UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al., Plaintiffs, v. NORRIS COCHRAN, Acting Secretary of Health & Human Services, et al., Defendants.	Case No. 1:21-cv-81-SEB-MJD

MOTION FOR LEAVE 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 leave to file a brief as amici curiae in the above captioned case. The Amici support the Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction. ECF No. 32. Amici have conferred with the parties, and this motion is not opposed by Defendants and is opposed by Plaintiffs. Amici's motion should be granted for several reasons: 1) no party represents the interests of covered entities that participate in the 340B program, such as Amici; 2) Amici have an interest in pending 340B administrative dispute resolution ("ADR") petitions that will be impacted by the

Court's ruling; and 3) Amici can provide the Court with the 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 one member that operates a clinic in Indianapolis, Indiana. 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 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. 19, 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 manufacturer'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. 19, 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 manufacturer'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 in deciding whether to permit *amicus curiae* participation." *McCarthy v. Fuller*, No. 1:08-CV-994-WTL-DML, 2012 WL 1067863, at *1 (S.D. Ind. Mar. 29, 2012). The Seventh Circuit has allowed amicus briefing by organizations such as RWC-340B, Little Rivers, and FamilyCare under the following circumstances:

> (1) a party is not adequately represented (usually, is not represented at all); or (2) when the would-be amicus has a direct interest in another case, and the case in which he seeks permission to file an amicus curiae brief may, by operation of stare decisis or res judicata, materially affect that interest; or (3) when the amicus has a unique perspective, or information, that can assist the court of appeals beyond what the parties are able to do.

Nat'l Org. for Women, Inc. v. Scheidler, 223 F.3d 615, 617 (7th Cir. 2000) (citing to *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063–64 (7th Cir.1997)). Amici need to demonstrate only one of these standards but can satisfy all three.

First, the Amici are not adequately represented in this case. *Nat'l Org. for Women, Inc.*, 223 F.3d at 617. Clearly, Plaintiffs do not represent Amici's interests because Plaintiffs refuse to ship 340B discounted drugs to Amici's contract pharmacies and now seek 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 Plaintiffs' 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, 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 with respect to Plaintiffs' Motion for Preliminary Injunction. *Eli Lilly & Co, et al v Azar*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 12, 2021), ECF No 39.

Second, the Amici have a direct interest in other cases that may be materially affected by the Court's decision in the instant action. *Nat'l Org. for Women, Inc.*, 223 F.3d at 617. All three Amici are plaintiffs in a lawsuit against several of the Defendants that concerns the ADR regulations that the Plaintiffs seek 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 Plaintiffs seek to enjoin. The Defendants' Opposition to the Plaintiffs' Motion for Preliminary Injunction provides some of the factual background for these actions by Amici. Defs.' Opp'n to Pls.' Mot. for Prelim. Inj., *Eli Lilly & Co, et al v Azar*, No. 1:21-cv-00081-SEB-MJD, 7 (S.D. Ind. Feb. 16, 2021), ECF No. 32 ("[d]uring the latter half of 2020 several drug makers, led by Plaintiff Eli Lilly ("Lilly"), took unilateral actions to restrict access to their drugs by covered entities that rely on contract pharmacies to take delivery of, and dispense, medications to low-income patients.").

When Lilly stopped shipping 340B discounted drugs to Amici's contract pharmacies, their 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 manufacturers, 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 manufacturers' actions. HHS subsequently issued the ADR regulations that are the subject of Plaintiffs' 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.[1] In addition, the United States 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,

[1] Little Rivers and FamilyCare have filed ADR petitions against another manufacturer that has also refused to provide 340B discounts through contract pharmacies, rather than Defendants. Decisions issued through the ADR process, however, are precedential. 42 C.F.R. § 10.20, 10.24(d). Therefore, the interest that Little Rivers and FamilyCare have in their respective ADR Petition proceedings remains and this Court's decision will undoubtedly have an impact on those proceedings.

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 Plaintiffs. 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.

Third, the Amici can provide the Court with a unique perspective in the instant case. *Nat'l Org. for Women, Inc.*, 223 F.3d at 617. 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 Plaintiffs 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 which neither the Plaintiffs nor the Defendants can possibly have because they are not 340B covered entities. The Court should grant this motion because the Amici have "a unique perspective, or information" that will assist the court "beyond what the parties are able to do." *Nat'l Org. for Women, Inc.*, 223 F.3d at 617 (citing *Ryan v. CFTC*, 125 F.3d 1062 (7th Cir. 1997) (chambers opinion)).

This motion and the attached Amicus Curiae brief are also timely. Because the Federal Rules of Civil Procedure or 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 Plaintiffs' Motion for Preliminary Injunction. Defendants filed the opposition to the Plaintiffs' Motion for Preliminary Injunction on February 17, 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 amici curiae Brief and accompanying exhibits.

Respectfully submitted,

/s/ Ronald S. Connelly

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Dated: February 22, 2021

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al., Plaintiffs, v. NORRIS COCHRAN, Acting Secretary of Health & Human Services, et al., Defendants.	Case No. 1:21-cv-81-SEB-MJD

[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 Plaintiffs' 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 Plaintiffs' 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.

DATE: _____

_____
Mark J. Dinsmore
United States Magistrate Judge
United States District Court
Southern District Indiana

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al.,

Plaintiffs,

v.

NORRIS COCHRAN, Acting Secretary of Health & Human Services, et al.,

Defendants.

Case No. 1:21-cv-81-SEB-MJD

BRIEF OF AMICI CURIAE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST 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"). Plaintiffs Eli Lilly & Co. and Lilly USA, ("Lilly") now ask 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 providers 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 Lilly has wholly ignored in its motion, and which far outweigh the alleged harms that Lilly has claimed it will incur.

I. 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. 21, 2021); 42 U.S.C. § 256b(a)(4)(D). One of RWC-340B's members operates a clinic in Indianapolis, Indiana.

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*, https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (last visited Feb. 21, 2021). Ryan White clinics provide critical support to this vulnerable population, serving over half a million individuals by furnishing "HIV primary medical care, medications, and support services for underserved and uninsured" people living with HIV/AIDS. RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2-3 (Oct. 2020), https://www.rwc340b.org/wp-content/uploads/2020/10/20200921-RWC340B-White-Paper-FINAL.pdf.

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.

The Secretary's database of 340B providers shows that 75% of Ryan White clinics have contract pharmacy arrangements. *See* HRSA, *Welcome to 340B OPAIS*, https://340bopais.hrsa.gov/ (last visited Feb. 21, 2021). For many Ryan White clinics, contract pharmacy arrangements are the primary, or even sole, path to 340B discounts and revenue. Loss of these discounts or revenue would jeopardize services provided by Ryan White clinics and irreparably harm the very vulnerable patients they serve.

II. 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. 21, 2021). 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*,

[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).

https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 21, 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 River's 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 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.

III. 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. 21, 2021). FamilyCare provides patient care services covering a wide variety of specialties, which include adult health

[2] The following declarations 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"); Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (Ex. B, Glover"); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (Ex. C, "Dickerson").

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% 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*, https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Feb. 21, 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.

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 an ADR ten years ago, but HHS finalized the regulations only recently. The lack of ADR became critically important last summer when Lilly led other drug companies on 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 Lilly 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 Lilly's motion for preliminary injunction and urge the Court to deny Lilly's motion. Mot. for Prelim. Inj., *Eli Lilly & Co, et al v. Azar*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Jan. 25, 2021), ECF No. 18 ("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 a drug's manufacturer. 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 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 or under-compensated care. Without the 340B program, taxpayers would have to absorb the costs of uncompensated care or covered entities would be forced to restrict access to services or even cease operations.

The 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

Lilly mischaracterizes the 340B contract pharmacy program as a massive giveaway to large, corporate chain pharmacies. Motion for PI at 5-8. 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. Contract Pharmacy Notice, 61 Fed. Reg. 43,549 (Aug. 23, 1996). "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." *Id*. at 43,550. Thus, for over twenty-four years, HHS recognized that the program could only function effectively if certain covered entities purchased 340B discounted drugs under contract with 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").[3] Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010). 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

[3] 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 Robinson-Patman Act, which added an additional exception to its price discrimination rules in the form of the NPIA. 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.*

the 340B statute and NPIA provide for the purchase and restrict the resale of discounted drugs by non-profit healthcare entities. 15 U.S.C. § 13-13c; 42 U.S.C. § 256b(a)(5)(B).

Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, four out of 700 manufacturers participating in the 340B program announced that they would either refuse to honor contract pharmacy arrangements or impose onerous conditions on contract pharmacy arrangements. Lilly led the charge and was quickly followed by Sanofi, AstraZeneca, and Novartis. HRSA, *Manufacturer Notices to Covered Entities* (July 2020)[4]; Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020)[5]; Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020)[6]; Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020)[7]; Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020).[8] More recently, Novo Nordisk, Inc. 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)[9]; Letter from Kevin Gray, Senior Vice President,

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[4] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.
[5] https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf
[6] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.
[7] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.
[8] Novartis has since retreated, in part. By letter dated October 30, 2020, Novartis informed covered entities that "all federal grantees, including Ryan White Clinics and Community Health Centers, will continue to receive 340B discounts" at contract pharmacies. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020). The letter also stated that, effective November 16, 2020, Novartis will honor contract pharmacy arrangements with 340B hospitals if the contract pharmacy is located within a 40-mile radius of the main hospital facility. *Id*. Sanofi has also partially retreated and recently announced that it will provide 340B drugs through contract pharmacy arrangements for all grantees other than FQHCs, 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).
[9] https://bit.ly/2NQlzpc.

Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[10] Hundreds of other drug companies that participate in the 340B program continue to ship to contract pharmacies. Lilly, Sanofi, 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.

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.

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

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 Lilly and other drug manufacturers 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. *National Association of Community Health Centers (NACHC) v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020) (stayed Jan. 7, 2021); *American Hospital Association, et al v. Azar,* 4:20-cv-08806-YGR, (N.D. Cal. Feb. 17, 2021) (case dismissed).

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 manufacturers regarding overcharges for drugs purchased under the 340B Program. Administrative Dispute Resolution Regulation, 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 LILLY AND OTHER MANUFACTURERS

Lilly devotes only one sentence of its brief to the harm that a preliminary injunction will cause covered entities. Lilly contends that no "covered entity [will] suffer cognizable harm by

virtue of an order enjoining the ADR process." Motion for PI at 35. Lilly offers no reasoning for its assertion and cannot because its assertion is false. 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 Lilly 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 clearly outweigh any harm that allowing the process to continue would cause Lilly. Similarly, Lilly offers a short and largely unsubstantiated assertion that a preliminary injunction will serve the public interest because the ADR Rule will result in Lilly being subjected to piecemeal litigation and because the ADR Rule violates its constitutional rights. Motion for PI at 35. In this case, the public interest includes the Amici, other covered entities, and the vulnerable patients that they serve. Currently, covered entities do not have access to 340B discounts via their contract pharmacies due to Lilly's policy and similar policies of other manufacturers. The ADR process is vital so that covered entities can bring this dispute to a neutral panel within HHS for adjudication. This Court should, therefore, deny Lilly'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 Seventh Circuit has recognized that a party requesting a preliminary injunction "must make a threshold showing that: (1) absent preliminary injunctive relief, he will suffer irreparable harm in the interim prior to a final resolution; (2) there is no adequate remedy at law; and (3) he has a reasonable likelihood of success on the merits." *Turnell v. CentiMark*

*Cor*p., 796 F.3d 656, 662 (7th Cir. 2015). If the movant makes this threshold showing, the court proceeds to consider the balance of harms between the parties and the effect of granting or denying a preliminary injunction on the "public interest." *Id*. In considering the effect on the public interest, this Court must consider "any effects that granting or denying the preliminary injunction would have on nonparties." *Baskin v. Bogan*, 983 F. Supp. 2d 1021, 1024-1025 (S.D. Ind. 2014).

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); *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982); *see also Whole Women's Health All. v. Hill*, 937 F.3d 864, 875 (7th Cir. 2019) ("Enforcing a constitutional right is in the public interest"); *Indiana Fine Wine & Spirits, LLC v. Cook*, 459 F. Supp. 3d 1157, 1170 (S.D. Ind. 2020) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm, and its remedy certainly would serve the public interest"). 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 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.

Lilly asserts that its constitutional rights will be violated through the ADR process. Motion for PI at 35. Defendants have already provided the Court with arguments as to why Lilly's assertions are groundless. Defs.' Opp'n to Pls.' Mot. for Prelim. Inj., *Eli Lilly & Co, et al v. Azar*, No. 1:21-cv-00081-SEB-MJD, 35-38 (S.D. Ind. Feb. 16, 2021), ECF No. 32. The Court should also weigh any constitutional claim by Lilly 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 Lilly'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," *Turnell*, 796 F.3d at 662, 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 violations of the 340B statute. Access to the ADR process is vitally importantly currently because Lilly'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 Lilly, and possibly other drug manufacturers, 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. As one 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 price, however, is significantly lower than non-340B prices, patients that relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30.

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 drug or pay 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 Lilly 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 CEO of Little Rivers, Gail Auclair, reviewed the increase in price, from 340B to non-340B, for two drugs that some of its uninsured patients are currently prescribed and found that the cost of a 30-day supply of Humulin®, an insulin product manufactured by Lilly for which no biosimilar is available, increased from $117.24 to $450.17.[11] Auclair Aff. ¶ 33. 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.

Lilly has made a tiny concession to allow covered entities to designate one pharmacy as a contract pharmacy if they do not operate their own retail, in-house pharmacies, but Lilly's policy

[11] The ever-increasing cost of insulin is well publicized, with several products increasing from about $93 in 2019 to close to $300 in 2019. Rachel Gillett & Shayanne Gal, *One Chart Reveals How the Cost of Insulin Has Skyrocketed in the US, Even Though Nothing About it Has Changed*, Business Insider (Sept. 18, 2019), https://www.businessinsider.com/insulin-price-increased-last-decade-chart-2019-9.

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.

Lilly has submitted with its motion for preliminary injunction affidavits from an ADR petition that was filed against it that demonstrate how Lilly is harming covered entities.[12] 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., Motion for PI, Ex. D, ECF No. 19-5, 361 ("[t]he travel distance between our northern most and southern most clinical delivery sites is 200 miles."); Francis Aff., Motion for PI, Ex. D, ECF No. 19-5, 378 ("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., Motion for PI, Ex. D, ECF No. 19-5, 401 ("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").

[12] The following declarations were submitted as part of Exhibit D to Plaintiff's Motion for PI, ECF No. 19-5: Declaration of J.R. Richards, CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus ("Richards Aff."); Declaration of Donald A. Simila, CEO of Upper Great Lakes Health Center, Inc. ("Simila Aff."); Declaration of Lee Francis, President and CEO of Erie Family Health Center ("Francis Aff."); Declaration of Kimberly Christine Chen, Director of Pharmacy at North County HealthCare, Inc. ("NCHC") ("Chen Aff."); Declaration of Ludwig M. Spinelli, CEO of Optimus Health Care Inc., ("Spinelli Aff.").

Lilly has made a meaningless exception to allow contact pharmacies to offer insulin through contract pharmacies if four conditions are met.[13] However, these four requirements are totally unworkable and legally suspect. For example, one of the requirements is that the pharmacy not charge a dispensing fee for providing the drug. It is entirely impractical to expect a pharmacy to fill a prescription for free. Also, it could subject covered entities to violations of the federal law that prohibits offering financial inducements to patients.[14] 42 U.S.C. § 1320a-7a(a)(5).

The CEO of Optimus Health Care Inc. ("Optimus") submitted an affidavit in an ADR petition separate from the Amici's. Spinelli Aff., Motion for PI, Ex. D, ECF No. 19-5, 407-12. Optimus describes two patients who rely on the 340B program to afford certain drugs that are manufactured by Lilly. Spinelli Aff., Motion for PI, Ex. D, ECF No. 19-5, 410-11. These patients have recently encountered barriers to accessing these drugs due to Lilly's restrictive policy on contract pharmacy arrangements. Spinelli Aff., Motion for PI, Ex. D, ECF No. 19-5, 410-11. One patient, who is visually impaired and does not speak English, previously paid only $15 a month for insulin manufactured by Lilly. Spinelli Aff., Motion for PI, Ex. D, ECF No. 19-5, 410-11. When she went back to the pharmacy to refill her prescription on September 4, 2020, the price of the medication increased to $270. Spinelli Aff., Motion for PI, Ex. D, ECF No. 19-5, 410-11. Another patient who was diagnosed with gestational diabetes relied on insulin manufactured by Lilly to help manage her high-risk pregnancy. Spinelli Aff., Motion for PI, Ex.

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

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

D, ECF No. 19-5, 411. At 27 weeks into her pregnancy, Lilly's new contract pharmacy policy required her to pay $320 for her insulin, which she could not afford. Spinelli Aff., Motion for PI, Ex. D, ECF No. 19-5, 411.

These are just a few examples that highlight the plight of thousands of patients nationwide who can no longer afford medications due to Lilly's restrictive policy. Without the ADR process, covered entities have limited recourse to fight for their right to access 340B prices at contract pharmacies, which allows them to pass savings on to the patients who rely on the 340B program to afford their medications. *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.

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., Motion for PI, Ex. D, ECF No. 19-5, 359-60; Francis Aff., Motion for PI, Ex. D, ECF No. 19-5, 376.

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; Simila Aff., Motion for PI, Ex. D, ECF No. 19-5, 360. 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 Lilly and the other drug companies that have refused to honor such arrangements. Auclair Aff. ¶ 23.

FamilyCare realizes at least $449,178 annually by purchasing products from the same manufacturers for delivery at contract pharmacies. Glover Aff. ¶ 22; Dickerson Aff. ¶ 6. *See also* Simila Aff., Motion for PI, Ex. D, ECF No. 19-5, 361 ("[s]ince 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.").

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 Lilly and the other drug companies. 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 manufacturers. 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., Motion for PI, Ex. D, ECF No. 19-5, 361. 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 certain drug manufacturers, including Lilly, 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 manufacturers' actions. Auclair Aff. ¶ 25. Thus, cutting or eliminating services to Little Rivers' patients will be detrimental to their health and well-being.

In response to Lilly's actions, covered entities have been working to switch patients' medications. Richards Aff., Motion for PI, Ex. D, ECF No. 19-5, 356; Francis Aff., Motion for PI, Ex. D, ECF No. 19-5, 380. Many patients may wish to stay on the medication they are familiar with or are fearful of the negative health impact of switching to a new medication. Richards Aff., Motion for PI, Ex. D, ECF No. 19-5, 356; Francis Aff., Motion for PI, Ex. D, ECF No. 19-5, 380. 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., Motion for PI, Ex. D, ECF No. 19-5, 380. If the new drug

treatment has different dosing, this could require significant patient education and "provider troubleshooting." Francis Aff., Motion for PI, Ex. D, ECF No. 19-5, 380.

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. 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. 21, 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 Lilly. 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 Lilly'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.'" *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985) (quoting *Va. Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958); *Am. Hosp. Ass'n v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980) ("Only harm that the district court cannot remedy following a final determination on the merits may constitute irreparable harm."); *see also Sampson v. Murray*, 415 U.S. 61, 90 (1974) (explaining that the possibility of adequate compensatory or other corrective relief at a later date weighs heavily against a claim of irreparable harm); *Population Institute v. McPherson*, 797 F.2d 1062, 1067 (D.C. Cir. 1986) (preliminary injunction issued where funds sought by plaintiff would be disbursed to others and unavailable at the conclusion of litigation).

Furthermore, Amici's losses would not be recoverable in any other forum because covered entities cannot bring a suit against Lilly for violating 340B requirements. *Astra*, 563 U.S. 110, 113-14. Even if Amici were able to recover economic losses, the Seventh Circuit has recognized that a damage award that might come "too late to save the plaintiff's business" constitutes irreparable harm. *Gateway E. Ry. Co. v. Terminal R.R. Ass'n of St. Louis*, 35 F.3d 1134, 1140 (7th Cir. 1994) (citing *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 386 (7th Cir. 1984)). The economic loss to the Amici from Lilly'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. Thus, the Amici cannot recover lost 340B savings through "the ordinary course of litigation" and have no adequate remedy at law and must therefore rely on the ADR regulations to remedy the harm suffered from Lilly's and other manufacturers' actions. *Wisconsin Gas Co.*, 758 F.2d at 674.

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

Lilly contends that, "unless the ADR process is enjoined, Lilly will be forced to expend enormous resources, none of which it will get back." Motion for PI at 34. Lilly can well afford

to pay for its litigation expenses. As noted in a letter to Lilly by the then HHS General Counsel, Lilly's financial status is quite robust:

> The price of Lilly's Stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from $1.414 billing during the second quarter of 2019 to $1.615 billion for the second quarter of 2020, an increase of more than 14 percent.

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), available at https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf.

Lilly's record profits are in sharp contrast to the financial plight of Amici and other covered entities:

> In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

Id.

Clearly, the financial harms that are befalling Amici and other covered entities due to Lilly's policy are devastating to Amici and covered entities and far outweigh any expense that Lilly may incur in responding to ADR petitions. The balance of financial harms weighs in favor of denying Lilly'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 Lilly and other drug companies. Amici therefore respectfully request that the Court deny Lilly's motion for preliminary injunction and permit the ADR regulations to remain in effect.

Respectfully submitted,

/s/ Ronald S. Connelly
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Dated: February 22, 2021

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al., Plaintiffs, v. NORRIS COCHRAN, Acting Secretary of Health & Human Services, et al., Defendants.	Case No. 1:21-cv-81-SEB-MJD

INDEX OF EXHIBITS TO BRIEF OF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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 Terri S. Dickerson, CFO, FamilyCare.

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.

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.

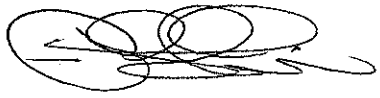
30) FamilyCare's Prescription Savings Program is offered for drugs that are purchased with 340B discounts. If FamilyCare cannot purchase drugs manufactured by Lilly, AstraZeneca, and Lilly with 340B discounts, those drugs will no longer be part of its program. FamilyCare does not have funds allocated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

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