Nos. 21-3128 & 21-3405

# IN THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY AND LILLY USA, LLC,

Plaintiffs-Appellants–Cross-Appellees,

*v.*

XAVIER BECERRA, et al.,
Defendants-Appellees–Cross-Appellants.

On Appeal from the United States District Court for the Southern District of Indiana, No. 1:21-cv-00081-SEB-MJD (Honorable Sarah Evans Barker)

## BRIEF OF *AMICI CURIAE* NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS AND RYAN WHITE CLINICS FOR 340B ACCESS IN SUPPORT OF DEFENDANTS-APPELLEES–CROSS-APPELLANTS

Matthew Sidney Freedus
FELDESMAN TUCKER LEIFER FIDELL LLP
1129 20th St. NW, 4th Floor
Washington, DC 20036
Tel: (202) 466-8960
*Counsel for Amicus Curiae National Association of Community Health Centers*

Ronald Shreve Connelly
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 466-6550
*Counsel for Amicus Curiae Ryan White Clinics for 340B Access*

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**APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT**

Appellate Court No: 21-3128 & 21-3405

Short Caption: Eli Lilly and Company, et al. v. Xavier Becerra, et al.

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RWC-340B

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(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

---

Attorney's Signature: /s/Ronald S. Connelly Date: July 1, 2022

Attorney's Printed Name: Ronald S. Connelly

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☑ No ☐

Address: 1501 M St., NW, 7th Floor

Washington, DC 20005

Phone Number: 202-872-6762 Fax Number: 202-785-1756

E-Mail Address: Ron.Connelly@PowersLaw.com

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Attorney's Signature: /s/Barbara Straub Williams Date: July 1, 2022

Attorney's Printed Name: Barbara Straub Williams

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☐ No ☑

Address: 1501 M St., NW, 7th Floor

Washington, DC 20005

Phone Number: 202-872-6733 Fax Number: 202-785-1756

E-Mail Address: Barbara.Williams@PowersLaw.com

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Attorney's Signature: /s/William H. von Oehsen Date: July 1, 2022

Attorney's Printed Name: William H. von Oehsen

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☐ No ☑

Address: 1501 M St., NW, 7th Floor
Washington, DC 20005

Phone Number: 202-872-6765 Fax Number: 202-785-1756

E-Mail Address: William.vonOehsen@PowersLaw.com

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Attorney's Signature: /s/Megan La Suer Date: July 1, 2022

Attorney's Printed Name: Megan La Suer

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☐ No ☑

Address: 1501 M St., NW, 7th Floor

Washington, DC 20005

Phone Number: 202-872-6726 Fax Number: 202-785-1756

E-Mail Address: Megan.LaSuer@PowersLaw.com

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Attorney's Signature: /s/Mark Ogunsusi Date: July 1, 2022

Attorney's Printed Name: Mark Ogunsusi

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☐ No ☑

Address: 1501 M St., NW, 7th Floor

Washington, DC 20005

Phone Number: 202-872-6759 Fax Number: 202-785-1756

E-Mail Address: Mark.Ogunsusi@PowersLaw.com

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N/A

---

Attorney's Signature: /s/Matthew Sidney Freedus Date: July 1, 2022

Attorney's Printed Name: Matthew Sidney Freedus

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☑ No ☐

Address: 1129 20th St. NW, 4th Floor

Washington, DC 20036

Phone Number: (202) 466-8960 Fax Number: (202) 293-8103

E-Mail Address: mfreedus@ftlf.com

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Attorney's Signature: /s/Rosie Dawn Griffin Date: July 1, 2022

Attorney's Printed Name: Rosie Dawn Griffin

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). Yes ☐ No ☑

Address: 1129 20th St. NW, 4th Floor
Washington, DC 20036

Phone Number: (202) 466-8960 Fax Number: (202) 293-8103

E-Mail Address: rgriffin@ftlf.com

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## GLOSSARY

| | |
|---|---|
| 340B Program | Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b |
| Agreement | Pharmaceutical Pricing Agreement |
| FamilyCare | Womencare, Inc. d/b/a/ FamilyCare Health Center |
| FDA | Food and Drug Administration |
| FTC | Federal Trade Commission |
| Health Centers | Federally-qualified health centers |
| HHS | Department of Health and Human Services |
| Hudson | Hudson Headwaters Health Network |
| HRSA | Health Resources and Services Administration |
| Little Rivers | Little Rivers Inc. |
| RWC-340B | Ryan White Clinics for 340B Access, Amicus |

## INTERESTS OF AMICI

The National Association of Community Health Centers and Ryan White Clinics for 340B Access ("RWC-340B") (collectively the "Amici"), are nationwide non-profit membership associations of safety-net health care providers—Federally-qualified health centers ("Health Centers") and Ryan White Clinics—that participate in the 340B Program as covered entities.[1] Both Health Centers and Ryan White Clinics rely heavily on 340B drug discounts and contract pharmacy arrangements to serve their vulnerable patients.[2] The Court's decision in this appeal will significantly impact the 340B Program's intended beneficiaries, including Amici's safety-net provider members.

Amici submit this brief to provide the Court with the perspective of those beneficiaries, detail how contract pharmacy arrangements enable safety-net

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[1] All parties consent to the filing of this brief. Fed. R. App. P. 29(a)(2). Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), undersigned counsel for Amici certify that no party's counsel authored this brief in whole or in part. No party or party's counsel contributed money intended to fund this brief. Amicus NACHC and RWC-340B contributed funding to this brief. Amicus RWC-340B also received funding from RxStrategies, Inc. and Wellpartner, LLC to prepare and submit this brief.

[2] Health Centers receive, or are eligible to receive, federal grants under Section 330 of the Public Health Service Act to serve members of four patient populations regardless of any patient's ability to pay: residents of federally-designated medically underserved areas; homeless individuals; migrant and seasonal farmworkers; and residents of public housing. 42 U.S.C. § 254b(a)(1). Ryan White Clinics receive federal grants to provide health care and related services to people living with HIV. *See* 42 U.S.C. § 300ff *et seq.*

providers to receive necessary discounts on outpatient drugs, and describe how the U.S. drug distribution system actually operates, which is critical to understanding the legal issues in this case. The 340B Program entitles safety-net healthcare providers to significant discounts on outpatient drugs at no cost to the federal government. Many covered entities do not have the resources to operate their own in-house pharmacies and can only participate in the program by purchasing drugs for shipment to contract pharmacies, where they are dispensed to the covered entities' patients. The contract pharmacy distribution model is the only viable way that many covered entities—including Amici's members—can participate in and obtain the benefits of the 340B Program. The future of the 340B Program will affect the Amici's members' continued ability to provide critical services and discounted drugs to vulnerable patients.

## INTRODUCTION

The 340B Program is indispensable to help offset the costs to safety-net providers of furnishing uncompensated and under-compensated care. Covered entities have long relied on 340B savings, and without them, many would be forced to restrict or curtail services or even cease operations. Without the drug discounts covered entities receive under the 340B Program, taxpayers would absorb the costs of the uncompensated care these providers are required to furnish. From 1996 until late 2020, Appellants–Cross-Appellees Eli Lilly and Company

and Lilly USA, LLC, (collectively "Lilly") sold their drugs to covered entities at 340B discounted prices when shipped to contract pharmacies. This suit arose as part of Lilly's campaign to undermine the 340B Program by cutting off discounts on drugs shipped to covered entities' contract pharmacies, imperiling safety-net providers and their patients.

Lilly radically reinterprets the 340B statute and its obligation under its Pharmaceutical Pricing Agreement ("Agreement") with the Department of Health and Human Services ("HHS"). Lilly contends that the 340B statute and the Agreement do not require it to offer 340B discounted drugs if those drugs are distributed through a contract pharmacy. Lilly is wrong. The 340B statute governs pricing, not distribution. It unambiguously requires drug manufacturers to provide covered entities with discounts on all covered outpatient drugs. The statute's silence on drug distribution generally, and contract pharmacies in particular, does not create ambiguity. The statute does not limit distribution at all, and drugs in this country are distributed by many means, including contract pharmacies. The statute does not allow drug manufacturers to limit or restrict their *own obligations* to provide discounts. Instead, the statute intentionally leaves distribution decisions to covered entities as governed by preexisting state and federal regulations. Indeed, Congress confirmed this statutory design and intent when it considered and rejected bills that would have placed limits on the distribution of 340B drugs.

If the Court adopts Lilly's reading, drug companies may unilaterally broaden their policies to apply to all covered entities, effectively shutting Amici's members out of the 340B Program. Moreover, if Lilly prevails, drug companies will be free to further condition their own statutory and contractual 340B pricing duties, including by attacking access at other components of the complex U.S. drug distribution system. The nation's healthcare safety-net will continue to be significantly harmed if the Court supports Lilly's unilateral restriction of sales of its 340B drugs to covered entities simply because the drugs reach their patients through contract pharmacies. Amici urge the Court to protect the nation's health care safety-net as Congress intended when it enacted the 340B Program by requiring drug companies to discount covered outpatient drugs regardless of where medications are dispensed to covered entity patients.

## BACKGROUND ON U.S. DRUG DISTRIBUTION

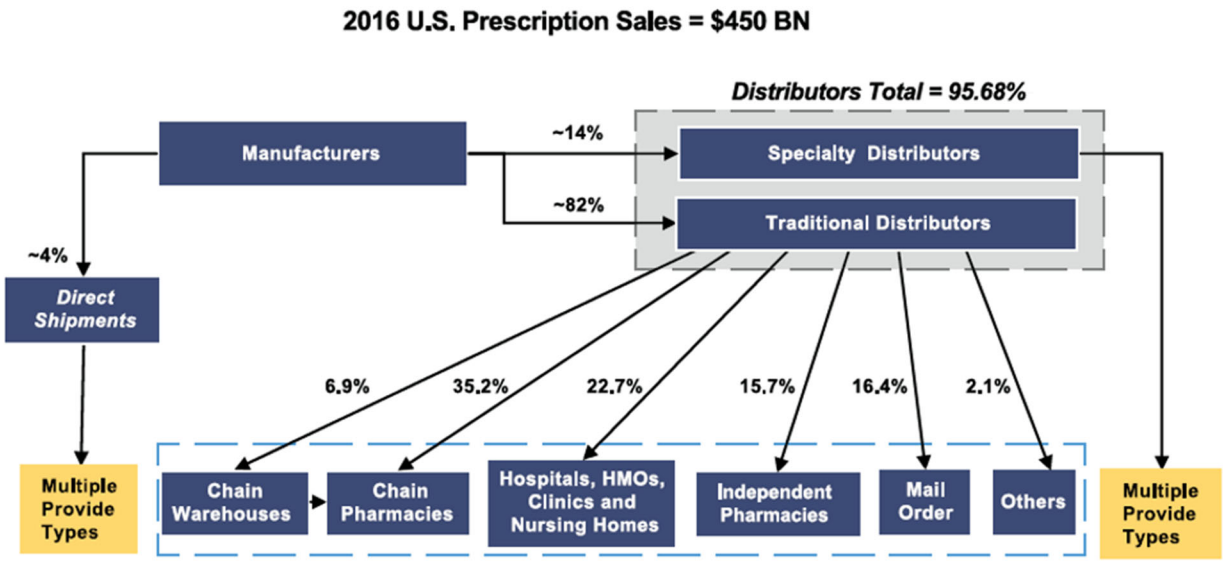
The U.S. drug distribution system is complex. Drugs are distributed via numerous mechanisms, only one of which is contract pharmacies. A short summary of the more common elements of drug distribution is provided to aid the Court's understanding of the broader context of this dispute.

***Wholesalers*** distribute the large majority of drugs in the U.S. *See* Terry Hisey *et al.*, Healthcare Distrib. All. & Deloitte Consulting LLP, The Role of Distributors in the US Health Care Industry (2019) [hereinafter "Deloitte

Report"].[3] Wholesalers are not only custodians of a manufacturers' drugs. They also purchase and take title to the drugs before reselling them to pharmacies and providers. *Id*. at 11. As a result, the drugs shipped by a manufacturer in response to a particular pharmacy's order are not the same drugs the wholesaler delivers on the manufacturer's behalf. They do not have to be the same because prescription drugs are manufactured in such a precise and reproduceable manner that they are treated as fungible in the commercial market. They share the same labeling, chemical composition, and administration route but are otherwise different products. The fungibility of prescription drugs in the U.S. enables wholesalers, rather than manufacturers, to be the primary suppliers of drugs, including 340B drugs. The chart below depicts the essential role that wholesalers/distributors serve in the U.S. pharmaceutical market:

[3] https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-hda-role-of-distributors-in-the-us-health-care-industry.pdf. The terms "wholesaler" and "distributor" are often used interchangeably. *See, e.g.*, 21 U.S.C. § 360eee(29) (defining "wholesaler distributor").

**Flow of U.S. Prescription Sales ($B) and Contribution by Dispenser Type (%)**




Healthcare Distrib. All. Rsch. Found., The Role of Reverse Distribution 6 (2018), https://pharmalinkinc.com/wp-content/uploads/2018/11/2018-Role-of-Reverse-Distribution.pdf.

Wholesalers typically buy their drugs from manufacturers at wholesale acquisition cost. Deloitte Report at 10. If they resell the drug at a lower cost, which is often the case, they are made whole by the manufacturer by submitting a "chargeback" invoice for the difference between wholesale acquisition cost and the price paid by the pharmacy or provider. *Id.*

***Consignment*** arrangements permit hospitals, pharmacies, and other providers to obtain physical possession of on-site inventories of high-cost drugs,

while legal title remains with the wholesaler or manufacturer.[4] After the drug is furnished to a patient, the consignment vendor bills the pharmacy or provider for the drug's cost.

***Contract Pharmacies***, as the name suggests, are pharmacies that contract with health care providers. Typically, drugs dispensed by contract pharmacies are purchased under a "bill to/ship to" arrangement in which the drugs are billed to the health care provider but shipped to the contract pharmacy. *See FAQs, What Is a "Ship to Bill to" Arrangement?* HRSA (July 2020).[5] The provider-purchaser takes title to the drugs but not physical possession of them and directs their shipment, usually by a wholesaler, to the contract pharmacy, which then takes physical custody of the drugs and dispenses them on the provider's behalf. Contract pharmacy arrangements are common and not unique to the 340B Program. *See, e.g.*, Fed. Trade Comm'n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010);[6] 134 Cong. Rec. H6971-02 (1988) (statement of Rep. Charlie Rose: "health centers often include onsite pharmacies or agreements

[4] *Consignment Program*, CardinalHealth, https://www.cardinalhealth.com/en/solutions/specialty-distribution/consignment.html (last visited July 1, 2022).
[5] https://www.hrsa.gov/opa/faqs/index.html/ (last visited July 1, 2022).
[6] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf (last visited July 1, 2022).

with community pharmacists to ensure that the medicines needed to treat or control these chronic conditions are available").

***Repackagers*** take a drug from its original manufacturer packaging and place it into smaller, often simpler, packaging, or combine various finished products for ease of dispensing at health care facilities. *See* 21 C.F.R. § 207.1. Repackaging is typically regulated under both federal and state law. Repackagers may provide such services on a contractual basis, despite never taking legal title to the drugs. Similar to contract pharmacies, repackagers often rely on bill to/ship to arrangements for shipment and receipt of the drugs prior to repackaging.

***Relabelers*** change the existing label on a drug package without repacking the drug. *Who Must Register, List and Pay the Fee*, FDA (Sept. 27, 2018).[7] Relabelers often help reduce manufacturer burden by printing new labels, changing artwork, or adding warning stickers to drug packages.

***Warehousing/third party logistics providers*** are hired by manufacturers, wholesalers, and pharmacies to coordinate drug storage and provide other logistical drug distribution services. These third parties neither take ownership of the product, nor have responsibility to direct the product's sale or disposition. 21

[7] https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee#relabeler.

U.S.C. § 360eee(22). They are generally required to be licensed under state and federal law. *Id.* § 360eee-3.

***Reverse Distributors*** move unsold, saleable pharmaceutical inventory within the supply chain or remove unsaleable inventory from it. The Role of Reverse Distribution at 1. Depending on the product, reverse distribution may occur through manufacturers, wholesalers, or reverse logistics providers. *Id.* at 3. An estimated 120 million units with a product value in excess of $14 billion flow through the combined saleable and unsaleable pharmaceutical reverse distribution channel annually. *Id*. at 1, 15.

## SUMMARY OF THE ARGUMENT

The 340B statute is a pricing statute that unambiguously requires drug manufacturers to provide discounts regardless of distribution mechanism. Congress considered and rejected proposals to regulate distribution of 340B drugs. Congress instead left distribution decisions to covered entities as governed by preexisting state and federal laws. Manufacturer policies restricting shipments of 340B drugs to contract pharmacies have already harmed covered entities and the vulnerable patients that they serve. This harm will only grow if this Court holds in favor of Lilly.

## ARGUMENT

### I. The 340B Statute Unambiguously Obligates Manufacturers to Provide Discounted Drugs Regardless of Delivery Location

Lilly's refusal to provide 340B pricing to eligible covered entities, simply because the drugs they purchase are shipped to and dispensed by contract pharmacies, is a clear violation of the 340B statute and Lilly's Agreement with HHS. The statute broadly requires manufacturers to provide discounts on all covered outpatient drugs regardless of how covered entities dispense the drugs to their patients. Congress has traditionally left regulation of the complex U.S. drug distribution system to the states. The absence of any mention in the 340B statute of any of the multiple channels and entities typically involved in drug distribution—including not only contract pharmacies but also wholesalers, repackagers, brokers, and third-party logistics providers, among others—demonstrates Congress's intent that covered entities obtain discounted drugs through existing mechanisms, including contract pharmacies. The 340B statute, by design, leaves those practical decisions to the covered entity within the preexisting and complex laws of the state(s) in which they operate.

This Court should reject Lilly's self-serving effort to restrict or condition its own statutory pricing obligations, including by limiting how 340B drugs are distributed. Such an interpretation would effectively gut the law by allowing manufacturers to avoid offering discounts at all.

### A. The Statute's Plain Text Requires Manufacturers to Sell Discounted Drugs and Places No Restrictions on Distribution

The 340B statute's plain text unambiguously requires drug companies, such as Lilly, to sell covered outpatient drugs to covered entities at statutorily determined prices regardless of the site of delivery or dispensation. 42 U.S.C. § 256b. The statute requires drug manufacturers to enter into an Agreement under which the manufacturer agrees to sell covered outpatient drugs to covered entities at or below the 340B ceiling price as a condition of coverage of those drugs under Medicaid and Medicare Part B. 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1). The Agreement must "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.* The statute does not permit Lilly to limit its obligation to offer 340B pricing by placing conditions on the drug's delivery location.

Indeed, HHS, through its Health Resources and Services Administration ("HRSA"), has correctly interpreted the 340B statute to require drug companies to sell discounted drugs for shipment to covered entities' contract pharmacies. *See, e.g.*, Contract Pharmacy Notice, 61 Fed. Reg. 43,549–50 (Aug. 23, 1996) ("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."). In 1996, HRSA stated, "[i]f 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.* In 2010, the Secretary reconfirmed the agency's longstanding interpretation that covered entities are entitled to 340B discounts on drugs shipped to a contract pharmacy, acknowledging that covered entities may enter into multiple contract pharmacy arrangements. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,275 (Mar. 5, 2010).

HHS's May 17, 2022, letters to Lilly and other drug companies restate what all 340B participants have long understood: "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." Appendix for Plaintiffs-Appellants at A-2.

### B. The 340B Statute Leaves Drug Distribution Regulation to the States and Dispensing Decisions to Covered Entities

The statute's silence on contract pharmacies is not a grant of authority to drug manufacturers to limit their own 340B obligations. Congress has traditionally left most regulation of drug distribution to the states. Permissible drug distribution takes many forms, including distribution by wholesalers, consignment arrangements, repackagers, and relabelers. Lilly's arguments, if accepted, would

empower manufacturers to restrict or deny 340B sales when drugs are distributed via any of these common mechanisms. Congress clearly did not intend this result in a statute designed to provide broad assistance to safety-net providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

When the 340B statute was enacted, there was a preexisting and complex framework of state and federal laws regulating drug distribution. *See, e.g.*, Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, §6, 102 Stat. 95, 98-99 (1988) (regulating wholesale distributors of prescription drugs under both state and federal law); Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 303, 84 Stat. 1236, 1253-54 (1970) (regulating distribution of controlled substances under both state and federal laws). By *not* inserting additional requirements for 340B drug distribution into this legal framework, such as dictating permissible shipment and dispensing locations, Congress left covered entities to avail themselves of any existing, established mechanism for delivering 340B drugs to their patients.

### *1. The 340B Statute Regulates Drug Pricing and Does Not Limit Distribution*

The 340B statute governs the sale and purchase of 340B drugs and dictates to whom 340B drugs may be dispensed or administered. 42 U.S.C. § 256b. It thus

regulates the beginning and end of a drug's journey from manufacturer to patient, but not the journey itself. The path that a drug travels from a drug company's manufacturing plant to the patient is both long and circuitous in the U.S. drug market. When Congress drafted and enacted the 340B statute, it intentionally chose not to specify or place limits on the mechanisms available to covered entities for delivering 340B drugs to patients. A ruling in Lilly's favor could permit manufacturers to dictate unilaterally how 340B drugs are distributed, or even to limit distribution to direct sales, eviscerating section 340B by depriving its intended beneficiaries of the discounted pricing it is designed to provide.

Congress considered placing geographical limitations on 340B drug distribution as part of the 340B statute, but purposefully declined to do so. Eight months before enacting the 340B statute, the Senate considered a precursor bill with several limits on drug distribution, including defining a covered entity as an entity capable of dispensing 340B drugs through "on-site pharmacy services." S. Rep. No. 102-259, at 2 (1992) (considering S. 1729, 102d Cong. (1992)). Under the Senate's proposed legislation, the distribution of 340B drugs was limited to on-site pharmacies using one of two options: "distribution with respect to drug purchases must be made through wholesalers," and direct distribution from manufacturers was the "secondary means of drug distribution." *Id.* at 3, 9.

Contract pharmacy distribution was explicitly discussed during the statute's enactment. *Bills to Amend the Public Health Service Act and the Social Security Act to Establish Limits on Certain Drug Prices, Hearing on H.R. 2890, H.R. 3405 and H.R. 5614 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 102d Cong. 77-82 (1992) (statement of Jose Camacho on behalf of Nat'l Ass'n of Cmty. Health Ctrs.) (testifying that federally mandated 340B drug distribution requirements "would [not] be the most efficient distribution arrangement [for health centers] due to the … disruption of … distribution avenues" and that of 141 health centers surveyed, only 75 operated their own pharmacies); *id.* at 285 (statement of John Rector, Vice President of Gov't Affs. & Gen. Counsel, Nat'l Ass'n of Retail Druggists) (testifying that drug distribution to contract pharmacies was a common practice for nonprofit hospitals well before the 340B statute's enactment and that "special contracts … [were] written for nonprofit sales, but the regular private drug distribution system [was] used to store and deliver the product"). Congress therefore understood that each type of covered entity had differing distribution needs, including contract pharmacies.

Congress chose not to adopt any distribution limits in the final 340B statute and instead left the regulation of 340B drug distribution to existing federal and state laws. Notably, the statute did not contain a single reference to the terms

"wholesaler," "distribute," or "pharmacy."[8] 42 U.S.C. § 256b (1992). The term "wholesaler" was first included in the 340B statute in 2010 as a "program integrity" provision to ensure "*manufacturer compliance*." *Id.* § 256b(d)(1)(B)(v) (2010) (emphasis added) (authorizing HHS to audit "manufacturers and wholesalers").

The House report accompanying the 340B statute underscores that Congress's silence on distribution was intended to accommodate covered entities' distribution needs rather than limit their purchases. The report stated, "The Committee bill does not limit the amount of drugs that a 'covered entity' may procure[,] … does not authorize the Secretary *to limit in any way* the volume of purchases that can be made at the [340B] price," and "does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, *or through some other mechanism."* H.R. Rep No. 102-384, pt. 2, at 15 (1992) (emphasis added). That report further stated, "A mechanism that is appropriate to one type of 'covered entity,' such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs," and "[t]he Committee expects that the Secretary

[8] The original 340B statute only used the term "distribution" to refer to the 340B "prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs." 42 U.S.C. 256b(a)(8). Rather than placing a limit on distribution, Congress created an additional distribution mechanism under the prime vendor program.

of HHS … will use the mechanism that is the most effective and most efficient *from the standpoint of each type of 'covered entity*.'" *Id.* (emphasis added). The report demonstrates Congress's clear intent to provide covered entities broad flexibility to procure 340B drugs, including through contract pharmacies used by many health care providers.

The notion that the 340B statute can be read to preclude bill to/ship to arrangements while saying nothing about wholesaler arrangements—through which most prescription drugs in the U.S. are distributed—is especially irrational. Prescription drugs may not legally be shipped directly from a manufacturer to a patient because they must be dispensed by a licensed pharmacy or health care provider pursuant to a valid prescription. Manufacturers must instead ship their drugs to a licensed pharmacy or health care provider. But manufacturers rarely ship prescription drugs directly to pharmacies and providers. Over 90 percent of prescription drugs in the U.S. are distributed by wholesalers on manufacturers' behalf. *See, e.g.*, Deloitte Report at 4. This is true regardless of whether the drug is purchased from the wholesaler under a 340B or non-340B account. The prevalence of contract pharmacies is nowhere near the 90-95 percent utilization rate of wholesaler arrangements.

Given the diversity and continued evolution of drug distribution arrangements in this country, it was both understandable and prudent that Congress

did not explicitly address or enumerate them in the 340B statute. Congress relied on existing laws that already regulated distribution. Congress's silence on 340B drug distribution in no way creates a sweeping exception to the statute. *See Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1753 (2020) ("Nor is there any such thing as a 'canon of donut holes.'").

### *2. Congress Has a Long History of Relegating Oversight of Drug Distribution to the States*

Congress has long recognized the role of states in regulating the distribution of prescription drugs. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009) (Federal Drug Administration ("FDA") has long regarded state law "as a complementary form of drug regulation" that "offers an additional, and important, layer of consumer protection"); *see also, e.g.*, The Prescription Drug Marketing Act of 1987, 21 U.S.C. § 503 *et seq.* (requiring wholesalers to obtain licenses from *each state* in which the wholesaler operates); Drug Supply Chain Security Act of 2013, 21 U.S.C. § 353(e) (requiring wholesalers to be licensed by the State from which, and to which, the drug is distributed); *id.* § 360eee-2 (requiring the FDA to establish national standards for the state licensure of wholesalers to curb counterfeit drugs). The FDA approves new drugs as safe and effective but has very limited authority to dictate how a pharmacy or provider may receive the drug. *See Am. Pharm. Ass'n v. Weinberger,* 377 F. Supp. 824 (D.D.C. 1974), *aff'd*, 530 F. 2d 1054 (D.C. Cir. 1976) (FDA lacks statutory authority to control post-

approval distribution of methadone to certain pharmacies and providers); *see also*, 21 U.S.C. § 355-1 (authorizing FDA to require post-approval risk evaluation and mitigation strategies solely for certain high-risk drugs).

States have traditionally shared authority with the federal government over the licensing and conduct of drug manufacturers and wholesale drug distributors. For example, in Indiana, wholesalers must meet specific application requirements and qualifications to satisfy necessary registration requirements. Ind. Code Ann. §§ 25-26-14-14(a), 25-26-14-16. In Illinois and Wisconsin, all resident and non-resident wholesale distributors must be licensed by the state to distribute prescription drugs. 225 Ill. Comp. Stat. Ann. 120/25(a); Wis. Stat. Ann. § 450.071. To allow the distribution of controlled substances, Illinois, Indiana, and Wisconsin all require that distributors be registered in their states and meet certain recordkeeping requirements. 720 Ill. Comp. Stat. Ann. 570/302(a), 570/306; Ind. Code Ann. §§ 35-48-3-3, 35-48-3-7; Wis. Stat. Ann. § 961.335. Indeed, the Pharmaceutical Research and Manufacturers of America, a trade association that includes Lilly, explicitly recognized states' police powers over drug distribution in the context of a covered entity's use of 340B contract pharmacies.[9] *See* Plaintiff's Complaint ¶ 37, *Pharm. Research & Mfrs. of Am. v. Shalala*, No. 1:96-cv-1630

[9] PhRMA's website lists Lilly as a member. *About*, PhRMA, https://phrma.org/About (last visited July 1, 2022).

(D.D.C. July 12, 1996) (citing Florida and Georgia controlled substance distribution laws and arguing that "[n]othing in Section 340B preempts state [controlled substance] laws").

When Congress enacted the 340B statute, it was aware of the existing legal framework for distributing drugs. Congress's silence on distribution was therefore the exact opposite of an invitation for manufacturers to impose their own limitations on the program. If Lilly's arguments prevail, drug companies would be free to condition 340B pricing on every iteration of each component of the distribution system, which would render the 340B statute ineffective and, in so doing, compromise the nation's public health against Congress's unambiguous intent.

## II. Lilly Misrepresents the Nature of Contract Pharmacies, Which Covered Entities Have Used for More Than Two Decades to Dispense Drugs to Their Patients

Lilly mischaracterizes the contract pharmacy model as an unconstitutional windfall for large, corporate chain pharmacies.[10] But contract pharmacies do not purchase 340B drugs. The covered entity, in a bill to/ship to arrangement, buys drugs at 340B discounts and directs the drugs to be shipped to a contract pharmacy, which stores and dispenses the drugs to the covered entity's patients, and,

[10] Opening Brief and Required Short Appendix for Plaintiffs-Appellants at 12-15, Eli Lilly & Co. v. Becerra et al., No. 21-3128 (7th Cir. May 25, 2022) [hereinafter Lilly Br.].

importantly, remits any third-party payments and/or patient copayments to the covered entity, minus the pharmacy's fee. Contract pharmacies provide needed pharmaceuticals and convenience to often underserved communities.

Most illnesses and injuries are treated or managed through one or more medications. Providers of health care—such as the Amici's members—must ensure that their patients have access to a pharmacy to fill their prescriptions. Some providers own and operate their own in-house pharmacies. However, because the construction and management of a pharmacy is expensive and requires special expertise, many providers contract with independently owned pharmacies to meet the needs of their patients. *See, e.g.*, McKesson Ed. Staff, *Starting a Pharmacy*, McKesson (Oct. 8, 2018) (cost of establishing a pharmacy is between $350,000 to $450,000).[11] In most cases, these contract pharmacies are in the provider's service area where they are convenient and accessible to the provider's patients. Wholesalers do not establish 340B accounts for contract pharmacies because contract pharmacies are not eligible for these discounts.

It became abundantly clear after passage of the 340B statute in 1992 that, if covered entities could not acquire drugs through bill to/ship to arrangements, many of them—those lacking in-house pharmacies—would never have been able to participate in the 340B Program, even though they clearly met the eligibility

[11] https://www.mckesson.com/Blog/Pharmacy-Ownership/.

criteria established by Congress. In 1996, HRSA thus issued guidance explicitly recognizing covered entities' existing right to use bill to/ship to arrangements for meeting their patients' pharmacy needs. Contract Pharmacy Notice, 61 Fed. Reg. at 43,549–50. For nearly three decades, every drug company participating in the 340B Program, including Lilly, honored bill to/ship to arrangements and treated covered entities' contract pharmacies no differently than covered entities' in-house pharmacies.

Contract pharmacy arrangements are not unique to the 340B Program. They are used whenever a purchaser wishes to use an independent pharmacy to dispense prescription drugs on the purchaser's behalf. The availability and use of bill to/ship to arrangements outside the 340B Program has been explicitly recognized by the Federal Trade Commission ("FTC"). In 2010, the FTC issued an advisory opinion affirming the right of certain non-profit organizations to contract with retail pharmacies for dispensing drugs subject to discounts within the parameters of the Robinson-Patman Antidiscrimination Act and the Non-Profit Institutions Act. Fed. Trade Comm'n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010). The FTC examined and approved the same bill to/ship to model used in the 340B Program with only one difference—the drugs dispensed by the contract pharmacies were subject to discounts obtained under the Non-Profit Institutions Act, not the 340B statute. *Id.*

Lilly also takes issue with the "replenishment model," in which a contract pharmacy dispenses a non-340B drug to a covered entity's patient from the pharmacy's inventory, and the covered entity then places a replenishment order for the same drug at 340B discounted prices. Lilly Br. 12-13, 34-35. Contrary to Lilly's assertions, the replenishment model is merely an accounting tool, which reconciles all 340B and non-340B sales after the fact, thereby ensuring that 340B discounted drugs are dispensed only to the covered entity's patients. Far from causing diversion to ineligible patients in violation of the 340B statute, the replenishment model's reconciliation process serves as an accurate and effective means to protect *against* 340B drugs being dispensed to individuals who are not patients of the covered entity.

As an alternative to the replenishment model, pharmacies may maintain a supply of drugs that the covered entity has pre-purchased at 340B discounts. *See* U.S. Dep't of HHS, Off. of Inspector Gen., OEI-05-13-00431, Contract Pharmacy Arrangements in the 340B Program 5 (2014). The pre-purchased inventory model, however, is a poor fit for most 340B contract pharmacy arrangements for at least two reasons. First, a pre-purchased inventory is an expense to the covered entity in advance of a potential prescription. Such inventory will go to waste if it expires before any covered entity patients need the drug. Second, the pharmacy often does not know whether the individual who presented the prescription is a patient of a

covered entity at the time the prescription is dispensed. Without that real-time information, the pharmacy cannot effectively use a pre-purchased 340B inventory. In contrast, under the replenishment model, the pharmacy fills all prescriptions from its inventory, and that inventory is replenished with 340B drugs purchased by the covered entity only if the contract pharmacy filled prescriptions for the covered entity's own patients, as determined outside the bustle of the pharmacy environment.

Furthermore, the replenishment model helps *prevent* prohibited duplicate discounts. The 340B statute protects manufacturers from providing a 340B discount and a Medicaid rebate on the same drug. 42 U.S.C. § 256b(a)(5)(A). To comply with this requirement, some covered entities "carve out" Medicaid patients, which means that these covered entities do not dispense 340B discounted drugs to any Medicaid patients. *See Duplicate Discount Prohibition*, HRSA (July 2020).[12] However, patients are often retroactively enrolled in Medicaid, and an individual's Medicaid status may not be known at the time the prescription is filled. Because replenishment occurs after the point of sale, the covered entity tends to have more current, updated information on its patients' Medicaid status when determining 340B eligibility. The replenishment model thus helps ensure that manufacturers are protected from paying duplicate discounts.

[12] https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html.

The Supreme Court has endorsed an inventory replenishment system as compliant with a statutory scheme analogous to 340B. The Court analyzed whether hospital purchases through group purchasing organizations are consistent with federal antitrust laws, which, like 340B, permit certain health care providers to purchase discounted drugs for some patients. *Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1, 3-4 (1976). The Supreme Court *recommended* a replenishment system where providers manage their inventories according to general accounting principles by adjusting inventories at a later date. *Id*. at 20-21. There is nothing nefarious or unusual about replenishment inventory systems, which serve the needs of both covered entities and manufacturers.

## III. Eliminating 340B Contract Pharmacy Shipments Would Inflict Significant Harms on All Covered Entities and Their Patients and Compromise Vital Safety-Net Services Throughout the Nation

Covered entities provide vast uncompensated or undercompensated safety-net services through 340B savings, much of which is attainable only through contract pharmacy arrangements. Covered entities, on the front lines of caring for our nation's most vulnerable patients, use 340B discounts to support their missions of increasing access to care, improving health outcomes, and fortifying the nation's safety net. Lilly's unilateral denial of 340B pricing is antithetical to Congress's design of the 340B Program, which is intended to expand care to patient populations served by safety-net providers. Without 340B savings, covered

entities cannot possibly "reach[] more eligible patients and provid[e] more comprehensive services" to those patients. H.R. Rep. No. 102–384, pt. 2, at 12 (1992). Drug manufacturers' deprivation of 340B Program benefits have already harmed covered entities, patients, and broader communities because covered entities have had to reduce critical 340B-funded services. Eliminating 340B contract pharmacy arrangements will harm our nation's most vulnerable communities by denying them affordable medications, critical health care, and related services that covered entities provide through the 340B Program.

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

The 340B Program enables covered entities to provide discounted drugs to financially needy patients. Because 340B discounted prices are significantly lower than non-340B prices, patients who previously relied on obtaining medications at the 340B cost must now pay much more. Glover Aff. ¶ 30.[13] Covered entities, or their patients, are now bearing the increased cost of drugs manufactured by Lilly

[13] The following declarations were submitted in the district court proceedings, *Eli Lilly & Co. et al. v. Becerra et al.*, No. 1:21-cv-00081: Declaration of Craig Glover, FamilyCare Health Center ("FamilyCare"), ECF No. 75-3 (Ex. A, "Glover Aff."); Declaration of D. Tucker Slingerland, CEO of Hudson Headwaters Health Network ("Hudson"), ECF No. 120-4 (Ex. B, "Slingerland Aff."); Declaration of Terri S. Dickerson, FamilyCare, ECF No. 75-4 (Ex. D, "Dickerson Aff."); Declaration of Heather Rickertsen, Crescent Community Health Center, ECF No. 19-5 (Ex. F, "Rickertsen Aff."). *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24-8 contains the Declaration of Peter Johnson, Springhill Medical Center (Ex. C, "Johnson Aff.").

for prescriptions filled at contract pharmacies. Auclair Aff. ¶¶ 22, 25, 29, 31, 33.[14] Lilly's policies cutting off 340B pricing at contract pharmacies will cause many patients to lose affordable access to life-sustaining diabetes, hypertension, asthma/chronic obstructive pulmonary disease, and heart disease medications. Rickertsen Aff. ¶ 30. For example, FamilyCare, a West Virginia-based Health Center, has a drug discount program allowing indigent patients to pay only FamilyCare's cost for the drug. Glover Aff. ¶ 17.

Through contract pharmacies, uninsured and under-insured covered entity patients get their prescriptions at convenient locations, often at a greatly reduced cost or no cost at all. Health Centers and Ryan White Clinics care for increasing numbers of patients with chronic conditions managed primarily through prescription drugs. Auclair Aff. ¶ 11; Glover Aff. ¶ 15. With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients lost access to life-saving medications.

Covered entities serving remote or rural communities in particular have lost access to discounted drugs over large geographic areas, making it nearly impossible for their patients to access affordable medications. Hudson, a Health Center based in upstate New York, provides care to over 90,000 patients across a

[14] The Declaration of Gail Auclair, Little Rivers Inc. ("Little Rivers"), is Exhibit E ("Auclair Aff."). Ms. Auclair also submitted a declaration in the district court proceedings below at ECF No. 75-2.

7,000 square-mile area that HHS designates as a Health Professional Shortage Area. Slingerland Aff. ¶ 10. Hudson's service area has only one major road that traverses from north to south, other roads are often impassable in the winter, and the service area is generally not served by public transport. Slingerland Aff. ¶ 10. Hudson uses contract pharmacies to minimize the many "geographic and logistical barriers" that its patients face to access affordable medications. Slingerland Aff. ¶ 10.

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

Amici's members use 340B Program savings to subsidize the cost of important, life-saving health care services. For insured patients, covered entities benefit from the difference between the 340B price and the insurer's payment for the drug. 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, pt. 2, at 12 (1992). Many of the programs and services that covered entities support with 340B savings are critical to treating the whole patient, but are not reimbursed by public or private insurance, and are often most needed by patients who lack insurance. Auclair Aff. ¶¶ 20-21; Glover Aff. ¶ 15; Johnson Aff. ¶ 10; Slingerland Aff. ¶ 7; Suppl. App. 119 (Simila Aff. ¶ 18). Congress designed the 340B Program to provide funding for just these sorts of programs and services.

Many 340B safety-net providers do not have the financial resources to bear the additional costs of drugs for financially needy patients. Auclair Aff. ¶¶ 25-26; Glover Aff. ¶ 27; Dickerson Aff. ¶ 9. Little Rivers, located in Wells River, Vermont, has consistently operated at a loss, with operating expenses barely exceeding its revenue in 2020, thanks only to federal COVID-19 relief funds. Auclair Aff. ¶¶ 23-24. Little Rivers calculates that it has lost, and will continue to lose, approximately $315,000 in 340B savings and revenue as a result of drug company policies that restrict or eliminate 340B pricing on drugs shipped to Little Rivers' contract pharmacies. Auclair Aff. ¶ 22. If Little Rivers continues to lose these savings, it will inevitably have to cut or eliminate services. Auclair Aff. ¶¶ 25, 29, 31.

Hudson estimates that it will lose $8,400,000 in revenue due to manufacturers cutting off access to 340B drugs at contract pharmacies. Slingerland Aff. ¶¶ 20-23. Community HealthCare System in St. Marys, Kansas announced that it is closing its emergency room and reducing its inpatient beds due, in part, to manufacturers' restrictive 340B contract pharmacy policies. Sarah Motter, *Community HealthCare System in St. Marys to Close Emergency Room Doors, Adjust Services*, WIBW (Apr. 28, 2021).[15]

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

Many covered entities, including Amici's members, rely entirely on contract pharmacies to dispense covered outpatient drugs to their patients. *See, e.g*, Auclair Aff. ¶ 18; Glover Aff. ¶ 18; Slingerland Aff. ¶ 10. For some covered entities, 340B Program revenue has meant the difference between remaining in operation and closing. Springhill Medical Center is a not-for-profit, 58-bed hospital located in Springhill, Louisiana, for which the net revenue from the 340B Program is the difference between keeping its facilities operational and closing. Johnson Aff. ¶ 2. For FamilyCare, revenue from its contract pharmacy arrangements is almost half the funding it receives from federal grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5.

The loss of all 340B savings to Amici's members would be even more devastating to their operations and the patients they serve. Auclair Aff. ¶ 32; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11; Slingerland Aff. ¶¶ 19-23. Per-patient costs will increase dramatically if these providers are burdened with covering the full price of manufacturers' drugs. Many covered entities that have relied on 340B participation lack the financial resources necessary to bear the additional costs of drugs for indigent patients. Auclair Aff. ¶¶ 35-36; Glover Aff. ¶ 25; Dickerson ¶ 9; Slingerland Aff. ¶¶ 20-23.

Holding in Lilly's favor would significantly harm covered entities, their patients, and the health care safety-net community by freeing Lilly and other drug

companies from their obligations under the 340B statute, upending an over two-decades-long status quo upon which all covered entities have depended.

## CONCLUSION

For the above reasons, Amici respectfully request this Court hold that the 340B statute obligates pharmaceutical manufacturers to provide 340B discounts on drugs ordered by covered entities for shipment to contract pharmacies.

Dated: July 1, 2022

Respectfully submitted,

/s/ Matthew S. Freedus
Matthew Sidney Freedus
D.C. Bar No. 475887
Rosie Dawn Griffin
D.C. Bar No. 1035462
FELDESMAN TUCKER LEIFER FIDELL LLP
1129 20th St. NW, 4th Floor
Washington, DC 20036
T: (202) 466-8960
F: (202) 293-8103
mfreedus@ftlf.com
rgriffin@ftlf.com
*Counsel for Amicus Curiae National Association of Community Health Centers*

/s/ Ronald S. Connelly
Ronald S. Connelly
D.C. Bar No. 488298
William von Oehsen
D.C. Bar No. 423381
Barbara Straub Williams
D.C. Bar 396582
Megan La Suer
D.C. Bar No. 1643443
Mark Ogunsusi
D.C. Bar No. 1708475
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 466-6550
Fax (202) 785-1756
Ron.Connelly@PowersLaw.com
Barbara.Williams@PowersLaw.com
*Counsel for Amici Curiae Ryan White Clinics for 340B Access*

## CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Fed. R. App. P. 29(d) and Circuit Rule 29 because, excluding the parts of the document exempted by Fed. R. App. P. 32(a)(7)(B)(iii), this document contains 6,604 words.

2. This document also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Office 365 in Times New Roman 14-point font.

Dated: July 1, 2022

Respectfully submitted,

/s/ Ronald S. Connelly
Ronald S. Connelly

## CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on July 1, 2022, I electronically filed the foregoing document with the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

Dated: July 1, 2022

Respectfully submitted,

/s/ Ronald S. Connelly
Ronald S. Connelly

# INDEX OF EXHIBITS
# TO BRIEF OF *AMICI CURIAE* NACHC AND RWC-340B IN SUPPORT OF DEFENDANTS-APPELLEES–CROSS-APPELLANTS[1]

**Exhibit A** Declaration of Craig Glover, MBA, MA, FACHE, CMPE, CEO of WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare"). Filed in *Eli Lilly & Co. et al. v. Becerra et al.*, No. 1:21-cv-00081 (S.D. Ind. Mar. 9, 2021), ECF No. 75-3

**Exhibit B** Declaration of D. Tucker Slingerland, M.D., CEO of Hudson Headwaters Health Network. Filed in *Eli Lilly & Co. et al. v. Becerra et al.*, No. 1:21-cv-00081 (S.D. Ind. June 21, 2021), ECF No. 120-4

**Exhibit C** Declaration of Peter Johnson, Rph., Chief of Pharmacy and Ancillary Services of Springhill Medical Center. Filed in *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24-8

**Exhibit D** Declaration of Terri S. Dickerson, CFO, FamilyCare. Filed in *Eli Lilly & Co. et al. v. Becerra et al.*, No. 1:21-cv-00081 (S.D. Ind. Mar. 9, 2021), ECF No. 75-4

**Exhibit E** Declaration of Gail Auclair, CEO of Little Rivers Inc. This is an update to a declaration filed in *Eli Lilly & Co. et al. v. Becerra et al.*, No. 1:21-cv-00081 (S.D. Ind. Mar. 9, 2021), ECF No. 75-2

**Exhibit F** Declaration of Heather Rickertsen, PharmD, Director of Clinical Pharmacy Services, Crescent Community Health Center. Filed in *Eli Lilly & Co. et al. v. Becerra et al.*, No. 1:21-cv-00081 (S.D. Ind. Mar. 9, 2021), ECF No. 24-8

[1] All prior ECF stamps have been redacted so that the ECF stamps for this Court are legible.

# Exhibit A

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

| | |
|---|---|
| Ryan White Clinics for 340B Access, et al.,<br><br>Plaintiffs,<br><br>v.<br><br>Alex M. Azar, Secretary U.S. Department of Health and Human Services, et al.,<br><br>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.

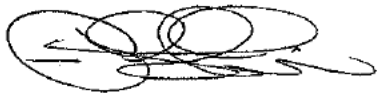
30) FamilyCare's Prescription Savings Program is offered for drugs that are purchased with 340B discounts. If FamilyCare cannot purchase drugs manufactured by Lilly, AstraZeneca, and Lilly with 340B discounts, those drugs will no longer be part of its program. FamilyCare does not have funds allocated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

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

RYAN WHITE CLINICS
FOR 340B ACCESS
1501 M Street, N.W., Suite 700
Washington, DC 20005,

and

MATTHEW 25 AIDS SERVICES, INC.
452 Old Corydon Road
Henderson, KY 42420,

and

CHATTANOOGA C.A.R.E.S., DBA
CEMPA
COMMUNITY CARE
1000 E. 3rd Street, Suite 300
Chattanooga, TN 37403,

*Plaintiffs,*

v.

ALEX M. AZAR II, in his official capacity as
Secretary of the United States Department of
Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201,

and

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201,

and

THOMAS J. ENGELS, in his official capacity as
Administrator for the Health Resources and
Services Administration
5600 Fishers Lane
Rockville, MD 20857,

and

) Civil Action No. 20-cv-2906

HEALTH RESOURCES AND SERVICES
ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20857

*Defendants*

**Declaration of D. Tucker Slingerland, M.D.**

I, D. Tucker Slingerland, M.D., declare as follows:

1. I am Chief Executive Officer for Hudson Headwaters Health Network (HHHN) and have held this role since July 1, 2017. As Chief Executive Officer I am responsible for responsible for the overall performance of the organization, including clinical, administrative, finance, and governance functions and related activities for the purpose of attaining the goals and strategies as set forth by the Board of Directors. This includes oversight of our 340B Drug Pricing Program management and compliance. To prepare this declaration, I consulted with our Chief Financial Officer, Chief Information Officer, Chief Medical Officer, Chief Operations Officer, and the President of Hudson Headwaters 340B, LLC.

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

3. Hudson Headwaters Health Network is a Federally-qualified health center that receives federal grant funds under Section 330 of the Public Health Service Act. Hudson Headwaters Health Network, a not-for-profit 501(c)3 organization, has served the Adirondack and North Country regions of Upstate New York as a Federally-qualified health center since 1981. Hudson Headwaters Health Network's service area includes the southern, eastern, and Tri-Lakes regions of the Adirondack Park, the City of Glens Falls and its surrounding suburbs, and the northern corridor communities centered on the Towns of Champlain and Plattsburg near the Canadian border. The area is approximately 140 miles by 50 miles (or 7,000-square miles) and mostly rural, with limited east-west transportation routes. The region is designated by the federal Bureau of Health Workforce as Health Professional Shortage Area due to significant health care provider shortages in primary care, dental health, and mental health. In many towns, HHHN is the sole medical provider.

4. In 2019, Hudson Headwaters Health Network provided care to 90,077 unique patients through 363,911 primary medical, dental, and behavioral health visits. Of 45,608 patients for whom income is known, 51.8% live at or below 200% of Federal poverty guidelines. Of

Hudson Headwater Health Network's 90,077 patients, 21.3% are covered under Medicaid, 25.9% are covered under Medicare or are dual-eligible, 2.1% are covered under another form of public insurance, 46.4% are covered by private insurance, and 4.3% are uninsured.

5. Hudson Headwaters Health Network is a "covered entity" for purposes of the 340B Drug Program. HHHN was approved as a covered entity in the 340B Drug Pricing Program on April 1, 2001. As required by law, it recertifies this status annually with the Health Resources and Services Administration (HRSA).

6. The 340B Drug Program allows Hudson Headwaters Health Network to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. HHHN purchases drugs from wholesalers via one third party administrator for its 101 contract pharmacies.

7. Hudson Headwaters Health Network's participation in the 340B Drug Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Federal law and regulations, as well as Hudson Headwaters Health Network's mission, require that every penny of 340B savings be invested in services that expand access for its medically underserved patient population. HHHN uses 340B savings to provide medication discounts and other financial assistance programs for uninsured patients and those living at or below 200% of the federal poverty level. In addition, Hudson Headwaters Health Network uses 340B savings to support core programs and services that are consistent with its mission, including dental care, patient and student education, home-based care, obstetrics and gynecology, palliative care, and phlebotomy. HHHN also uses these revenues to offset the costs of COVID-19 antigen and antibody testing in its service area. Finally, Hudson Headwaters Health Network also uses 340B savings to improve infrastructure, renovating facilities, and expanding services into underserved communities in Northeastern New York who otherwise would have limited or no local access to care.

8. From January 1, 2019 to December 31, 2019, Hudson Headwaters Health Network captured 51,066 prescriptions for 340B savings at its 101 contract pharmacies.

9. As a covered entity, Hudson Headwaters Health Network is permitted to choose how it will deliver pharmacy services to its patients. HHHN does this by contract pharmacy prescription capture. Hudson Headwaters Health Network has 101 contract pharmacies through 13 written agreements. A list of active contract pharmacies and locations is provided in the attached "Hudson Headwaters Health Network Active Contract Pharmacies."

10. Hudson Headwaters Health Network does not operate an in-house pharmacy. Given the Network's 7,000 square mile service area, by necessity HHHN must rely on contract pharmacies to provide 340B-eligible prescription drugs to its patients. The use of contract pharmacies has greatly expanded Hudson Headwaters Health Network patients' ability to

access affordable drugs, given the size and geographic isolation of the Network. There is only one major road, Interstate 87, that traverses the area from north to south. No four-lane highways cross the service area from east to west, so residents of the region must travel on mountainous two-lane roads to access services. Patients living within the Adirondack Park or North Country must travel significant distances for treatment and care. Public transportation is available in the towns of Plattsburgh and Glens Falls, but there is no public transportation elsewhere in the region. The nearly six months of winter conditions in the region, often rendering roads impassable for days at a time, also complicates travel. To minimize these geographic and logistical barriers to accessing prescription drugs, HHHN has agreements with 101 contract pharmacies. The use of contract pharmacies also increases the Network's 'capture rate' (i.e., the percentage of prescriptions written by the health center for its patients). This allows Hudson Headwaters Health Network to retain more 340B savings, and therefore support more services for its patients.

11. Hudson Headwaters Health Network's use of contract pharmacies is authorized under the Section 330 statute that authorizes the Federally-qualified health center program. That statute allows organizations like HHHN to contract out for required services that they do not provide.

12. In 2018, Hudson Headwaters Health Network estimates that 340B savings generated from contract pharmacies accounts for about 31.0% of our direct patient care expenses.

13. On or about July 30,2020, I became aware that certain drug manufacturers, including Astra Zeneca, Eli Lilly, Merck, Novartis, and Sanofi, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Hudson Headwaters Health Network's contract pharmacies.

14. On or about November 2, 2020, I became aware that Novartis had unilaterally decided to honor contract pharmacy arrangements as long as they're within 40 miles of a Hudson Headwaters Health Network facility. I also became aware that Novartis had again begun providing outpatient prescription drugs at 340B prices to some but not all of HHHN's contract pharmacies.

15. Because of the actions taken by certain drug manufacturers, including Astra Zeneca, Eli Lilly, Merck, Novartis, and Sanofi, some Hudson Headwaters Health Network patients have decreased access to critically needed medicines. Other patients still have access to their eligible medications at their local pharmacy, but HHHN will no longer receive the 340B revenue.

16. In 2011, the U.S. Supreme Court held that 340B-covered entities like Hudson Headwaters Health Network do not have the right to sue drug manufacturers for overcharges. Only the Secretary of the Department of Health and Human Services may enforce the pricing requirements of the 340B Drug Program. *Astra*, 563 U.S. at 113-14. This ruling was

premised, in part, on the Department of Health and Human Services' representation that an administrative dispute resolution process as required by Section 7102 of the Patient Protection and Affordable Care Act would be forthcoming:

> The [2010 administrative dispute resolution provision] provides for more rigorous enforcement [and] directs the Secretary to develop formal procedures for resolving overcharge claims. Under those procedures, which are not yet in place, HRSA will reach an 'administrative resolution' that is subject to judicial review under the Administrative Procedure Act (APA). *Astra*, 563 U.S. at 116.

18. Due to the Department of Health and Human Services lack of action to enforce the 340B statue, include the failure to implement an administrative dispute resolution process as required by Section 7102 of the Patient Protection and Affordable Care Act, Hudson Headwaters Health Network has no legal recourse to remedy manufacturer overcharging for 340B-covered drugs.

19. Hudson Headwaters Health Network is suffering immediate and irreparable harm from the Secretary's failure to enforce its right to purchase discounted 340B-eligible drugs via contract pharmacy arrangements.

20. Based on an analysis of current 340B-eligible drugs currently prescribed to patients, HHHN will lose approximately $8,400,000 in revenue as a result of the actions taken unilaterally by the drug manufacturers.

21. As a result of the loss in revenue, key patient services and programs are at risk of being diminished or potentially eliminated. This includes reducing provider, nursing, and care management staffing levels, eliminating the prescription drug assistance program, altering the sliding fee scale, reducing palliative care and home-based health services, and eliminating the direct provision of specialty services like dental, obstetrics and gynecology, and phlebotomy. COVID-19 testing services could be reduced or eliminated at a time when the pandemic still threatens the health and well-being of Americans.

22. In addition to this reduction or loss of services, reduced contract pharmacy 340B savings would negatively affect plans for renovations to modernize existing health centers and planned expansion of services into unserved areas of New York's Clinton, Franklin, and Washington Counties.

23. Reduced contract pharmacy 340B savings may also result in the closing of Hudson Headwaters Women's Health Center (currently staffed by 50 employees, including seven physicians, one physician assistant, one nurse practitioner, and nine nurse-midwives) or other health centers in rural areas, further reducing patient access to care in a region that is already designated as a Health Professional Shortage Area.

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

Executed on December 10, 2020 D. Tucker Stroupeland, MD

## Attachment: Hudson Headwaters Health Network Active Contract Pharmacies

| Pharmacy Name | DBA | Street Address | City | State | Zip | Contract Begin Date | Contract Approval Date |
|---|---|---|---|---|---|---|---|
| ACCREDO HEALTH GROUP INC | | 1620 CENTURY CENTER PKWY # 109 | MEMPHIS | TN | 38134 | 4/1/2019 | 1/8/2019 |
| ACCREDO HEALTH GROUP INC | | 3000 ERICSSON DRIVE, SUITE 100 | WARRENDALE | PA | 15086 | 4/1/2019 | 1/8/2019 |
| ACCREDO HEALTH GROUP INC | | 2040 W RIO SALADO PKWY STE 101B | TEMPE | AZ | 85281 | 4/1/2019 | 1/8/2019 |
| ACCREDO HEALTH GROUP, INC. | | 2825 W PERIMETER RD SUITE 112 | INDIANAPOLIS | IN | 46241 | 4/1/2019 | 1/8/2019 |
| ACCREDO HEALTH GROUP, INC. | | 6272 LEE VISTA BLVD SUITE 100 | ORLANDO | FL | 32822 | 4/1/2019 | 1/8/2019 |
| ACCREDO HEALTH GROUP, INC. | | 2 BOULDEN CIR STE 1 | NEW CASTLE | DE | 19720 | 4/1/2019 | 1/8/2019 |
| ADIRONDACK APOTHECARY LLC | SCHROON LAKE PHARMACY | 1081 MAIN STREET US RT.9 | SCHROON LAKE | NY | 12870 | 12/30/2011 | 12/30/2011 |
| ADIRONDACK APOTHECARY LLC | MORIAH PHARMACY | 4315 MAIN ST | PORT HENRY | NY | 12974 | 12/30/2011 | 12/30/2011 |
| ADVANCED CARE SCRIPTS, INC | ACS PHARMACY #48226 | 6251 CHANCELLOR DRIVE | ORLANDO | FL | 32809 | 10/1/2020 | 7/10/2020 |
| CAREMARK FLORIDA SPECIALTY | CVS/SPECIALTY | 7930 WOODLAND CENTER BLVD STE 500 | TAMPA | FL | 33614 | 7/1/2017 | 4/13/2017 |
| CAREMARK ILLINOIS SPECIALTY | CVS/SPECIALTY | 800 BIERMANN COURT | MOUNT PROSPECT | IL | 60056 | 7/1/2017 | 4/13/2017 |
| CAREMARK KANSAS SPECIALTY PHARMACY | CVS/SPECIALTY | 11162 RENNER BLVD | LENEXA | KS | 66219 | 7/1/2017 | 4/13/2017 |
| CAREMARK LLC | CVS/SPECIALTY #48604 | 1001 SPINKS ROAD, STE 280 | FLOWER MOUND | TX | 75028 | 10/1/2020 | 7/10/2020 |
| CAREMARK MASSACHUSETTS SPECIALTY PHARMACy | INGENIORX SPECIALTY OR CVS SPECIALTY | 25 BIRCH STREET, BLDG B, SUITE 100 | MILFORD | MA | 01757 | 7/1/2017 | 4/13/2017 |
| CAREMARK MICHIGAN SPECIALTY PHARMACY LLC | CVS/SPECIALTY | 1307-H ALLEN DR | TROY | MI | 48083 | 7/1/2017 | 4/13/2017 |
| CAREMARK NEW JERSEY SPECIALTY PHCY, LLC | CVS/SPECIALTY OR INGENIORX SPECIALTY | 180 PASSAIC AVENUE, UNIT B-5 | FAIRFIELD | NJ | 07004 | 7/1/2017 | 4/13/2017 |
| CAREMARK NORTH CAROLINA SPECIALTY PHARMA | CVS/SPECIALTY | 10700 WORLD TRADE BLVD STE 110 | RALEIGH | NC | 27617 | 7/1/2017 | 4/13/2017 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| CAREMARK PUERTO RICO SPECIALTY PHARMACY, | CVS CAREMARK | 280 AVENIDA JESUS T. PINERO | RIO PIEDRAS | PR | 00927 | 10/1/2020 | 7/10/2020 |
| CAREMARK TENNESSEE SPECIALTY PHARMACY, L | CVS/SPECIALTY | 8370 WOLF LAKE DRIVE | BARTLETT | TN | 38133 | 7/1/2017 | 4/13/2017 |
| CAREMARK, LLC | CVS/SPECIALTY | 1127 BRYN MAWR AVE | REDLANDS | CA | 92374 | 7/1/2017 | 4/13/2017 |
| CAREMARK, LLC | CVS/SPECIALTY | 7251 S. EASTERN AVE. | LAS VEGAS | NV | 89119 | 10/1/2020 | 7/10/2020 |
| CVS ALBANY, LLC | CVS/PHARMACY # 00419 | 216 QUAKER ROAD | QUEENSBURY | NY | 12804 | 4/1/2014 | 1/13/2014 |
| CVS ALBANY, LLC | CVS/PHARMACY # 02091 | 5 MAIN STREET | QUEENSBURY | NY | 12804 | 4/1/2014 | 1/13/2014 |
| CVS ALBANY, LLC | CVS/PHARMACY # 02685 | 1253 DIX AVE. | HUDSON FALLS | NY | 12839 | 4/1/2014 | 1/13/2014 |
| CVS ALBANY, LLC | CVS/PHARMACY # 05166 | 170 BROADWAY SUITE 1 | WHITEHALL | NY | 12887 | 1/1/2018 | 10/13/2017 |
| CVS ALBANY, LLC | CVS PHARMACY # 16951 | 578 AVIATION RD STE 1S | QUEENSBURY | NY | 12804 | 1/1/2018 | 10/13/2017 |
| CVS ALBANY, LLC | CVS/PHARMACY # 17512 | 60 SMITHFIELD BLVD | PLATTSBURGH | NY | 12901 | 7/1/2019 | 4/4/2019 |
| CVS ALBANY, LLC | CVS/PHARMACY # 05456 | 2027 DOUBLEDAY AVE. | BALLSTON SPA | NY | 12020 | 4/1/2020 | 1/2/2020 |
| CVS ALBANY, LLC | CVS/PHARMACY # 05348 | 1169 ROUTE 29 | GREENWICH | NY | 12834 | 4/1/2020 | 1/2/2020 |
| CVS ALBANY, LLC | CVS/PHARMACY # 03379 | 653 RTE. 9 | WILTON | NY | 12831 | 4/1/2020 | 1/2/2020 |
| CVS ALBANY, LLC | CVS/PHARMACY # 00731 | 34 CONGRESS ST. | SARATOGA SPRINGS | NY | 12866 | 4/1/2020 | 1/2/2020 |
| CVS CAREMARK | | 1 GREAT VALLEY BOULEVARD | WILKES BARRE | PA | 18706 | 1/1/2021 | 10/15/2020 |
| CVS CAREMARK ADVANCED TECHNOLOGY PHARMAC | CVS/CAREMARK | 1780 WALL ST | MT PROSPECT | IL | 60056 | 1/1/2021 | 10/15/2020 |
| CYSTIC FIBROSIS SERVICES, LLC | ALLIANCERX WALGREENS PRIME #16280 | 10530 JOHN W ELLIOTT DRIVE | FRISCO | TX | 75033 | 4/1/2020 | 1/6/2020 |
| ECKERD CORPORATION | RITE AID #10717 | 124 RIDGE STREET | GLENS FALLS | NY | 12801 | 3/7/2012 | 3/7/2012 |
| ESI MAIL PHARMACY SERVICE | EXPRESS SCRIPTS | 7909 S HARDY DR STE 106 | TEMPE | AZ | 85284 | 4/1/2019 | 1/8/2019 |
| EXPRESS SCRIPTS | ESI MAIL PHARMACY | 4600 N HANLEY RD | SAINT LOUIS | MO | 63134 | 4/1/2019 | 1/8/2019 |

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| | SERVICE INC | | | | | | |
| EXPRESS SCRIPTS PHARMACY, INC. | EXPRESS SCRIPTS | 2040 ROUTE 130 NORTH | BURLINGTON | NJ | 08016 | 4/1/2019 | 1/8/2019 |
| EXPRESS SCRIPTS PHARMACY, INC. | EXPRESS SCRIPTS | 4750 E. 450 S. | WHITESTOWN | IN | 46075 | 4/1/2019 | 1/8/2019 |
| GLENS FALLS HOSPITAL INC | | 100 PARK ST | GLENS FALLS | NY | 12801 | 1/1/2014 | 10/3/2013 |
| GOLUB CORPORATION | | 354 BROADWAY | FORT EDWARD | NY | 12828 | 4/1/2017 | 1/2/2017 |
| GOLUB CORPORATION | MARKET 32 PHARMACY 168 | 19 CENTRE DRIVE | PLATTSBURGH | NY | 12901 | 10/1/2019 | 7/10/2019 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #104 | 161 CAREY ROAD | QUEENSBURY | NY | 12804 | 5/18/2012 | 5/18/2012 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #52 | 868 STATE RTE. 11 | CHAMPLAIN | NY | 12919 | 10/27/2012 | 1/11/2013 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #19 | 288 CORNELIA STREET | PLATTSBURGH | NY | 12901 | 4/1/2015 | 1/5/2015 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #40 | 6 VETERANS LANE | PLATTSBURGH | NY | 12901 | 4/1/2015 | 1/5/2015 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #50 | 1588 MILITARY TURNPIKE | PLATTSBURGH | NY | 12901 | 4/1/2015 | 1/5/2015 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #76 | 7550 COURT STREET | ELIZABETHTOWN | NY | 12932 | 4/1/2015 | 1/5/2015 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #39 | 94 DEMARS BLVD. | TUPPER LAKE | NY | 12986 | 7/1/2020 | 4/1/2020 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #02 | 277 BROADWAY ST. | SARANAC LAKE | NY | 12983 | 7/1/2020 | 4/1/2020 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #59 | C/O PHARMACY | PLATTSBURGH | NY | 12901 | 10/1/2020 | 7/8/2020 |
| KPH HEALTHCARE SERVICES, INC. | KINNEY DRUGS #121 | 3 GORMAN WAY | PERU | NY | 12972 | 10/1/2020 | 7/8/2020 |
| MARTIN'S FOODS OF SOUTH BURLINGTON, LLC | HANNAFORD SUPERMARKET & PHARMACY #83 | 27-41 GANSEVOORT ROAD | SOUTH GLENS FALLS | NY | 12803 | 7/1/2016 | 4/7/2016 |
| MARTIN'S FOODS OF SOUTH BURLINGTON, LLC | HANNAFORD SUPERMARKET & PHARMACY #83 | 190 QUAKER ROAD | QUEENSBURY | NY | 12804 | 4/1/2017 | 1/4/2017 |
| MARTIN'S FOODS OF SOUTH BURLINGTON, LLC | HANNAFORD FOOD & DRUG #8374 | 175 BROAD STREET | GLENS FALLS | NY | 12801 | 4/1/2017 | 1/4/2017 |

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| MARTIN'S FOODS OF SOUTH BURLINGTON, LLC | HANNAFORD SUPERMARKET & PHARMACY #83 | 3758 BURGOYNE AVENUE | HUDSON FALLS | NY | 12839 | 4/1/2017 | 1/4/2017 |
| NOBLE HEALTH SERVICES INC. | | 6040 TARBELL ROAD | SYRACUSE | NY | 13206 | 1/1/2016 | 10/1/2015 |
| OMNICARE OF EDISON | CARE4, L.P. | 120 FIELDCREST AVE | EDISON | NJ | 08837 | 1/1/2021 | 10/15/2020 |
| OPTUM PHARMACY 702, LLC | | 1050 PATROL ROAD | JEFFERSONVILLE | IN | 47130 | 7/1/2020 | 4/15/2020 |
| OPTUM PHARMACY 703, LLC | | 8350 BRIOVA DR. | LAS VEGAS | NV | 89113 | 7/1/2020 | 4/15/2020 |
| OPTUMRX INC | OPTUMRX | 2858 LOKER AVE E STE 100 | CARLSBAD | CA | 92010 | 7/1/2020 | 4/15/2020 |
| OPTUMRX INC | OPTUMRX | 6800 W 115TH ST STE 600 | OVERLAND PARK | KS | 66211 | 7/1/2020 | 4/15/2020 |
| PHARMACY ASSOCIATION OF GLENS FALLS | OMNICARE OF BALLSTON SPA | 14 COMMERCE DR | BALLSTON SPA | NY | 12020 | 1/1/2021 | 10/15/2020 |
| PRICE CHOPPER OPERATING CO., INC. | HOUSE CALLS PHARMACY 200 | 100 BROAD ST PLAZA | GLENS FALLS | NY | 12801 | 12/30/2011 | 12/30/2011 |
| PRICE CHOPPER OPERATING CO., INC. | HOUSECALLS PHARMACY 201 | 3761 MAIN STREET | WARRENSBURG | NY | 12885 | 2/23/2012 | 2/23/2012 |
| PRIME THERAPEUTICS SPECIALTY PHARMACY LLC | ALLIANCERX WALGREENS PRIME #16568 | 2354 COMMERCE PARK DRIVE | ORLANDO | FL | 32819 | 4/1/2020 | 1/6/2020 |
| PROACT PHARMACY SERVICES, INC. | | 1226 US HIGHWAY 11 | GOUVERNEUR | NY | 13642 | 4/1/2015 | 1/5/2015 |
| PROCARE PHARMACY DIRECT, LLC | CVS/SPECIALTY | 105 MALL BOULEVARD | MONROEVILLE | PA | 15146 | 7/1/2017 | 4/13/2017 |
| PROCARE PHARMACY DIRECT, LLC | CVS/PHARMACY #2909 | 1521 4TH AVE., SOUTH | BIRMINGHAM | AL | 35233 | 10/1/2020 | 7/10/2020 |
| PROCARE PHARMACY DIRECT, LLC | CVS/PHARMACY #2915 | ONE WATERFRONT PLAZA | HONOLULU | HI | 96813 | 10/1/2020 | 7/10/2020 |
| PROCARE PHARMACY DIRECT, LLC | DBA CVS/PHARMACY #2923 | 3250 HARDEN ST. EXT. SUITE #300 | COLUMBIA | SC | 29203 | 10/1/2020 | 7/10/2020 |
| THE GOLUB CORPORATION | PRICE CHOPPER PHARMACY 040 | 677 UPPER GLEN ST | QUEENSBURY | NY | 12804 | 12/30/2011 | 12/30/2011 |
| WALGREEN EASTERN CO., INC | WALGREENS # 17860 | 94 MAIN ST. | SOUTH GLENS FALLS | NY | 12803 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC | WALGREENS # 19689 | 3864 MAIN STREET | WARRENSBURG | NY | 12885 | 2/8/2018 | 2/8/2018 |

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| WALGREEN EASTERN CO., INC | WALGREENS # 19426 | 724 UPPER GLEN ST | QUEENSBURY | NY | 12804 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC | WALGREENS # 17154 | 284 MAIN STREET | NORTH CREEK | NY | 12853 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC | WALGREENS # 17722 | 90 WEST AVE | SARATOGA SPRINGS | NY | 12866 | 7/1/2019 | 4/12/2019 |
| WALGREEN EASTERN CO., INC | WALGREENS # 17227 | 173 CHURCH ST. | SARANAC LAKE | NY | 12983 | 7/1/2020 | 4/1/2020 |
| WALGREEN EASTERN CO., INC | WALGREENS # 19706 | 4 PLEASANT AVE | TUPPER LAKE | NY | 12986 | 7/1/2020 | 4/1/2020 |
| WALGREEN EASTERN CO., INC. | WALGREENS | 202 BROAD ST. | GLENS FALLS | NY | 12801 | 4/1/2018 | 1/15/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 10384 | 3020 ROUTE 50 | SARATOGA SPRINGS | NY | 12866 | 4/1/2018 | 1/15/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS | 301 CORNELIA ST. | PLATTSBURGH | NY | 12901 | 4/1/2018 | 1/15/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 17717 | 116 QUAKER ST | GRANVILLE | NY | 12832 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 19965 | 6272 STATE R0UTE 9 | CHESTERTOWN | NY | 12817 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 19328 | 2160 STATE ROUTE 9 | LAKE GEORGE | NY | 12845 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 17960 | 1262 DIX AVENUE | HUDSON FALLS | NY | 12839 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 19911 | 1 PALMER AVE | CORINTH | NY | 12822 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS | 887 STATE ROUTE 11 | CHAMPLAIN | NY | 12919 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 18030 | 1161 NYS ROUTE 9N | TICONDEROGA | NY | 12883 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 19494 | 92 MAIN ST | HUDSON FALLS | NY | 12839 | 2/8/2018 | 2/8/2018 |
| WALGREEN EASTERN CO., INC. | WALGREENS # 18207 | 2 NORTH PARK ST | CAMBRIDGE | NY | 12816 | 7/1/2019 | 4/12/2019 |
| WALGREENS MAIL SERVICE, LLC | ALLIANCERX WALGREENS PRIME #03397 | 8350 S RIVER PARKWAY | TEMPE | AZ | 85284 | 4/1/2018 | 1/15/2018 |
| WALGREENS SPECIALTY PHARMACY LLC | ALLIANCERX WALGREENS PRIME #15443 | 10530 JOHN W. ELLIOTT DRIVE | FRISCO | TX | 75033 | 4/1/2020 | 1/6/2020 |
| WALGREENS SPECIALTY PHARMACY LLC | ALLIANCERX WALGREENS PRIME #16287 | 130 ENTERPRISE DRIVE | PITTSBURGH | PA | 15275 | 4/1/2020 | 1/6/2020 |

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| WALGREENS SPECIALTY PHARMACY, LLC | ALLIANCERX WALGREENS PRIME #12314 | 9775 SW GEMINI DR, STE 1 | BEAVERTON | OR | 97008 | 4/1/2020 | 1/6/2020 |
| WALGREENS SPECIALTY PHARMACY, LLC | ALLIANCERX WALGREENS PRIME #15438 | 41460 HAGGERTY CIRCLE SOUTH | CANTON | MI | 48188 | 4/1/2020 | 1/6/2020 |
| WALGREENS.COM, INC. | WALGREENS | 2225 S. PRICE ROAD | CHANDLER | AZ | 85286 | 4/1/2018 | 1/15/2018 |
| WAL-MART CENTRAL FILL 10-2670 | | 608 SPRING HILL DR # 3 SUITE 300 | SPRING | TX | 77386 | 10/1/2017 | 7/3/2017 |
| WAL-MART PHARMACY | WAL-MART PHARMACY 10-1994 | 25 CONSUMER SQUARE | PLATTSBURGH | NY | 12901 | 10/1/2014 | 7/1/2014 |
| WAL-MART PHARMACY | WAL-MART PHARMACY 10-2056 | 16 OLD GLICK ROAD | SARATOGA SPRINGS | NY | 12866 | 1/1/2016 | 10/1/2015 |
| WAL-MART PHARMACY | WAL-MART PHARMACY 10-2116 | 891 ROUTE #9 | QUEENSBURY | NY | 12804 | 1/25/2013 | 1/25/2013 |
| WAL-MART PHARMACY | WAL-MART PHARMACY 10-2424 | 1134 WICKER STREET | TICONDEROGA | NY | 12883 | 1/24/2013 | 1/24/2013 |
| WAL-MART PHARMACY | WAL-MART PHARMACY 10-4403 | 24 QUAKER RIDGE BLVD. | QUEENSBURY | NY | 12804 | 4/1/2014 | 1/3/2014 |
| WAL-MART PHARMACY | WAL-MART PHARMACY 10-5997 | 9600 PARKSOUTH CT. SUITE 100 | ORLANDO | FL | 32837 | 10/1/2017 | 7/3/2017 |

# 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, Peter Johnson, RPh,, hereby attest and state as follows:

1) I am the Chief of Pharmacy and Ancillary Services at Springhill Medical Center located in Springhill, Louisiana. I have held this position since January 2019.

2) Springhill is a not-for-profit, 58-bed hospital that is designated by the Center for Medicare and Medicaid Services as a sole community hospital or "SCH". SCH status is granted to rural hospitals that meet certain criteria to demonstrate that they are the sole source of inpatient care within a certain geographic area. 42 C.F.R. § 412.92.

3) According to an article by Evan Comen in "24/7 Wall Street", entitled "*Who is missing out on economic recovery? America's 30 poorest towns*", Springhill, Louisiana is one of the thirty (30) most improverished towns in America.[1] The data for this article was based on U.S. Census Bureau's American Community Survey in every American town

[1] https://www.rgj.com/story/money/economy/2018/06/18/who-missing-out-economic-recovery-americas-30-poorest-towns/35936583/

with a population between 1,000 and 25,000.[2] At the time that this article was written, the median household income in Springhill was $26,260 and the poverty rate was 36.7%

4) Based on my personal experience, I know that the poverty level and unemployment rate in Springhill are very high.

5) Springhill was one of three hospitals located in Louisiana that was named as "100 Top Hospitals" in 2018 by IBM Watson Health.[3]

6) Springhill has operated at a loss for at least the last two fiscal years. Springhill's operating loss in 2020 was approximately $70,000 and its operating loss in 2019 was approximately $750,000.

7) Springhill participates in the 340B federal drug discount program as a SCH. Between January 1 and October 30, 2020, Springhill realized net revenue from its contract pharmacies of approximately $982,829. In 2019, Springhill realized net revenue from its contract pharmacies of approximately $976,551. Springhill also realizes net revenues from administering 340B drugs within its hospital, but the net revenues from those 340B drugs purchases is only about $36,000 annually.

8) Based on my review of revenues from Springhill's contract pharmacies, Springhill will lose about $24,000 per month, or $288,000 annually, due to the recent actions of Eli Lilly Company ("Lilly"), Zeneca Pharmaceuticals, L.P. ("AstraZeneca"), and Sanofi-Aventis US LLC ("Sanofi"), and Novartis Pharmaceuticals ("Novartis") with respect to contract pharmacies.

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[2] https://www.rgj.com/story/money/economy/2018/06/18/who-missing-out-economic-recovery-americas-30-poorest-towns/35936583/

[3] https://www.ktbs.com/news/springhill-hospital-one-of-3-in-state-named-to-top-100-hospitals/article_e6233bd2-26ff-11e8-97dd-b76991e72fd0.html

9) I believe, and I have heard a member of the Board of Directors of Springhill state, that the difference between keeping Springhill operational and closing its doors is the net revenues from the 340B program.

10) Springhill provides many services to its community including participation in community health fairs at which it provides free health screenings. It has a financial assistance policy that allows it to provide health care services to individuals that are uninsured or underinsured.

11) Springhill offers a "Cash Savings Program" that allows eligible patients to purchase retail, self-administered drugs at low prices at its contract pharmacies. The Cash Savings Program assists uninsured patients or patients who have to meet a high deductible. If a patient qualifies for the Cash Savings Program, the patient pays Springhill's 340B cost for the drug plus a dispensing fee to the pharmacy.

12) A pharmacist at one of our contract pharmacies told me that a patient that was eligible for the Cash Savings Program recently came to the pharmacy to refill a prescription for Lantus®, a long-acting insulin product manufactured by Sanofi- Aventis. Many diabetic patients are better able to stabilize their blood sugar levels using Lantus® than they are with other insulin products because the effects of Lantus® last longer than other products. This individual had previously paid approximately $17.00 for the Lantus® prescription but because Sanofi-Aventis products are no longer available at 340B prices at contract pharmacies, the cost for the Lantus® increased to approximately $1,300. The patient left the pharmacy without the prescription in order to return to his or her doctor to get a prescription for another insulin product that is not manufacturer by Sanofi-Aventis.

13) I have concerns that the safety and health of diabetic patients who have a history of taking Lantus® will be compromised if they have to switch to another product due to the cost of Lantus®.

14) I do not have any expectation that the cost of insulin will come down given the recent trends of drug manufacturers to increase the cost of insulin.[4]

15) I also have concerns that other Springhill patients eligible for the Cash Savings Program will discontinue their medications manufactured by Lilly, AstraZeneca, Sanofi and Novartis because the cost of those drugs will be much higher if they are not purchased at 340B discounts. The first month of not having access to medications from these manufacturers for the Cash Savings program customer savings were down $16,331.00 ($195,000 annually).

16) Lilly has stated that it will allow 340B covered entities to access its insulin products at contract pharmacies if certain conditions are met. One of those conditions is that the pharmacy not collect a dispensing fee as compensation for filling the prescription. This condition makes the Lilly insulin "exception" entirely impractical because pharmacies will not agree to dispense drugs without any compensation.

17) Springhill has several hospital outpatient departments that are located many miles from the main facility. For example, Springhill has a hospital outpatient department in Homer, Louisiana, which is located between 31 to 38 miles from the main facility, depending on the route taken. Springhill has two contract pharmacies located in Homer that allow patients that are seen at the Springhill outpatient department in Homer to participate in the Cash Savings Program by using one of those pharmacies.

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[4] Rajkumar, S. Vincent, The High Cost of Insulin in the United States: An Urgent Call to Action, Mayo Clinic Proceedings, Jan. 1, 2020; available at https://www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/fulltext .

18) Lilly has stated that it will allow 340B covered entities to access 340B drugs at one contract pharmacy only. Springhill has designated The Corner Drug Store, located in Springhill, as its one contract pharmacy for purposes of accessing 340B pricing for drugs manufactured by Lilly. A patient that is treated at the Springhill outpatient department in Homer and is prescribed a drug manufactured by Lilly will have to drive up to 38 miles to have his or her prescription filled at the Corner Drug Store if that patient wants to take advantage of the Cash Savings Program.

19) Springhill recently registered some specialty contract pharmacies in the 340B program in order to access 340B pricing for certain specialty drugs. These specialty pharmacies are located more than 40 miles from Springhill's inpatient facility. Springhill will not be able to access 340B pricing for Novartis drugs at these pharmacies because Novartis recently announced that it will not provide 340B prices at contract pharmacies that are located more than 40 miles from the main hospital facility.

20) I am concerned that other drug manufacturers will follow the lead of Lilly, AstraZeneca, Sanofi and Novartis and decide to no longer provide 340B pricing through contract pharmacies. If Springhill lost access to all 340B drugs at its contract pharmacies, I do not believe that it will be able to remain in operation.

[*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 _____ day of November 2020.

Respectfully submitted,

Peter Johnson, RPh, MBA
Chief of Pharmacy and Ancillary Services
Springhill Medical Center

# Exhibit D

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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

**AFFIDAVIT**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[*Signature on next page*]

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

Respectfully submitted,

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

# Exhibit E

Nos. 21-3128, 21-3405

# IN THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY AND LILLY USA, LLC,

Plaintiffs-Appellants-Cross-Appellees,

*v.*

XAVIER BECERRA, et al.,
Defendants-Appellees–Cross-Appellants.

On Appeal from the United States District Court for the Southern District of Indiana, Nos. 1:21-cv-00081-SEB-MJD (Honorable Sarah Evans Barker)

## 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 over fifteen (15) years. I have over forty (40) years of experience as a nurse.

2) Little Rivers has four facilities in Vermont. The facilities are located in Wells River, Newbury, 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]

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 2020, Little Rivers provided services to 5,753 patients. Approximately 16.55% of these patients were under the age of 18 and 25.24% were 65 years of age or older.[2]

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[1] Little Rivers Health Care, *About*, https://www.littlerivers.org/about (last visited May 12, 2022).
[2] Health Resources and Services Administration, Bureau of Primary Care: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId

9) In 2020, Little Rivers patients included 100 agricultural workers and families, 35 homeless individuals, 248 veterans, and 276 uninsured.[3]

10) Between March 16, 2020 to March 15, 2021, Little Rivers conducted 5,864 behavioral health visits and 4,105 phone and behavioral health televisits.[4]

11) 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. The chronic care management team also provided education about COVID-19, as well as state and CDC guidelines to staff, patients, and people from the communities, including non-patients. In 2020, 122 patients were enrolled in the Little Rivers' chronic care management program.[5]

12) 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.[6] 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. During the COVID-19 public health emergency ("PHE"), Little Rivers increased deliveries of fresh produce and dairy from 205 pounds to 405-460 pounds a week.[7]

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[3] *Id.*
[4] Little Rivers 2020 Annual Report, p. 8, https://www.littlerivers.org/annual-meeting.
[5] *Id.*, p. 9.
[6] *Id.*, p. 11.
[7] *Id.*, p. 9.

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

14) Little Rivers operates a Medication Assisted Treatment ("MAT") program, which provides services to individuals who are on a drug regimen to treat addiction. In 2020, Little Rivers MAT program served approximately 100 patients.[9]

15) 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."[10]

16) Based on my 40 plus 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.

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[8] *Id.*, p. 7-8.
[9] *Id.*, p. 8.
[10] *Id.*, p. 7.

17) 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 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.

18) 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.

19) Little Rivers has six 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 four of the contract pharmacies registered by Little Rivers on the OPA database dispense 340B drugs directly to Little Rivers' patients. Because Little Rivers is located in a rural area with many low-income residents, lack of transportation is one of the most common problems for accessing resources. Having four contract pharmacy locations is very important for patients that do not have the means or ability to travel to pick up their medications.

20) 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.

21) 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.

22) 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"), Sanofi-Aventis US LLC ("Sanofi"), and Pfizer, Inc. ("Pfizer") and their corporate affiliates, Little Rivers has lost approximately $315,000 in 340B savings over a 22-month period as a result of the decision by these manufacturers not to honor contract pharmacy arrangements.

23) 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.[11]

24) The COVID-19 PHE has had a detrimental impact on Little Rivers' finances because patients have been reluctant to schedule in-person appointments for health care services. If not for one-time funding from the U.S. Department of Health and Human Services to support health care providers during the COVID-19 PHE, Little Rivers would have operated at a loss in 2020 as well.

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

25) Little Rivers will have to cut or eliminate some of the services that it provides if Little Rivers loses another $315,000 as the result of the actions of Lilly, AstraZeneca, Pfizer, 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 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, Pfizer, 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 $315,000 in 340B savings as the result of the actions of Lilly, AstraZeneca, Pfizer, 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 $315,000 has exacerbated 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, Pfizer, 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) In 2020, 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.

34) In 2021, I requested information from Hudson Headwaters, which assists Little Rivers in processing 340B contract pharmacy claims, to provide pricing on the 340B price and non-340B price of Bevespi Aerosphere®. Bevespi Aerosphere® is an inhaler produced by AstraZeneca to treat chronic obstructive pulmonary disorder (COPD), and for which no generic substitute is available. Hudson Headwaters provided this information:

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

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

36) Because Little Rivers has historically operated at a loss, 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 29th day of June 2022.

Respectfully submitted,

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

# Exhibit F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

**Declaration of Heather Rickertsen**

I, Heather Rickertsen, PharmD, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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