® than they are with other insulin products because the effects of Lantus® last longer than other products.

5) Diabetic patients often must try several insulin products in order to find one that is effective at stabilizing their blood sugar levels. A diabetic patient cannot simply switch from one product to another without working closely with a physician to find the right dosage of insulin. Finding the right insulin medication and dosage for a diabetic patient often requires numerous visits to a physician and blood sugar tests.

6) One Springhill patient ("Patient X") is also a customer of The Corner Drug Store and uses The Corner Drug Store for monthly refills of Lantus®. Patient X is a Medicare beneficiary but is currently in the Medicare "donut hole". As described on the website of the Centers for Medicare and Medicaid Services ("CMS"), "[m]ost Medicare drug plans have a coverage gap (also called the "donut hole"). This means there is a temporary limit on what the drug plan will cover for drugs." CMS, *Costs in the Coverage Gap*, available at https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap (last accessed Nov. 20, 2020). Because Patient X is in the donut hole, Patient X is eligible for the Cash Savings Program.

7) When Patient X requested a refill of Lantus® in October, the cost to Patient X was $17.30 because the drug was purchased at a 340B price. My understanding is that the 340B price was available in October because there were some operational glitches in

Sanofi communicating the pricing changes to the drug wholesaler through which The Corner Drug Store purchases its drug by October 1.

8) The following month, Patient X returned to The Corner Drug Store for a refill of Lantus®, but the cost had risen to $1,360.57 because Sanofi no longer allowed the drug to be purchased with 340B discounts.

9) Patient X left The Corner Drug Store without the prescription. A few days later, Patient X returned to The Corner Drug Store and requested that The Corner Drug Store submit the claim for the Lantus® to Medicare. Patient X's co-payment was $300.00 under the Medicare plan. Patient X said that she was able to pay the co-payment for that month's supply but that she would not be able to do so for the following month.

10) Another Springhill patient ("Patient Y") is uninsured, eligible for the Cash Savings Program, and had also been prescribed Lantus®. When Patient Y requested that The Corner Drug Store refill a monthly prescription of Lantus® in October, the cost to Patient Y was $17.30 because the drug was purchased at a 340B price. My understanding is that the 340B price was available in October because there were some operational glitches in Sanofi communicating the pricing changes to the drug wholesaler through which The Corner Drug Store purchases its drug by October 1.

11) The following month, Patient Y returned to The Corner Drug Store to request a monthly refill of Lantus®, but the cost had risen to $1,360.57 because Sanofi no longer allowed the drug to be purchased with 340B discounts.

12) Patient Y left The Corner Drug Store without the prescription. Patient Y returned to The Corner Drug Store a few days letter with a prescription for Levemir®, an insulin product produced by Nova Nordisk, Inc.

13) Another Springhill patient ("Patient Z") is uninsured, eligible for the Cash Savings Program, and takes several medications to treat Patient Z's congestive heart failure and other serious heart conditions.

14) One of the medications that Patient Z's physician had prescribed was Brilinta®, which is a blood thinner produced by AstraZeneca PLC ("AstraZeneca").

15) When Patient Z requested a refill of Brilinta® in October, the cost to Patient Z was $124.95 because the drug was purchased at a 340B price. My understanding is that the 340B price was available in October because there were some operational glitches in AstraZeneca communicating the pricing changes to the drug wholesaler through which The Corner Drug Store purchases its drug by October 1.

16) The following month, Patient Z returned to The Corner Drug Store for a refill of Brilinta®, but the cost had risen to $409.78 because AstraZeneca no longer allowed the drug to be purchased with 340B discounts.

17) Patient Z left The Corner Drug Store without the prescription. Patient Z said that he is already spending more than he can reasonably afford on prescription medications.

18) There are numerous other examples of Springhill patients who are eligible for the Cash Savings Program but are no longer able to afford their medications because the medications are produced by Sanofi or AstraZeneca and cannot be purchased with 340B discounts.

[*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,

James Daniel Duck
Owner, The Corner Drug Store
Springhill, Louisiana

EXHIBIT I

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 J

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