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 NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC., DBA FAMILYCARE HEALTH CENTER IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTERESTS OF AMICI CURIAE

Amici Curiae have a critical interest in this case, which concerns the 340B Drug Discount Program ("340B Program"), administered for their benefit by the Defendant, the Department of Health and Human Services ("HHS"). The 340B Program allows certain healthcare providers (known as "covered entities") serving medically vulnerable, uninsured, and under-insured patients to purchase outpatient drugs at significant discounts. 42 U.S.C. § 256b. Amici Curiae are two national trade associations of federally-funded covered entities—Federally-qualified health centers ("FQHCs") and Ryan White clinics ("RWCs")—that participate in the 340B Program, and two FQHC covered entities (collectively, the "Amici"). Amici submit this brief to apprise the Court of the broad-based and far-reaching legal, social, and economic implications inherent in any change to the 340B Program, as well as the substantial impact that enjoining the 340B Administrative Dispute Resolution ("ADR") regulations will have on covered entities and their patients. No covered entity is a party to this action, but all covered entities will be negatively impacted if the Court grants Lilly's motion to preliminarily enjoin the 340B ADR regulations. Amici have a significant interest in the continued viability of the 340B Program, including the availability of the ADR process, because three of the Amici have ADR petitions currently pending, and ADR provides the sole forum for covered entities to challenge drug company overcharges.[1]

The National Association of Community Health Centers ("NACHC"), a nonprofit and tax-exempt organization, is the national membership organization for FQHCs. Founded in 1971, NACHC's primary objective is to further—through extensive education, training, and advocacy—FQHCs' mission and purpose.

[1] NACHC filed ADR claims on behalf of 225 FQHCs on January 13, 2021; Little Rivers filed its petition on February 4, 2021; and FamilyCare filed its petition on February 12, 2021.

FQHCs are predominantly community-based, patient-directed nonprofit organizations that play a vital role in our nation's health care safety-net by providing primary and other health care and related services—including pharmaceutical services—to medically underserved populations throughout the nation, regardless of any individual patient's insurance status or ability to pay for such services. FQHCs receive, or are eligible to receive, federal grant funding under Section 330 of the Public Health Service ("PHS") Act to serve four general patient populations: residents of federally-designated medically underserved areas; homeless populations; migrant and seasonal farmworkers; and residents of public housing. 42 U.S.C. § 254b(a)(1). In addition to providing comprehensive primary care to approximately one in twelve Americans who fall into one or more of these categories, FQHCs serve on the front lines in preventing, treating, and containing serious, nationwide public health threats such as the HIV epidemic, the opioid addiction crisis, and the ongoing COVID-19 pandemic.

FQHCs treat a population that is disproportionately poor: 91% of health center patients are under 200% of the federal poverty level ("FPL"); 69% percent of patients are at or below 100% of the FPL. *See* NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-8, 2-9 and 2-11.[2] Eighty-two percent of FQHC patients are either publicly insured (e.g., Medicare and Medicaid beneficiaries) or lack health insurance entirely. *See id.*, Fig. 1-5. For decades, FQHCs have relied on 340B Program savings and revenue to meet the needs of their vulnerable patient populations, which in 2020 included approximately one in three people living in poverty, one in five residents of rural areas, one in nine children, one in eight people of a racial or ethnic minority, and one in six Medicaid beneficiaries. *Id.*, Fig. 1-1.

[2] https://www.nachc.org/research-and-data/research-fact-sheets-and-infographics/chartbook-2020-final/ (hereinafter "NACHC Chartbook").

Ryan White Clinics for 340B Access ("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., and participate as covered entities in the 340B Program. Entities that receive Ryan White CARE Act funding are commonly referred to as "Ryan White clinics." One of RWC-340B's members operates a clinic in Indianapolis, Indiana.

Ryan White clinics provide critical support to the vulnerable HIV/AIDS 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).[3] Ryan White clinic patients 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. Nevertheless, Ryan White clinic patients are more likely to achieve HIV viral suppression than patients seen elsewhere. *Id*. at 4 (explaining that viral load suppression can result in reduced transmission risk). *Id*.

Seventy-five percent 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, a funding source on which these clinics have long relied.

Little Rivers is an FQHC covered entity with several facilities in Vermont. Little Rivers' mission is to provide respectful, comprehensive primary health care—including family medicine,

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

pediatrics, obstetrics, behavioral health, and oral health care—for all residents in its region, regardless of their ability to pay. Of Little Rivers' patients with known incomes, 61.2% had income at or below 200% of the FPL, including 19.48% with income at or below 100% of the FPL. HRSA, *Health Center Program Data for Little Rivers, Patient Characteristics*.[4] In 2019, more than 25% of Little Rivers' patients were Medicaid recipients, and approximately 5% of its patients were uninsured. *Id.* A covered entity since 2006, Little Rivers does not operate an in-house pharmacy and instead relies exclusively on contract pharmacy arrangements to dispense 340B drugs to its patients. Auclair Aff. ¶ 19.[5]

FamilyCare is an FQHC covered entity with several facilities in West Virginia, including three mobile units and facilities at local schools. In addition to providing required comprehensive primary care services, FamilyCare operates a birthing center, a pediatric medicine clinic, and an addiction treatment center. FamilyCare served 32,353 patients in 2019; of those patients with known incomes, 99.53% had annual incomes at or below 200% of the FPL, including 50.43% with annual incomes at or below 100% of the FPL. HRSA, *Health Center Program Data*.[6] A covered entity since 2000, FamilyCare does not operate an in-house pharmacy and instead relies exclusively on contract pharmacy arrangements to dispense 340B drugs to its patients. Glover Aff. ¶ 4. FamilyCare's service area is very large; some patients drive for an hour to reach one of its locations.

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[4] https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 21, 2021).

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

[6] https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId (last visited Feb. 21, 2021).

ARGUMENT

Covered entities have only one direct way to challenge drug company violations of 340B requirements: ADR. *See Astra USA, Inc. v. Santa Clara Cty., Cal.*, 563 U.S. 110 (2011) ("*Astra*") ("Congress did not . . . invit[e] 340B entities to launch lawsuits in district courts . . . . Instead. . . . Congress . . . opted to . . . make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,' . . . and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA.") (internal citations omitted). Although Congress instructed HHS to promulgate regulations to establish an ADR process ten years ago, HHS finalized the regulations only recently. 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) ("ADR Rule"). The longstanding lack of ADR became critically important last summer when Lilly advanced a self-serving reinterpretation of Section 340B, and led other drug companies on a campaign to undermine the 340B Program by cutting off discounts on drugs shipped to covered entities' contract pharmacies. Now, having failed to convince HHS to bless its unlawful acts,[7] and with both houses of Congress evidently against it,[8] Lilly has turned to the judiciary to condone its clearly unlawful behavior.[9]

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[7] *See, e.g.*, Letter from Robert P. Charrow to Anat Hakim (Sept. 21, 2020), ECF No. 19-5 at 60–61; HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, ECF No. 19-5 at 38–45.

[8] *See* Letter from Members of Congress to Alex M. Azar II at 1 (Sept. 14, 2020), ECF No. 19-5 at 47–48 (Mem. In Supp. of Pls.' Mot. Prelim. Inj.); Letter from United States Senators to Alex M. Azar II at 1 (Sept. 17, 2020); Letter from House Committee on Energy & Commerce to Alex M. Azar II at 1 (Sept. 3, 2020).

[9] Lilly's litigation strategy is not limited to this suit. *See, e.g.*, Mem. in Supp. of Eli Lilly and Co's Mot. to Intervene, ECF No. 12-1, *RWC-340B v. Azar*, Case No. 1:20-cv-02906 (D.D.C. filed Oct. 9, 2020). Two other major drug companies are also acting in close concert with Lilly. *See, e.g.*, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Human Servs.*, 3:21-cv-00634 (D.N.J. Jan. 12, 2021); *AstraZeneca Pharm. LP v. Azar*, No. 1:21-cv-00027 (D. Del. Jan. 12, 2021); Mem. in Supp. of Sanofi-Aventis U.S. LLC's Mot. to Intervene, ECF No. 13-1, *RWC-340B v. Azar*, Case No. 1:20-cv-02906; Mem. in Supp. of AstraZeneca's Mot. to Intervene, ECF No. 29-1, *RWC-340B*, No. 1:20-cv-02906 (Nov. 24, 2020).

The public interest will be significantly harmed if this Court grants the extraordinary relief Lilly requests. This case impacts *thousands* of covered entities delivering health care to *millions* of Americans, many of whom are among the most medically underserved and vulnerable in our nation. To divert attention from its own profit motive, Lilly attempts to villainize large chain pharmacies and mischaracterizes them as de facto covered entities. But Lilly cannot erase covered entities and their patients by shining the spotlight on CVS and Walgreens any more than it can hide the true motivation behind this suit in meritless constitutional arguments against a rule that finally established a process for covered entities to challenge its unlawful acts.

The truth is that Lilly's unlawful acts damage covered entities that treat the most vulnerable. Weakening a significant portion of the health care safety net runs counter to the public interest in the best of times; here, Lilly boldly asks this Court to ratify its anti-social actions during the worst public health crisis in a century. Enjoining ADR will irreparably harm covered entities by leaving them at the mercy of Lilly and other manufacturers that have similarly cut off covered entities' access to drugs at 340B discount pricing. Without access to 340B pricing, covered entities will inevitably cut services supported by 340B discounts, and patients will lose access to low-cost medications, with some forgoing 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., ECF No. 18 ("Mot. for PI").

I. The Status Quo Lilly Seeks to Preserve Is the Result of Unsanctioned and Unlawful Conduct and Reverses More Than Two Decades of Practice

As a threshold matter, the status quo Lilly asks this Court to preserve pending final resolution of its claims is the result of Lilly's own unsanctioned and unlawful conduct, upsets

more than two decades of policy and practice, violates Lilly's legal and contractual obligations, and runs counter to Congress's plans for how covered entities should operate. The *true* status quo is one in which covered entities rely on contract pharmacies to dispense their 340B-purchased drugs and otherwise best serve their patients' pharmaceutical needs, consistent with Congress's intent and HHS's longstanding interpretations of both Sections 330 and 340B of the PHS Act. It is also a state of affairs in which, as Congress intended, drug manufacturers' honor their obligation to provide discounted drugs to covered entities, allowing covered entities to rely on 340B savings to fund crucial aspects of their operations.

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

Lilly mischaracterizes the 340B contract pharmacy program as a massive giveaway to large, corporate chain pharmacies. Mot. for PI at 5–8. But a contract pharmacy is simply a dispensing agent for the covered entity: the covered entity purchases drugs at 340B discounts and directs the drugs' shipment to a contract pharmacy, which, in exchange for a dispensing fee, stores and dispenses the drugs to the covered entity's patients, and, importantly, relinquishes third-party payments and/or patient co-payments to the covered entity.

HHS, through its Health Resources and Services Administration ("HRSA"), has consistently interpreted the 340B statute to require drug companies to sell discounted drugs for shipment to covered entities' contract pharmacies. *See, e.g.*, Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996) ("Contract Pharmacy Notice") ("There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. . . . Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities."); Notice Regarding 340B Drug Pricing

Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272- (Mar. 5, 2010). In 1996, HRSA explained why contract pharmacies are essential for the "many covered entities" that "do not operate their own licensed pharmacies":

> Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Contract Pharmacy Notice, 61 Fed. Reg. at 43,549.[10]

Despite honoring contract pharmacy arrangements for over 24 years, in the summer of 2020, Lilly led the charge in either refusing to honor contract pharmacy arrangements or imposing onerous conditions that effectively eliminated covered entities' access to drugs at 340B pricing. HRSA, *Manufacturer Notices to Covered Entities* (July 2020);[11] Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020).[12] Lilly was quickly followed by Sanofi, AstraZeneca, and other major drug manufacturers. Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020);[13] Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020);[14] Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020).[15] More recently, Novo

[10] Because obtaining a pharmacy license is 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.
[11] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.
[12] https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf
[13] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/Sanofi-Letter.pdf.
[14] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.
[15] Novartis has since retreated, in part, by shipping to federal grantees' contract pharmacies and to hospital contract pharmacies within a 40-mile radius. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin.,

Nordisk, Inc. and United Therapeutics Corporation have likewise announced limitations on providing 340B drugs through contract pharmacies, illustrating the danger inherent in depriving covered entities of a means to challenge such behavior. *See* Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020);[16] Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[17] That said, hundreds of other drug company participants in the 340B Program continue to honor their 340B contract pharmacy obligations. It is clearly Lilly and its compatriots that seek to prolong a "status quo" only recently created by their own upending of the 340B contract pharmacy program.

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

In 1992, when Congress created the 340B Program, it had every reason to anticipate that FQHCs, RWCs, and other covered entities would use pre-existing authority and flexibility to provide covered outpatient drugs to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy. Indeed, contract pharmacy arrangements have been used by all types of covered entities, even before 340B was enacted.

As community and patient-based providers, FQHCs necessarily have flexibility in determining how best to meet the needs of their patients and communities, but FQHCs must—and do—use any 340B savings and revenue (as well as any other income generated from grant-supported activities) in furtherance of their health center projects. 42 U.S.C. § 254b(e)(5)(D).

Novartis Pharmaceuticals Corp. (Oct. 30, 2020). Sanofi has also partially retreated and 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).

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

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

FQHCs have also long had an express grant of authority to provide their services, including pharmacy services, either directly through their own staff or through contracts or cooperative arrangements with other entities, or a combination thereof. *See*, *e.g.*, Public Health Service Act, Pub. L. 78-410, § 330(a), 58 Stat. 682, 704 (1944) ("For purposes of [Sec. 330], the term 'health center' means an entity that serves a population that is medically underserved . . . either through the staff an (sic) supporting resources of the center or through contracts or cooperative arrangements"); Special Health Revenue Sharing Act of 1975, Pub. L. 94-63, § 501, 89 Stat. 304, 342–43 (1975) (amending § 330(a) of the PHS Act to read: "For purposes of this section, the term 'community health center' means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides" health care services, including "pharmaceutical services").

Contract pharmacy arrangements are not unique to the 340B Program. These arrangements are a well-settled aspect of non-profit healthcare entities' drug distribution systems. In 2010, the Federal Trade Commission ("FTC") formally recognized the right of certain non-profit organizations to contract with for-profit retail pharmacies 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").[18] Federal Trade Commission, University of Michigan Advisory Op., Letter to

[18] 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 discrimination in the sale of fungible products, including drugs. *See id.* The Robinson-Patman Act added the NPIA, which permits manufacturers to sell discounted medical supplies, including pharmaceuticals, to certain non-profit entities by exempting "purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" from the Robinson-Patman Act's prohibitions against price discrimination. 15 U.S.C. § 13c.

Dykema Gossett (Apr. 9, 2010).[19] Absent an exemption like the NPIA, the resale of discounted drugs purchased by a non-profit hospital to its patients could violate antitrust laws. The FTC examined and approved the exact contract pharmacy model at issue here, with only one difference—the drugs dispensed by the contract pharmacies were subject to discounts obtained under the NPIA, not the 340B statute. *Id.* Both the 340B statute and NPIA provide for the purchase and restrict the resale of discounted drugs by non-profit healthcare entities. 15 U.S.C. § 13-13c; 42 U.S.C. § 256b(a)(5)(B).

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

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

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

for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

Lilly seeks here to prolong a self-serving and self-created "status quo" in which it is blocking access to Lilly's drugs at 340B discount pricing, while simultaneously attacking the process that exists to remedy that same unlawful behavior. Lilly's reframing of the status quo ignores that, for decades, covered entities have, as Congress intended, structured their operations in reliance on 340B discounts, which are often accessible only through contract pharmacies.

II. The Balance of Harms Weighs in Favor of Denying the Preliminary Injunction Because the Public Interest Is Not Served by a Preliminary Injunction That Will Deprive Covered Entities of Redress Against Lilly and Other Manufacturers

The public interest will not be served by disabling the sole remedial scheme Congress mandated to deter and correct unlawful drug manufacturer overcharging. Consideration of the public interest must include an analysis of the impact of the Court's decision on covered entities and the millions of vulnerable patients they serve. *See Turnell v. CentiMark Cor*p., 796 F.3d 656, 662 (7th Cir. 2015) (where threshold preliminary injunction showing is made, court must consider the effect of granting or denying a preliminary injunction on the "public interest"); *Baskin v. Bogan*, 983 F. Supp. 2d 1021, 1024–25 (S.D. Ind. 2014) (in considering the public interest, court must consider "any effects that granting or denying the preliminary injunction would have on nonparties"). Without the ADR process, drug manufacturers are free to deny covered entities a crucial funding stream Congress designed.

Lilly devotes only one sentence of its brief to the harm a preliminary injunction will cause covered entities, contending, without reasoning, that no "covered entity [will] suffer cognizable harm by virtue of an order enjoining the ADR process." Mot. for PI at 35. Lilly offers a similarly short and largely unsubstantiated assertion that a preliminary injunction will *serve* the public interest because the ADR Rule, if left in place, will result in a violation of Lilly's

constitutional rights and will subject Lilly to piecemeal litigation. *Id*. The assertions are patently false. The harms covered entities, their patients, and the communities in which they operate will continue to suffer if the ADR Rule is enjoined significantly damage the public interest, and far outweigh any harm the continuation of ADR poses to Lilly. Participation in the ADR process is the only means available to covered entities to challenge Lilly's unlawful actions and to stop the ongoing and significant harm Lilly is causing to the public interest.

A. The Public Interest Is Not Served by a Preliminary Injunction That Will Prolong Irreparable Harm to Covered Entities and Their Patients

Covered entities' access to the ADR process is vitally important to the public interest, as covered entities and their patients will continue to suffer significant, irreparable harms if the extraordinary relief Lilly seeks is granted. Enjoining the ADR Rule will give Lilly—and other drug companies—a free pass to continue to flout 340B Program requirements, depriving covered entities of discount pricing to which they are statutorily entitled. Covered entities are on the front lines of caring for our nation's most vulnerable patients and use 340B discounts to support the broad goals of increasing access to care and improving health outcomes.

Denying 340B pricing is antithetical to Congress's design of the 340B Program, which contemplates expanded care to the most vulnerable and at-risk patient populations. Without 340B funding, covered entities cannot possibly "reach[] more eligible patients and provid[e] more comprehensive services" to those patients. H.R. Rep. No. 102–384(II), at 12 (1992). Indeed, Lilly's deprivation of 340B Program benefits has already harmed covered entities, their patients, and their broader communities, because covered entities have had to reduce and/or cut critical services supported with 340B-derived funding. Enjoining ADR will prolong Lilly's unlawful policy and will directly and indirectly harm our nation's most vulnerable patients by depriving them of affordable medications and critical health care and related services that

covered entities provide through 340B Program participation. Covered entities' losses—financial and otherwise—will not be fully recoverable in the ordinary course of litigation. These outcomes would be tragic at any time, but during the COVID-19 pandemic, they are unconscionable.

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

Covered entities are able, through 340B Program participation, to offer discounted drugs to financially needy patients. For example, FamilyCare's drug discount program allows indigent patients to pay only FamilyCare's cost for the drug. Glover Aff. ¶ 17. Because 340B discounted prices are significantly lower than non-340B prices, patients who relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30. Little Rivers operates a similar drug discount program that subsidizes the costs of drugs for financially needy patients. Auclair Aff. ¶ 18 (explaining patients pay a percentage of costs, including $0, on an income-based sliding scale). Little Rivers, and other covered entities, are now bearing the increased cost of Lilly's drugs for prescriptions filled at contract pharmacies. Auclair Aff. ¶¶ 21, 30, 31–34 (indicating Little Rivers will struggle financially if forced to continue incurring these increased costs). Little Rivers reviewed the increase in price due to Lilly's policy for drugs prescribed to some of its uninsured patients and found that 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. Auclair Aff. ¶ 33. Covered entities like Little Rivers can only afford to bear these unanticipated costs for so long before they will have to fall on individual patients.

Through contract pharmacy arrangements, uninsured and under-insured covered entity patients can fill prescriptions at convenient locations, often at a greatly reduced cost or no cost at all. FQHC and Ryan White covered entities care for increasing numbers of patients with chronic conditions managed primarily through prescription medications. From 2013 through 2018, the

number of FQHC patients with HIV increased 66% (from 115,421 to 191,717), patients presenting with substance use disorders increased 80% (from 506,279 to 908,984), and patients with depression and mood and anxiety disorders increased by 72% (from 2,740,638 to 4,724,691). Sara Rosenbaum et al., *Cmty. Health Ctrs. Ten Years After the Affordable Care Act: A Decade of Progress and the Challenges Ahead* at 9, Geiger Gibson RCHN Community Health Foundation Research Collaborative (Mar. 2020).[20]

With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients have lost access to lifesaving medications. Lilly has made a tiny concession to allow covered entities to use one contract pharmacy if they do not operate their own retail, in-house pharmacies, but Lilly's policy does little to aid many indigent covered entity patients. For example, FamilyCare serves a very large area in rural West Virginia and uses contract pharmacy arrangements across its service area to meet its patients' pharmaceutical needs. *See, e.g.*, Glover Aff. ¶ 19 (noting that contract pharmacy network enables FamilyCare to provide its patients discounted drugs near their homes).

The record contains affidavits from an ADR petition filed by Amicus NACHC, on behalf of 225 FQHC covered entities, against Lilly and other manufacturers for unlawful overcharging.[21] The affidavits illustrate the significant harm to the public interest Lilly's actions have already caused. Covered entities serving remote or rural areas in particular have lost access to discount drugs over large geographic areas, making it nearly impossible for their patients to access affordable medications. *See, e.g.*, Simila Aff. ¶ 27, ECF No. 19-5 ("[t]he travel distance

[20] https://www.rchnfoundation.org/wp-content/uploads/2020/03/FINAL-GG-IB-61-ACA-CHC-3.4.20.pdf

[21] The following NACHC 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.").

between our northern most and southern most clinical delivery sites is 200 miles."); Francis Aff. ¶ 19, ECF No. 19-5 ("Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships."); Chen Aff. ¶ 21, ECF No. 19-5 ("NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel [35-180 miles] (one-way trip), to reach the closest of NCHC's in-house pharmacies").

The affidavit from Optimus Health Care Inc. provides just a few examples of the negative impact Lilly's actions have already had on covered entity patients. Spinelli Aff. ¶ 12, ECF No. 19-5. One Optimus patient, who is visually impaired and does not speak English, previously paid only $15 a month for Lilly insulin.[22] Spinelli Aff. ¶ 23, ECF No. 19-5. When she attempted to refill her prescription on September 4, 2020, the price of the medication was $270. *Id*. Another Optimus patient, diagnosed with gestational diabetes, relied on Lilly insulin to help manage her high-risk pregnancy. Spinelli Aff. ¶ 24, ECF No. 19-5. Twenty-seven weeks into her pregnancy, Lilly's new contract pharmacy policy required her to pay $320 for her insulin, which she could not afford. *Id*.

In response to Lilly's actions, covered entities have struggled to switch patients' medications to affordable alternatives. Richards Aff. ¶ 23, ECF No. 19-5; Francis Aff. ¶ 26, ECF No. 19-5. Many patients want to continue taking familiar medications or are fearful of the negative health impact of changing to a new medication. Richards Aff. ¶ 23, ECF No. 19-5;

[22] Lilly has made a legally suspect and unworkable exception to allow covered entities to offer insulin through contract pharmacies if four conditions are met. The requirements are premised on the entirely unreasonable expectation that a pharmacy will fill prescriptions for free, and could subject covered entities to violations of the federal law that prohibits offering financial inducements to patients. 42 U.S.C. § 1320a-7a(a)(5). While there are exceptions to the prohibition against offering patient inducements, routinely providing drugs free of charge to *all* patients, regardless of ability to pay, is not one of the exceptions. 42 U.S.C. § 1320a-7a(i)(6); 42 C.F.R. § 1003.110.

Francis Aff. ¶ 26, ECF No. 19-5. Additionally, before a patient can change medications, a medical provider must "review the patient chart, consider comorbidities, and assess the appropriate dosing for the substitute medication." Francis Aff. ¶ 26, ECF No. 19-5. If the new drug treatment has different dosing, this could require significant patient education and "provider troubleshooting" to avoid adverse health outcomes. *Id*. The administrative and clinical burden of largescale shifts in patient medication regimes presents an unanticipated strain on covered entity staffing, removing resources from day-to-day patient care.

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

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

Many of the programs and services covered entities support with 340B funding are critical to treating the whole patient, but are not reimbursed by public or private insurance, and regardless are often most needed by patients who lack insurance altogether. Auclair Aff. ¶ 22; Glover Aff. ¶ 15; Simila Aff. ¶ 18, ECF No. 19-5. Congress designed the 340B Program to provide a funding stream for just these sorts of programs and services. And, for decades, FQHCs have structured their operations in reliance on 340B funding, just as Congress intended. *See, e.g.*, Auclair Aff. ¶¶ 10–11; Glover Aff. ¶¶ 11, 25.

FQHCs and Ryan White clinics provide, among other services, case management to assist patients with transportation, insurance enrollment, linkage to affordable housing, food access,

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

Covered entities also rely on 340B funding to provide a range of other critical services responsive to serious ongoing public health crises, such as medication assisted treatment programs and other treatment options for opioid use disorder. Auclair Aff. ¶ 15; Glover ¶ 14; Simila Aff. ¶ 5, ECF No. 19-5; Francis Aff. ¶ 9, ECF No. 19-5; *see also* U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Bureau of Primary Health Care, 2018 Health Center Data: National Data, Other Data Elements (2019) (noting FQHCs are "the first line of care in combatting the nation's opioid crisis" and indicating health centers screened and identified nearly 1.4 million people for substance use disorder, provided medication-assisted

treatment to nearly 143,000 patients, provided over 2.7 million HIV tests, and treated 1 in 5 patients diagnosed with HIV nationally).

Lilly's deprivation of access to 340B Program benefits has already resulted in cuts and reductions to critical services supported in whole or in part with 340B-derived funding. *See, e.g*, Auclair Aff. ¶ 23 (Little Rivers realizes approximately $200,000 annually by purchasing drugs at 340B discounts from Lilly and the other manufacturers currently violating their 340B obligations and dispensing those drugs to patients through contract pharmacies); Glover Aff. ¶ 22, ECF No. 19-5; Dickerson Aff. ¶ 6; Simila Aff. ¶¶ 28–30, ECF No. 19-5 (estimating annual revenue loss of approximately $600,000 from *Lilly's actions alone*, resulting in "major reductions in services" and "significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community"); Richards Aff. ¶¶ 24, 25, ECF No. 19-5 (estimating covered entity will lose approximately $350,000 in annual net revenue due to 340B restrictions, forcing reduction in services); Dickerson Aff. ¶¶ 34, 36, ECF No. 19-5 (estimating approximate annual loss of $1 million in revenue and $500,000 to $2 million increase in cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program).

Without preventive and enabling services, patient health will undoubtedly suffer. As a result, patients will require additional, more expensive health care visits at the Amici's locations, as well as more expensive hospital and specialist care. Auclair Aff. ¶¶ 26–27; Glover Aff. ¶¶ 26–27; *see also* Robert S. Nocon, et al., *Health Care Use and Spending for Medicaid Enrollees in Fed. Qualified Health Ctrs. Versus Other Primary Care Settings*, Am. J. Public Health (Sep. 15, 2016) ("Medicaid patients who obtain primary care at FQHCs had lower use and spending than

did similar patients in other primary care settings"). The cost of providing additional health care visits will further strain covered entities' resources.

Lilly's refusal to offer its drugs at 340B discount pricing has also already resulted in covered entities reducing staff. *See, e.g.*, Simila Aff. ¶ 29, ECF No. 19-5 (health center forced to reduce staffing for OB/GYN services and planning other major service reductions—including service delivery site closures, employee terminations, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services); Mahaniah Aff. ¶ 20, ECF No. 19-5 (health center preparing to permanently eliminate 5% of employees); Chen Aff. ¶ 42, ECF No. 19-5 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic locations). FQHC and RWC covered entities will also have to divert remaining staff to seek out and apply for additional federal grants or other sources of funding to make up for lost 340B funding. *See, e.g.*, Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9. Expending already scarce financial and human resources will further burden tight budgets and will cause irreparable harm in the form of additional—and often inevitably unbearable—operational expense. Auclair Aff. ¶ 28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9.

Many covered entities, including numerous NACHC and RWC-340B members and Amici Little Rivers and FamilyCare, rely entirely on contract pharmacies to dispense covered outpatient drugs to their patients. *See, e.g*, Auclair Aff. ¶ 19; Glover Aff. ¶ 18. For some covered entities, 340B Program revenue has meant the difference between remaining in operation and closing their doors. For FamilyCare, revenue from its contract pharmacy arrangements is comparatively almost half of the funding it receives from federal grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5. The loss of all 340B savings to the Amici would be even more "devastating" to their operations and the patients they serve. Auclair Aff. ¶ 31; Glover Aff. ¶ 31;

Dickerson Aff. ¶ 11. Little Rivers currently operates at a loss and FamilyCare's revenue barely exceeds its operating expenses. Dickerson Aff. ¶ 7. In 2019, Little Rivers' average cost per patient was $1,270.64; FamilyCare's average cost per patient was $764.39. HRSA, *Health Center Program Data*.[23] Per patient costs will increase dramatically if these providers are burdened with the obligation of covering the full price of Lilly's drugs. Many covered entities, including Amici Little Rivers and FamilyCare, lack the financial resources necessary to bear the additional costs of drugs for indigent patients. Auclair Aff. ¶ 34.

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

Enjoining the ADR Rule will result in unrecoverable economic losses to the covered entities. This Court's final decision on the merits of Lilly's ADR claims will not provide relief to the Amici and other covered entities and, therefore, their losses are not recoverable through "'compensatory or other corrective relief . . . at a later date, in the ordinary course of litigation.'" *Wisconsin Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985) (quoting *Va. Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958)); *see also 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."); *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (explaining possibility of adequate compensatory or other corrective relief at a later date weighs heavily against a claim of irreparable harm).

Further, Amici's losses would not be recoverable in any other forum because, without the ADR process, 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

[23] https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited Feb. 21, 2021).

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)). Covered entities' economic losses due to 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. Such losses thus cannot be recovered through "the ordinary course of litigation" and, without ADR, covered entities have no adequate remedy for the harm from Lilly's and other manufacturers' actions. *Cf. Wisconsin Gas Co.*, 758 F.2d at 674.

B. 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 several Amici explained in their lawsuit against HHS, this delay raises very serious due process concerns. Amended Compl., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21, (stayed Jan. 13, 2021); *see also Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982); *Whole Women's Health All. v. Hill*, 937 F.3d 864, 875 (7th Cir. 2019) ("Enforcing a constitutional right is in the public interest").

The Patient Protection and Affordable Care Act ("ACA"), signed into law on March 23, 2010, mandated 340B ADR regulations within 180 days of enactment. 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. 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 Lilly's—and others'—refusal 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*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21 (stayed Jan. 13, 2021); *NACHC v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020) (stayed Jan. 7, 2021).

Shortly after the Amici filed their lawsuits, HRSA issued the ADR Rule. 85 Fed. Reg. 80,632 (Dec. 14, 2020). As a result, the Amici's lawsuits are stayed so they may pursue ADR claims against manufacturers for refusing to sell drugs at 340B discounts for delivery to contract pharmacies. Joint Mot. for Stay, *RWC-340B*, No. 1:20-cv-02906, ECF No. 58 (D.D.C. Jan. 13, 2021); Status Report, *RWC-340B*, No. 1:20-cv-02906, ECF No. 59 (D.D.C. Feb. 16, 2021); Joint Mot. to Stay, *NACHC*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020), ECF No. 12 (D.D.C. Dec. 17, 2020). Indeed, three Amici—NACHC, Little Rivers, and FamilyCare—have filed ADR petitions, which are currently pending. Enjoining the ADR Rule will further delay the ADR process by months or even years.

Lilly asserts the ADR process violates its constitutional rights. Mot. for PI at 35. Defendants have already explained why Lilly's assertions are groundless. Defs.' Opp'n to Pls.' Mot. for Prelim. Inj., ECF No. 32, 35–38. The Court should also weigh any constitutional claim by Lilly against the Amici's loss of due process if they are denied the ability 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 rights through the ADR process.

C. Covered Entities' Losses 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." Mot. for PI at 34. Lilly can well afford its litigation expenses. Any harms Lilly would suffer defending its self-help pale in comparison to the current and ongoing harms to covered entities. As noted in an HHS General Counsel's letter, Lilly's "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 to Anat Hakim (Sept. 21, 2020), ECF No. 19-5 at 60–61. Lilly's record profits are in sharp contrast to covered entities' financial plight. As HHS noted, during the same period, "most health care providers" including covered entities "were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act." *Id.*

The financial harms to covered entities due to Lilly's violations of its 340B Program obligations far outweigh any expense Lilly may incur in responding to ADR petitions. The 340B Program was not designed to allow Lilly—or any drug manufacturer—to place profits over the patients and providers that 340B discounts were designed to benefit. The longer Lilly can shirk its 340B Program obligations, the greater and more permanent the harm to the public interest.

CONCLUSION

Granting Lilly's motion would significantly harm covered entities, their patients, their staff, and their broader communities by enabling Lilly's unlawful upending of a decades-long status quo, and would leave covered entities with no remedy at law. The ADR Rule provides covered entities with the administrative proceeding they need to correct these harms. Amici therefore respectfully request that the Court deny Lilly's motion for preliminary injunction and permit the ADR Rule to remain in effect.

Dated: March 9, 2021

Respectfully submitted,

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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 NACHC, RWC-340B, LITTLE RIVERS HEALTH CARE, INC., AND FAMILYCARE HEALTH CENTER IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION[1]

Exhibit A	Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Health Care Inc ("Little Rivers").
Exhibit B	Declaration of Craig Glover, MBA, MA, FACHE, CMPE, CEO of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare").
Exhibit C	Declaration of Terri S. Dickerson, CFO, FamilyCare.

[1] All prior ECF stamps have been redacted so that the ECF stamps for this Court are legible. Exhibits A through C were submitted with the plaintiffs' motion for temporary restraining order and preliminary injunction in *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24.

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

AFFIDAVIT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23) Based on its calculations of the 340B savings that Little Rivers has historically achieved through filling prescriptions for drugs manufactured by Eli Lilly Company ("Lilly"),

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

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

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

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

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

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

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

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

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

30) Little Rivers will not be able to provide low-cost drugs through its drug discount program if Little Rivers cannot purchase drugs at 340B prices and instead will have to pay undiscounted prices for those drugs. As one example, behavioral health drugs are an expensive category of drugs. In my experience as a nurse, there are important societal reasons, such as controlling unemployment, family strife and crime, for ensuring that behavioral health patients have access to their medications.

31) The loss of $200,000 annually in 340B savings as the result of the actions of Lilly, AstraZeneca and Sanofi will have a severe financial impact on Little Rivers. Little Rivers strives to keep three months' operating expenses in reserves, which is consistent with sound business practices and guidance from the Bureau of Primary Care within the Health Resources and Services Administration, the federal agency that administers the FQHC program. Little Rivers often struggles to meet this goal and the loss of $200,000

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

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

33) I compared the 340B price and non-340B price of two drugs that some of our financially needy patients are prescribed. I found that the cost of a 30 day supply of Humulin®, an insulin product manufactured by Lilly for which no biosimilar is available, increased from $117.24 to $450.17. I found that the cost of Bevespi Aerosphere®, an inhaler produced by AstraZeneca to treat chronic obstructive pulmonary disorder (COPD), and for which no generic substitute is available, increased from $198.42 to $1910.13.

34) Because Little Rivers has operated at a loss for the last two fiscal years, it does not have the financial resources to bear the additional cost of these drugs for our financially needy patients. The increased costs to Little Rivers to pay for the drugs under its drug discount program will exacerbate its already precarious financial position.

[*Signature on next page*]

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

Respectfully submitted,

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

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

AFFIDAVIT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[7] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .

[8] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .

[9] Source: https://familycarewv.org/wp-content/uploads/2020/05/FamilyCare_AnnualReport2019.pdf , p.6.

[10] Source: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId .

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

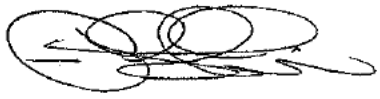
30) FamilyCare's Prescription Savings Program is offered for drugs that are purchased with 340B discounts. If FamilyCare cannot purchase drugs manufactured by Lilly, AstraZeneca, and Lilly with 340B discounts, those drugs will no longer be part of its program. FamilyCare does not have funds allocated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

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

[*Signature on next page*]

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

Respectfully submitted,



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

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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