THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, in her official capacity as Acting Administrator, Health Resources and Services Administration, et al., Defendants.	Case No. 1:21-cv-01479-DLF

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

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The National Association of Community Health Centers ("NACHC"), Ryan White Clinics for 340B Access ("RWC-340B"), Little Rivers Health Care, Inc. ("Little Rivers"), and WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare") (collectively the "Amici"), by and through undersigned counsel, respectfully submit this brief as amici curiae. Amici's brief will support Defendants' Motion for Summary Judgment and oppose Plaintiff's Motion for Preliminary Injunction. No party to this litigation is a 340B covered entity. Amici, which are covered entities and their membership organizations, rely heavily on the 340B contract pharmacy program to serve their vulnerable patients. The future of the contract pharmacy program will affect the Amici's ability to continue to provide services and discounted drugs to vulnerable patients. Amici submit this brief to provide the Court the perspective of the covered entities the 340B drug discount program ("340B Program") was intended to benefit; the brief details how contract pharmacy arrangements enable safety-net health care providers to receive critically necessary discounts on outpatient drugs.[1]

INTRODUCTION

Plaintiff asks this Court to drastically alter the fundamentals of the 340B Program, which provides discounts to safety-net providers known as "covered entities," many of which cannot afford to operate their own pharmacies or cannot fulfill their patients' pharmaceutical needs through their own pharmacies. Contract pharmacies are the only way that many covered enti-

[1] Pursuant to Local Rule 7(o)(5), Amici confirm that they are non-profit corporations that do not issue stock and do not have parent corporations; that no party's counsel authored this brief in whole or in part; that no party or party's counsel contributed money that was intended to fund preparing or submitting this brief. Amici NACHC and RWC-340B contributed funding to this brief. Amici RWC-340B, Little Rivers, and FamilyCare also received funding from RxStrategies, Inc. and Wellpartner, LLC to prepare or submit this brief.

ties—including Amici Little Rivers and FamilyCare and many of the members of NACHC and RWC-340B—can obtain 340B discounted drugs. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") attempts to create a boogeyman of for-profit contract pharmacy companies by misrepresenting how covered entities' 340B contract pharmacy arrangements actually work. If Novartis succeeds in this litigation, covered entities that operate on narrow margins and serve low-income, rural, and medically fragile patients will be shut out of the 340B Program because they will have no way to distribute drugs to their patients.

Novartis is obligated to sell discounted drugs to nonprofit covered entities, and all covered entity types have relied on contract pharmacy arrangements for over twenty years to distribute drugs to their patients. Many covered entities do not operate in-house pharmacies because the requirements to obtain and maintain a pharmacy license are complex and operating a pharmacy is expensive. One of the largest costs of opening a pharmacy—acquiring the initial drug inventory at standard prices—is precisely the type of expenditure the 340B Program is designed to reduce. Many covered entities wisely choose not "to expend precious resources to develop their own in-house pharmacies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("Contract Pharmacy Notice").

Both the longstanding history of the 340B Program and the welfare of safety-net providers were compromised when, in August 2020, Novartis announced its reinterpretation of its obligations under its Pharmaceutical Pricing Agreement with the Department of Health and Human Services ("HHS"), as well as the 340B statute, and joined other drug companies on a campaign to undermine the 340B Program by cutting off discounts on drugs shipped to covered entities' contract pharmacies. Currently, Novartis has halted 340B contract pharmacy shipments

only for covered entity hospital purchases where the dispensing contract pharmacy is located beyond a "40-mile radius" of the covered entity's parent location. Novartis continues to ship 340B drugs to contract pharmacies when the drugs are ordered by "federal grantee covered entities," such as Amici. Administrative Record ("VLTR") 7741-42. Amici appreciate that Novartis continues to honor its obligations to provide 340B pricing to Amici and other federal grantees. Critically, however, Novartis contends that its offer of 340B pricing for any drugs shipped to a covered entity's contract pharmacy is entirely voluntary and that the 340B statute does not require it to offer 340B discounted drugs to Amici and similarly situated covered entities if those drugs are distributed through a contract pharmacy. Thus, if the Court holds for Novartis, Novartis can again unilaterally alter its policy with little or no warning to shut Amici out of the 340B Program. Moreover, a favorable ruling from this Court would signal approval of the much more restrictive policies of Eli Lilly & Company, Sanofi, and AstraZeneca, each of which currently refuses to sell their drugs at 340B discounted pricing to covered entities which intend to dispense the drugs through contract pharmacies. In fact, on June 30, 2021, drug manufacturer Boehringer Ingelheim Pharmaceuticals, Inc. announced that it would no longer honor hospital covered entities' contract pharmacy arrangements. The nation's healthcare safety-net and countless underserved communities will thus continue to be significantly harmed if the Court supports Novartis's refusal to sell its 340B drugs to hospital covered entities that dispense through contract pharmacies.

After failing to convince HHS to bless its unlawful and unprecedented acts,[2] and with both houses of Congress unmistakably opposed to the unprecedented actions by Novartis and the

[2] Email and letter from Dan Lopuch to RADM Krista M. Pedley (Nov. 13, 2020), VLTR_7740-51; HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, VLTR_8048-55 ("Advisory Op.") (withdrawn June 18, 2021).

other drug companies,[3] Novartis—like Lilly, Sanofi, and AstraZeneca—has turned to the judiciary to condone its unlawful behavior. Novartis currently seeks to gut this vital federal drug pricing program by asking the Court to prevent Defendants from initiating enforcement actions against Novartis's unlawful behavior and to override a comprehensive and well-reasoned HHS cease-and-desist letter finding that Novartis is in violation of the 340B statute and commanding it to cease its unlawful actions.[4]

This case impacts *thousands* of covered entities delivering health care to *millions* of Americans, many of whom are among our most medically underserved and vulnerable. To divert attention from its own profit motive, Novartis attempts to villainize large chain pharmacies and mischaracterizes them as de facto covered entities. But contract pharmacies are not covered entities, do not function as covered entities, and do not purchase 340B discounted drugs. Contract pharmacies are simply the sites where patients pick up drugs prescribed and purchased by covered entities. Novartis cannot dismiss covered entities and their patients by shining the spotlight on for-profit retail pharmacies. The truth is that Novartis's unlawful acts already damage covered entities that treat the nation's most vulnerable patients and, if left unchecked, could cause significantly more harm by cutting additional categories of covered entities and their patients out of the 340B Program.

Novartis would have the Court rewrite the 340B statute to exclude many covered entities from participating in the 340B Program. In essence, Novartis wants the lucrative benefit of its Pharmaceutical Pricing Agreement with HHS—having its products covered under Medicare Part

[3] Letter from Members of Congress to Alex M. Azar II (Sept. 14, 2020), VLTR_7675-87; Letter from United States Senators to Alex M. Azar II (Sept. 17, 2020), VLTR_7701-03; Letter from House Committee on Energy & Commerce to Alex M. Azar II (Sept. 3, 2020), VLTR_7660-62.
[4] Letter from Diana Espinosa to Dan Lopuch (May 17, 2021) ("May 17 letter"),VLTR_5-6.

B and Medicaid—without the associated responsibility of offering 340B pricing to hospital covered entities when those hospitals choose to distribute those drugs to their patients through contract pharmacies. Without access to 340B pricing and contract pharmacy distribution systems, covered entities will inevitably be forced to cut services and staff that are supported by 340B savings, and patients will lose access to low-cost medications, leaving many to face the potentially life-threatening choice of forgoing their prescriptions altogether.

No covered entity is a party to this action, but all covered entities will be negatively impacted if the Court grants Novartis's motion to vacate HHS's May 17 cease-and-desist letter. Amici have a significant interest in the continued viability of the 340B Program, and therefore support the Defendants' motion for summary judgment and opposition to Novartis's motion for preliminary injunction, ECF No. 14, and oppose Novartis's motion for preliminary injunction ECF No. 5 ("Novartis Mot. PI"). Simply put: Amici urge the Court to protect the nation's health care safety-net as Congress intended.

ARGUMENT

I. Novartis Misrepresents Contract Pharmacy Relationships, Which Have Been a Critical Component of the 340B Program for More Than Two Decades

Novartis mischaracterizes the contract pharmacy model as a "scheme" that has turned into a massive, forced giveaway to large, corporate chain pharmacies. Novartis Mot. PI at 8, 14, 26-27. But contract pharmacies do not purchase 340B drugs. The covered entity 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, importantly, remits third-party payments and/or patient co-payments to the covered entity, minus the pharmacy's fee, while providing needed pharmaceuticals and convenience to often underserved communities.

Typically, health care providers purchase a pharmaceutical manufacturer's drugs from

third-party wholesalers. A covered entity will establish a 340B account with the wholesaler, under the covered entity's name, enabling the covered entity to purchase 340B discounted drugs. If the covered entity has one or more contract pharmacies, the wholesaler creates a "bill-to, ship-to" arrangement in which the drugs are billed to the covered entity and shipped to the contract pharmacy. *See* HRSA, *FAQs, What is a "ship to bill to" arrangement?*[5] Wholesalers do not establish 340B accounts for contract pharmacies, which are not eligible for these discounts.

Novartis 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. Novartis alleges that the "explosive growth" in the 340B Program has "greatly exacerbated longstanding systemic 340B program integrity concerns" and has led to "hundreds of instances of diversion at contract pharmacies" because many contract pharmacies rely on the replenishment model for distributing 340B drugs. Novartis Mot. PI at 9-10 (citing GAO, GAO-18-480, Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, at 28 (2018)).[6] Contrary to Novartis's assertion, the replenishment model is merely an accounting tool, which reconciles all 340B and non-340B sales after the fact and thereby ensures that 340B discounted drugs are dispensed only to 340B-eligible patients. Far from causing diversion to ineligible patients, the replenishment model's reconciliation process serves as an accurate and effective means to protect *against* diversion.

Moreover, Novartis mischaracterizes the relationship between covered entities and contract pharmacies, alleging that "there is a serious open question whether the covered entities

[5] https://www.hrsa.gov/opa/faqs/index.html/
[6] https://www.gao.gov/assets/gao-18-480.pdf.

retain[] title, as required, to 340B drugs shipped to contract pharmacies." Novartis Mot. PI at 25. In fact, covered entities maintain title to the drugs, "as required," throughout the entire process. Covered entities purchase the drugs at 340B prices and direct the shipments to their contract pharmacies. The sale is to the covered entity, which is the entity that receives savings and revenue contemplated by the 340B statute. At no point does the contract pharmacy place an order for or purchase the drugs. A 2014 HHS Office of Inspector General ("OIG") report on contract pharmacies confirmed that "the *covered entity purchases* . . . the drug at the discounted 340B price and has it delivered to the contract pharmacy." HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014) ("2014 HHS-OIG Report") (emphasis added)[7]; *see also* Contract Pharmacy Notice, 61 Fed. Reg. at 43,552 ("The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity."). The contract pharmacy is merely a covered entity's dispensing location.

The alternative to the replenishment model is for the pharmacy to maintain a supply of drugs that the covered entity has pre-purchased at 340B discounts. *See* 2014 HHS-OIG Report at 5 (discussing "pre-purchased inventory model"). 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 just that—an expense to the covered entity in advance of a potential prescription. Such inventory would go to waste if it expires and is never dispensed. 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. Even if that information were available, a pre-purchased inventory model introduces an element of risk because it

[7] https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp.

requires a busy pharmacist or technician to select the correct inventory when dispensing. 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 to the extent that the contract pharmacy filled prescriptions for the covered entity's own patients, as determined outside the bustle of the pharmacy environment.

Novartis's misunderstanding about the replenishment model extends to its impact on Medicaid duplicate discounts. Novartis Mot. PI at 9. The replenishment model actually helps *prevent* 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* HRSA, *Duplicate Discount Prohibition*.[8] Patients are often retroactively enrolled in Medicaid, and an individual's Medicaid status may not be known at the time a prescription is filled. Because replenishment occurs after the point of sale, the covered entity by then has updated information on its patients' Medicaid status. Far from being a "scheme," the replenishment model helps ensure that manufacturers are protected from paying duplicate discounts.

There is nothing nefarious or unusual about replenishment inventory systems. As the HHS OGC explained, replenishment is a common inventory management tool in many enterprises. Advisory Op. at 6 n.6. Moreover, the Supreme Court has endorsed an inventory replenishment system as compliant with a statutory scheme analogous to 340B. In *Abbott Laboratories v. Portland Retail Druggists Ass'n, Inc.*, the Supreme Court analyzed whether hospital purchases

[8] https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html. Other covered entities "carve in" Medicaid patients by furnishing 340B discounted drugs to Medicaid patients and then informing the state Medicaid program of the 340B purchases. *Id.*

through group purchasing organizations are consistent with federal antitrust law, which permits certain health care providers to purchase discounted drugs for some patients (as does 340B). *Abbott Laboratories 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.

II. Novartis Seeks to Undo a Statutorily Required Program In Which It Participated for More Than Two Decades

Novartis asks this Court to set aside the HHS May 17 letter and prohibit Defendants from pursuing any enforcement actions against Novartis' unlawful act—effectively asking the Court to declare that Novartis has no obligation to ship or otherwise facilitate the transfer of 340B discounted drugs to contract pharmacies. Such an outcome would upset more than two decades of practice, free Novartis from its legal and contractual obligations, run counter to legislative intent, and significantly damage the viability of the nation's health care safety-net. Until Novartis and other drug companies unilaterally violated federal law and their contracts with HHS, covered entities relied on contract pharmacies to best serve their patients' pharmaceutical needs, consistent with Congress's intent and HHS's longstanding interpretations of both Sections 330 and 340B of the Public Health Service Act.[9] Congress intended drug manufacturers to honor their statutory and contractual obligations to provide discounted drugs to covered entities, allowing covered entities to rely on 340B savings and revenue to fund crucial aspects of their safety-net operations.

Despite honoring contract pharmacy arrangements for at least twenty-four years, in

[9] Federally qualified health centers ("FQHCs") receive, or are eligible to receive, federal grant funding under Section 330 of the Public Health Service ("PHS") Act to serve four general patient populations: residents of federally-designated medically underserved areas; homeless populations; migrant and seasonal farmworkers; and residents of public housing. 42 U.S.C. § 254b(a)(1).

August of 2020, Novartis informed covered entities it would no longer honor contract pharmacy arrangements for covered entities that refuse to provide all of their claims data for 340B drugs purchased through contract pharmacies to a system called 340B ESP. *See* Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020), VLTR_5640-42. Novartis has since retreated, in part, making submission of claims data to 340B ESP voluntary and honoring contract pharmacy arrangements for pharmacies located within a 40-mile radius of the parent site for hospital covered entities. *See* Email and letter from Dan Lopuch to RADM Krista M. Pedley (Nov. 13, 2020), VLTR_7740-51. Notably for Amici, which are eligible for the 340B Program by virtue of receiving federal grant funds, Novartis also exempted federal grantees and sub-grantees from its unlawful policy. Although Amici and other federal grantees continue to receive 340B pricing on Novartis's drugs dispensed at contract pharmacies, a decision by this Court in favor of Novartis would impact all covered entity types by setting a dangerous precedent that may encourage Novartis to revoke this exemption and implement the more restrictive policies that other manufacturers have already adopted.

Led by drug manufacturer Eli Lilly, and apparently in concert with Novartis, other drug manufacturers took strikingly similar actions to halt 340B pricing on drugs shipped to contract pharmacies, effective during September and October 2020. *See* HRSA, *Manufacturer Notices to Covered Entities* (July 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf; Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020) ("Lilly LDP"), https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf; Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020), https://www.rwc340b.org/wp-

content/uploads/2020/12/Sanofi-340B-Program-Integrity-Initiative-Notification-7.2020.pdf; Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020), http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf. Three months later, Novo Nordisk, Inc. and United Therapeutics Corporation likewise adopted limitations similar to Novartis and other drug manufacturers. Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020), https://bit.ly/2NQlzpc; Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020), https://bit.ly/3pNrfgZ. Hundreds of other drug company participants continue to honor their contract pharmacy obligations, consistent with established practice, but these drug companies may be emboldened to follow the lead of Novartis and its like-minded peers if the May 17 letter is invalidated.

HHS, through its Health Resources and Services Administration ("HRSA"), has consistently interpreted the 340B statute to require drug companies to sell discounted drugs for shipment to covered entities' contract pharmacies. *See, e.g.*, Contract Pharmacy Notice, 61 Fed. Reg. at 43,549–50 ("There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. . . . Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities."); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,275 (Mar. 5, 2010). HHS confirmed this longstanding interpretation in its May 17 letter to Novartis, noting that "[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." VLTR_5-6.

In 1996, HRSA acknowledged that covered entities were already using contract pharma-

cies to dispense 340B drugs. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550 ("[A] number of large organizations" were using a contract pharmacy model, which was developed "as early as 1993"). At that time, HRSA explained why contract pharmacies are essential for the "many covered entities" that "do not operate their own licensed pharmacies":

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

Contract Pharmacy Notice, 61 Fed. Reg. at 43,549.

When Congress created the 340B Program in 1992, it had every reason to anticipate that FQHCs, Ryan White Clinics ("RWCs"), and other covered entities would use pre-existing authority and flexibility to provide drugs to their patients through contracts with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy. As community and patient-based providers, FQHCs necessarily have flexibility to determine how best to meet the needs of their patients and communities, but FQHCs must—and do—use any 340B savings and revenue (as well as any other income generated from grant-supported activities) to further their health center projects. 42 U.S.C. § 254b(e)(5)(D). FQHCs have long had an express grant of authority to provide their services, including pharmacy services, either directly through their own staff or through contracts or cooperative arrangements with other entities, or a combination thereof. *See*, *e.g.*, Public Health Service Act, Pub. L. 78-410, § 330(a), 58 Stat. 682, 704 (1944) ("For purposes of [Sec. 330], the term 'health center' means an entity that serves a population that is medically underserved . . . either through the staff an (sic) supporting resources of the center or through contracts or cooperative arrangements"); Special Health Revenue Sharing Act of

1975, Pub. L. 94-63, § 501, 89 Stat. 304, 342–43 (1975) (amending § 330(a) of the Public Health Service Act to read: "For purposes of this section, the term 'community health center' means an entity which either through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities provides" health care services, including "pharmaceutical services").

Novartis argues that "the statute does not require manufacturers to agree to ship the purchased drugs to some remote pharmacy for dispensing to patients" and suggests that the agency relationship between covered entities and their contract pharmacies is a fiction. Novartis Mot. PI at 13-14. But Novartis and other manufacturers continue to sell drugs to hospital covered entities to be distributed through contract pharmacies, albeit at much higher prices than the 340B discounted price. Many hospital covered entities have discontinued purchasing drugs through their contract pharmacies from Novartis and other manufacturers that have adopted policies similar to Novartis's. Other hospital covered entities, however, continue to purchase drugs from Novartis and those other manufacturers for shipment to contract pharmacies, but at much higher, non-340B prices. Novartis, therefore, recognizes that an agency relationship exists when it is able to sell drugs to a covered entity through its contract pharmacy at non-discounted prices.

Contract pharmacy arrangements are not unique to the 340B Program. They are a well-established means for non-profit health care providers to dispense drugs to their patients. In 2010, the Federal Trade Commission ("FTC") recognized the right of certain non-profit organizations to contract with for-profit retail pharmacies to dispense discounted drugs within the parameters of the Robinson-Patman Antidiscrimination Act ("Robinson-Patman Act") and the Non-Profit Institutions Act ("NPIA"). *See* Federal Trade Commission, University of Michigan

Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).[10] Both the 340B statute and NPIA provide for the purchase, and restrict the resale, of discounted drugs by non-profit healthcare entities. 15 U.S.C. § 13c; 42 U.S.C. § 256b(a)(5)(B). The NPIA provides an exemption from antitrust laws for certain resales of discounted drugs purchased by a non-profit hospital. The FTC examined and approved the exact contract pharmacy model at issue here, with only one difference—the drugs dispensed by the contract pharmacies were subject to discounts obtained under the NPIA, not the 340B statute. *Id.*

The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). When HHS formally recognized the contract pharmacy model in 1996, it acknowledged that drug manufacturers were already, either directly or through wholesale distributors, shipping 340B drugs purchased by covered entities to contract pharmacies. Contract Pharmacy Notice, 61 Fed. Reg. at 43,550. All but a handful of the hundreds of drug manufacturers participating in the 340B Program continue to do so.

Covered entities have long used 340B Program savings and revenue as Congress intended: to enable and expand health care services to populations desperately in need of care, including populations affected by a public health crisis or serious chronic conditions. Money saved or generated by covered entities through the 340B Program covers the cost of medications for uninsured or underinsured patients, and funds expanded access to necessary medical and

[10] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf. Congress enacted the Robinson-Patman Act to protect small businesses from larger businesses using their size advantages to obtain more favorable prices and terms from suppliers and to prohibit discrimination in the sale of fungible products, including drugs. 15 U.S.C. §§ 13–13b. The Robinson-Patman Act added the NPIA, which permits manufacturers to sell discounted medical supplies, including drugs, to certain non-profit entities. *Id*. § 13c.

crucial enabling services. These services include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

Novartis attacks HHS's May 17 cease-and-desist letter and HHS's interpretation of the 340B statute to prolong its unprecedented and self-serving refusal to provide covered entities access to drugs at 340B discount pricing in violation of federal law. Novartis ignores that, for decades, covered entities have, as Congress intended, structured their safety-net operations in reliance on 340B discounts, which are often accessible only through contract pharmacies.

III. Granting Novartis's Motion for Preliminary Injunction Would Set a Dangerous Precedent, Inflict Significant Harms on All Covered Entities and Their Patients, and Compromise Vital Safety-Net Services Throughout the Nation

Novartis claims that its restrictive contract pharmacy policy was formulated in a way that would "better protect the program's integrity and ensure that the program's discounts benefit vulnerable patients." Novartis Mot. PI at 26. However, nowhere in Novartis's court filings does it discuss the vast uncompensated or undercompensated safety-net services *currently* provided by covered entities by virtue of 340B savings and revenue, much of which is attainable only from contract pharmacy arrangements. Covered entities are on the front lines of caring for our nation's most vulnerable patients and use 340B discounts to support their missions of increasing access to care, improving health outcomes, and fortifying the nation's safety net. Novartis seeks to upend the 340B Program by asking the Court to override Defendants' enforcement of the 340B statute and affirm Novartis's claim that it is not obligated to ship to any covered entity's contract pharmacy. If it succeeds, Novartis could revoke the current exemption from its unlawful policy that it provides for eligible federal grantees that participate in the 340B program.

Denying 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(II), at 12 (1992). Indeed, drug manufacturers' deprivation of 340B Program benefits has already harmed covered entities, their patients, and their broader communities, because covered entities have had to reduce critical services supported with 340B-derived funding. Eliminating 340B contract pharmacy arrangements will directly and indirectly harm our nation's most vulnerable communities by denying them affordable medications, critical health care, and related services that covered entities are able to provide through 340B Program participation. A decision favorable to Novartis will signal to it and other drug companies that they are authorized to stop shipping covered entity-purchased drugs to contract pharmacies. Just the day before this filing, drug manufacturer Boehringer Ingelheim Pharmaceuticals, Inc., became the most recent manufacturer to announce its policy to ignore contract pharmacy arrangements under its own unilateral rules and exceptions. Such an outcome could cause many safety-net providers to shut their doors. These outcomes would be tragic at any time, but are unconscionable in the midst of the now 15-month battle led by covered entities against the COVID-19 pandemic.

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 offer discounted drugs to financially needy patients. For example, FamilyCare, a West Virginia-based FQHC, has a drug discount program that allows indigent patients to pay only FamilyCare's cost for the drug. Glover Aff. ¶ 17.[11]

[11] The following declarations were originally submitted as exhibits in a lawsuit by three Amici against HHS, Mot. for TRO and Prelim. Inj., RWC-340B v. Azar, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24, (stayed Jan. 13, 2021): Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (Ex. A. "Glover Aff."); Declaration of Peter

Because 340B discounted prices are significantly lower than non-340B prices, patients who relied on obtaining medications at the 340B cost now have to pay much higher costs. Glover Aff. ¶ 30. Vermont-based FQHC Little Rivers operates a similar drug discount program that subsidizes the costs of drugs for financially needy patients. Auclair Aff. ¶ 18 (patients pay a percentage of costs, including $0, on an income-based sliding scale).[12] Springhill Medical Center ("Springhill"), located in Springhill, Louisiana, operates a "Cash Savings Program," which helps uninsured individuals or individuals who must meet a high deductible with paying for their prescription drugs. Johnson Aff. ¶ 11. Springhill only charges the 340B price and a dispensing fee to patients who qualify for Springhill's Cash Savings Program. Johnson Aff. ¶ 11. Little Rivers, FamilyCare, Springhill, and other covered entities, and/or their patients, are now bearing the increased cost of certain manufacturers' drugs for prescriptions filled at contract pharmacies. Auclair Aff. ¶¶ 23, 27, 30, 31–34 (Little Rivers will struggle financially if forced to continue incurring these increased costs).

The affidavit from Optimus Health Care Inc. provides just a few examples of the negative impact drug manufacturers' restrictive contract pharmacy policies have already had on covered entity patients. [13] Spinelli Aff. ¶ 12. One Optimus patient, who is visually impaired and does not

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Johnson, RPh, Chief of Pharmacy and Ancillary Services at Springhill Medical Center (Ex. B,. "Johnson Aff."); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (Ex. C, "Dickerson Aff.").

[12] The Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Inc. is Exhibit D to this brief ("Auclair Aff.").

[13] The following declarations were submitted as exhibits to an Administrative Dispute Resolution petition filed by Amicus NACHC, on behalf of 225 FQHC covered entities, against Lilly, Sanofi, and AstraZeneca for unlawful overcharging and are included in the Administrative Record manually filed by Defendants, ECF No. 10 (June 11, 2021). *Nat'l Ass'n of Cmty. Health Ctrs. v. Eli Lilly and Co., et al.*, ADR Pet. No. 210112-2 (Jan. 13, 2021). Declaration of Donald A. Simila, Upper Great Lakes Health Center, Inc. (VLTR_007260-64, "Simila Aff."); Declaration of Lee Francis, Erie Family Health Center (VLTR_007277-83, "Francis Aff."); Declaration of

speak English, previously paid only $15 a month for Lilly insulin prior to Lilly implementing its restrictive contract pharmacy policy. Spinelli Aff. ¶ 23. When she attempted to refill her prescription on September 4, 2020, the price was $270. *Id*. An Optimus patient with gestational diabetes relied on Lilly insulin to help manage her high-risk pregnancy, but twenty-seven weeks into her pregnancy, Lilly's contract pharmacy policy resulted in a price of $320 for her insulin, which she could not afford. Spinelli Aff. ¶ 24. These patients are left without these crucial safety-net protections due to drug companies' policies. Covered entities like Optimus have absorbed these increased costs to date, but they cannot afford to do so indefinitely.

Through contract pharmacies, uninsured and under-insured patients fill prescriptions at convenient locations, often at a greatly reduced cost or no cost at all. FQHCs and RWCs care for increasing numbers of patients with chronic conditions that are managed primarily through prescription drugs. From 2013 through 2018, the number of FQHC patients with HIV increased 66%, patients with substance use disorders increased 80%, and patients with depression, mood and anxiety disorders increased 72%. Sara Rosenbaum et al., *Cmty. Health Ctrs. Ten Years After the Affordable Care Act: A Decade of Progress and the Challenges Ahead*, Geiger Gibson RCHN Community Health Found. Research Collaborative (Mar. 2020).[14]

With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients lost access to lifesaving medications. Novartis has made a tiny concession

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Kimberly Christine Chen, North County HealthCare, Inc. ("NCHC") (VLTR_007300-06, "Chen Aff."); Declaration of Ludwig M. Spinelli, Optimus Health Care Inc., (VLTR_007309, "Spinelli Aff."); Declaration of J.R. Richards, Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus (VLTR_007255-58, "Richards Aff."); Declaration of Heather Rickertsen, Crescent Community Health Center (VLTR_007270-75, "Rickertsen Aff."); and Declaration of Jackson Mahaniah, Lynn Community Health Center (VLTR_007295-98, "Mahaniah Aff.").

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

by continuing to honor 340B pricing on drugs dispensed at a contract pharmacy that is within a 40-mile radius of the hospital covered entity's parent location. This exception does little to aid many indigent covered entity patients who live outside of the arbitrarily set 40-mile area and, thus, cannot access closer pharmacies. Many covered entities that rely on 340B contract pharmacy arrangement serve large geographic areas, most of which are remote, rural, and critically underserved areas, and have thus lost access to discounted drugs in these areas, making it nearly impossible for their patients to access affordable medications. *See, e.g.*, Simila Aff. ¶ 27 ("[t]he travel distance between our northern most and southern most clinical delivery sites is 200 miles"); Francis Aff. ¶ 19 ("Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships."); Chen Aff. ¶ 21 ("NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel [35-180 miles] (one-way trip), to reach the closest of NCHC's in-house pharmacies.").

FamilyCare serves a very large area in rural West Virginia and uses contract pharmacy arrangements across its service area to meet its patients' pharmaceutical needs. Glover Aff. ¶ 19 (noting that its contract pharmacy network enables FamilyCare to provide patients discounted drugs near their homes); *see also* Simila Aff. ¶ 26 ("a single pharmacy for all our patients would severely limit our patients' access to life saving medications"). Hudson Headwaters Health Network ("HHHN"), an FQHC based in upstate New York, provides care to over 90,000 patients across a 7,000 square-mile area that HHS designated as a Health Professional Shortage Area. Slingerland Aff. ¶ 10. HHHN'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.[15] HHHN uses contract pharmacies to minimize the many "geographic and logistical barriers" that its patients face to access affordable medications. Slingerland Aff. ¶ 10. FQHCs have an obligation to ensure that all patients have equal access to services. 42 U.S.C. § 254b(k)(3)(A). Meeting that obligation is logistically impossible if only one pharmacy serves a large service or "catchment" area.

Moreover, in response to the drug companies' actions, covered entities have generally struggled to switch patients' medications to affordable alternatives, especially given that certain medications do not have an approved generic formulation. Chen Aff. ¶ 34; Francis Aff. ¶¶ 24, 26. Many patients want to continue taking familiar medications or are fearful of the negative health impact of changing to a new medication. Richards Aff. ¶ 23; Francis Aff. ¶ 26. Additionally, before a patient can change medications, a medical provider must "review the patient chart, consider comorbidities, and assess the appropriate dosing for the substitute medication." Francis Aff. ¶ 26. If the new drug treatment has different dosing, this could require significant patient education and "provider troubleshooting" to avoid adverse health outcomes. *Id*. The administrative and clinical burden of largescale shifts in patient medication regimes strains covered entity staffing and removes resources from day-to-day patient care.

Crescent Community Health Center (Crescent Community Health) in Dubuque, Iowa, notes that the policies adopted by certain drug companies to cut off 340B pricing at contract pharmacies will cause many patients to lose access to diabetes, hypertension, asthma/chronic obstructive pulmonary disease ("COPD"), and heart disease medications. Rickertsen Aff. ¶ 30. Crescent Community Health's clinical pharmacy director determined that approximately thirty-two uninsured patients will be unable to afford asthma/COPD medications, seventy-six diabetic

[15] The Declaration of D. Tucker Slingerland, M.D. is Exhibit E to this brief ("Slingerland Aff.")

patients will lose access to critical oral medications to treat diabetes, fifty-one patients will lose access to their insulin, and forty patients will lose access to medications to treat other acute and chronic conditions. Rickertsen Aff. ¶ 30. These patients have no choice but to ration their medications, leading to a decline in their health and increased uninsured hospital costs just as rural hospitals cope with the COVID-19 public health emergency. Rickertsen Aff. ¶ 12, 19, 30.

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

Covered entities use 340B Program savings to subsidize the cost of important and 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 income, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992). Many of the programs and services 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 altogether. Auclair Aff. ¶¶ 21-22; Glover Aff. ¶ 15; Johnson Aff. ¶ 10; Simila Aff. ¶ 18; Slingerland Aff. ¶ 7. Congress designed the 340B Program to provide a funding stream for just these sorts of programs and services.

Covered entities provide, among other services, case management to assist patients with transportation, insurance enrollment, links to affordable housing resources, food access, patient care advocacy, in-home support, health screenings, and education for chronic health care conditions. Auclair Aff. ¶¶ 12–16, 22 (noting provision of behavioral health services at local public schools for students and families); Glover Aff. ¶¶ 11, 14–15; Slingerland Aff. ¶ 7 (noting that 340B savings are used 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"); Johnson Aff. ¶ 10 ("Springhill provides many services to its community including participation in community health fairs at which it provides free health screenings."). Case management and care coordination are particularly critical for homeless and indigent individuals, who require these services to encourage their use of necessary primary and other health care services. Auclair Aff. ¶ 17; Glover Aff. ¶ 26; *see also* 42 U.S.C. § 254b(a)(1) (designating the homeless as one of four patient populations served); RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020) (Ryan White patients are more likely to be homeless than general HIV/AIDS population). Education and in-home assistance for patients with chronic health conditions are also vitally important for disease management and prevents exacerbation or deterioration that would require more costly care. Glover Aff. ¶¶ 15, 27; *see also* NACHC, *Cmty. Health Ctr. Chartbook 2020* (Jan. 2020), Figs. 1-11 (health center patients diagnosed with a chronic health condition grew 25% from 2013 to 2017), 1-10 (21% of FQHC patients have diabetes compared to the national rate of 11%), http://www.nachc.org/wp-content/uploads/2020/01/Chartbook-2020-Final.pdf.

Covered entities also rely on 340B funding to provide a range of other critical services responsive to serious ongoing public health crises, such as medication assisted treatment programs and other treatment options for opioid use disorder and fighting the COVID-19 pandemic. *See* Auclair Aff. ¶ 15; Glover ¶ 14; Simila Aff. ¶ 5; Francis Aff. ¶ 9; Slingerland Aff. ¶ 7; *see also* HRSA, Bureau of Primary Health Care, *2018 Health Ctr. Data: Nat'l Data, Other Data Elements* (2019) (FQHCs are "the first line of care in combatting the Nation's opioid crisis," screening and identifying nearly 1.4 million people for substance use disorder, providing medication-assisted treatment to nearly 143,000 patients, providing over 2.7 million HIV tests, and treating 1 in 5 patients diagnosed with HIV nationally).

Drug companies' refusal to provide 340B discounts has already resulted in cuts and reductions to critical services supported in whole or in part with 340B-derived funding. *See, e.g.*, Auclair Aff. ¶ 23 (Little Rivers will lose approximately $44,860.35 annually in 340B savings as a result of the decision by the drug companies not to honor contract pharmacy arrangements); Glover Aff. ¶ 22; Dickerson Aff. ¶ 6; Johnson Aff. 8 (estimating annual revenue loss of $288,000 due to actions of drug manufacturers); Spinelli Aff. ¶¶ 28–30 (estimating annual revenue loss of over $560,000 from drug manufacturers' refusal to offer 340B pricing, which risks vital primary care services including dental, podiatry, clinical nutrition, and others); Richards Aff. ¶¶ 24, 25 (estimating annual loss of $350,000 due to 340B restrictions, forcing reduction in services); Rickertsen Aff. ¶¶ 34, 36 (estimating annual loss of $1 million in revenue and $500,000 to $2 million in increased cost of goods sold, forcing reduction in coverage of patient copays, clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health program). HHHN estimates that it will lose approximately $8,400,000 in revenue due to manufacturer actions to cut off access to 340B drugs at contract pharmacies. Slingerland Aff. ¶¶ 20-23. Community HealthCare System in St. Marys, Kansas recently announced that it is closing its emergency room and reducing its inpatient beds due, in part, to manufacturers' restrictive 340B contract pharmacy policies. WIBW, *Community HealthCare System in St. Marys to close emergency room doors, adjust services* (Apr. 28, 2021).[16]

Without preventive and enabling services, patient health will undoubtedly suffer. Patients will require additional, more expensive health care visits at the Amici's locations and more expensive hospital and specialist care. Auclair Aff. ¶¶ 28–29; Glover Aff. ¶¶ 26–27; *see also*

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

Robert S. Nocon, et al., *Health Care Use and Spending for Medicaid Enrollees in Fed. Qualified Health Ctrs. Versus Other Primary Care Settings*, Am. J. Public Health (Sep. 15, 2016) ("Medicaid patients who obtain primary care at FQHCs had lower use and spending than did similar patients in other primary care settings."). The cost of providing additional health care visits will further strain Amici's and other covered entities' resources.

The drug companies' refusal to offer drugs at 340B discount pricing has also already resulted in covered entities reducing staff. *See, e.g.*, Simila Aff. ¶ 29 (health center forced to reduce staffing for OB/GYN services and planning other major service reductions—including service delivery site closures, employee terminations, reductions in health care providers, and likely closure of OB/GYN, dental, and mental health services); Mahaniah Aff. ¶ 20 (health center preparing to permanently eliminate 5% of employees); Chen Aff. ¶ 42 (likely elimination of clinical pharmacists and closure of one or more rural clinics); Richards Aff. ¶ 25 (significant financial loss will result in reducting clinical and patient services); Slingerland Aff. ¶ 23 (HHHN may be forced to close its Women's Health Center). Covered entities will also have to divert remaining staff to attempt to provide alternative or palliative services to vulnerable patients and seek out additional federal grants or other sources of funding to make up for lost 340B funding. *See, e.g.*, Chen Aff. ¶ 40; Auclair Aff. ¶ 30; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9; Slingerland Aff. ¶ 21. Expending already scarce financial and human resources will further burden tight budgets and cause additional and unbearable operational expenses. Auclair Aff. ¶ 27-28; Glover Aff. ¶ 28; Dickerson Aff. ¶ 9.

Many covered entities, including numerous NACHC and RWC-340B members, as well as Amici Little Rivers and FamilyCare, rely entirely on contract pharmacies to dispense covered outpatient drugs to their patients. *See, e.g*, Auclair Aff. ¶ 19; Glover Aff. ¶ 18; Slingerland Aff. ¶

10. For some covered entities, 340B Program revenue has meant the difference between remaining in operation and closing their doors. For Springhill, the difference between keeping its facilities operational and closing its doors is the net revenue from the 340B Program. Johnson Aff. ¶ 10. For FamilyCare, revenue from its contract pharmacy arrangements is comparatively almost half of the funding it receives from federal grants. Glover Aff. ¶ 21; Dickerson Aff. ¶¶ 4-5. The loss of all 340B savings to the Amici and other FQHCs and RWCs would be even more "devastating" to their operations and the patients they serve. Auclair Aff. ¶ 34; Glover Aff. ¶ 31; Dickerson Aff. ¶ 11; Slingerland Aff. ¶¶ 19-23. Little Rivers currently operates at a loss and FamilyCare's revenue barely exceeds its operating expenses. Dickerson Aff. ¶ 7. In 2019, Little Rivers' average cost per patient was $1,270.64; FamilyCare's average cost per patient was $764.39. HRSA, *Health Ctr. Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited June 30, 2021). Per patient costs will increase dramatically if these providers are burdened with covering the full price of Novartis's drugs. Many covered entities, including Amici Little Rivers and FamilyCare, lack the financial resources necessary to bear the additional costs of drugs for indigent patients.

CONCLUSION

Granting Novartis's motion would significantly harm covered entities, their patients, their staff, and the health care safety-net by freeing Novartis and other drug companies from their obligations under the 340B statute and upending an over two-decades-long status quo upon which all covered entity types depend. HHS's May 17 letter describes what Novartis has understood for decades—drug companies that choose to participate in the 340B federal drug pricing program must offer 340B pricing to covered entities, regardless of where the drugs are dispensed to the covered entity's patients. Amici thus respectfully request that the Court grant HHS's motion for summary judgment and deny Novartis's motion for preliminary injunction.

Dated: July 2, 2021

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THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, in her official capacity as Acting Administrator, Health Resources and Services Administration, et al., Defendants.	Case No. 1:21-cv-01479-DLF

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

Exhibit A	Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare.
Exhibit B	Declaration of Peter Johnson, RPh, Chief of Pharmacy and Ancillary Services at Springhill Medical Center.
Exhibit C	Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center.
Exhibit D	Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Health Care Inc.
Exhibit E	Declaration of D. Tucker Slingerland, M.D., CEO of Hudson Headwaters Health Network.

[1] All prior ECF stamps have been redacted so that the ECF stamps for the United States District Court for the District of Columbia are legible. Exhibits A, B, and C were submitted as exhibits in a lawsuit by three Amici against HHS. Mot. for TRO and Prelim. Inj., *RWC-340B v. Azar*, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 24, (stayed Jan. 13, 2021). Exhibits D and E were submitted with Amici's amicus curiae brief in *Eli Lilly & Co, et al v. Becerra, No.* 1:21-cv-00081-SEB-MJD (S.D. Ind. June 21, 2021), ECF Nos. 120-3, 120-4.

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

AFFIDAVIT

I, 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.

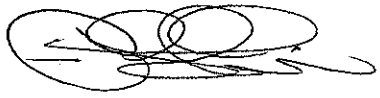
30) FamilyCare's Prescription Savings Program is offered for drugs that are purchased with 340B discounts. If FamilyCare cannot purchase drugs manufactured by Lilly, AstraZeneca, and Lilly with 340B discounts, those drugs will no longer be part of its program. FamilyCare does not have funds allocated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

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 C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

AFFIDAVIT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[*Signature on next page*]

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

Respectfully submitted,

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

Exhibit D

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

ELI LILLY AND COMPANY, et al.,	)	
	)	
Plaintiffs,	)	
	)	Case No. 1:21-cv-81-SEB-MJD
v.	)	
	)	
Xavier Becerra, Secretary	)	
U.S. Department of Health and Human	)	
Services, et al.,	)	
Defendants	)	
_____	)	

AFFIDAVIT

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

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

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

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

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

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

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

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

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

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

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

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

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

[2] Source: Health Resources and Services Administration, Bureau of Primary Care: https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE#titleId
[3] Source: Little Rivers 2019 Annual Report, p. 10 (available at littlerivers.org).
[4] Source: Little Rivers 2019 Annual Report, p. 6 and 10 (available at littlerivers.org).

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

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

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

14) Little Rivers offers behavioral health services at local public schools that include counseling for students and families. At some public schools, Little Rivers provides extensive training and education for faculty and staff regarding resiliency, classroom

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

behaviors, and trauma-informed approaches.[8] (Trauma-informed care recognizes the presence of trauma symptoms and the role that trauma may play in an individual's life.)

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

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

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

18) Little Rivers offers a sliding fee scale to patients whose incomes are under 200% of the Federal Poverty Level. This discount includes access to prescription drugs through our 340B program when they receive a prescription as the result of health care services provided by Little Rivers. If a patient's income is at or below 100% of the federal poverty level, and the patient does not have insurance coverage for retail prescription

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

drugs, Little Rivers pays 100% of that patient's drug costs. For patients whose income is between 100% and 200% of the federal poverty level, Little Rivers pays a percentage of the cost of the drug (25%, 50% or 75%, depending on the patient's income level). Most of our patients in the sliding fee program qualify for the 100% discount.

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

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

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

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

23) Based on its calculations of the 340B savings that Little Rivers has historically achieved through filling prescriptions for drugs manufactured by Defendant, Little Rivers will lose approximately $44,860.35 annually in 340B savings as a result of the decision by

Defendant not to honor contract pharmacy arrangements. This calculation was based on data from the period September 1, 2020 to December 30, 2020 and extrapolated to an annual calculation.

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

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

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

27) Little Rivers will have to cut or eliminate some of the services that it provides, or make salary cuts to current employees, if Little Rivers loses $44,860.35 annually as the result of the actions of Defendant.

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

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

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

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

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

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

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

33) The loss of $44,860.35 annually in 340B savings as the result of the actions of Defendant will have a severe financial impact on Little Rivers. Little Rivers strives to keep three months' operating expenses in reserves, which is consistent with sound business practices and guidance from the Bureau of Primary Care within the Health Resources and Services

Administration, the federal agency that administers the FQHC program. Little Rivers often struggles to meet this goal and the loss of $44,860.35 annually will exacerbate the problem and impose undue operational and financial burdens on Little Rivers.

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

35) Humalog® KwikPen is a small, lightweight pen that is prefilled with insulin for use by insulin-dependent diabetics at mealtime. 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 Humalog® KwikPen. Hudson Headwaters provided this pricing information, effective on May 23, 2021:

NDC	Average Wholesale Price	Wholesale Acquisition Cost	340B Cost
00002879959-HUMALOG KWIK PEN 5X3ML	$636.48	$530.40	$0.16

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

37) Defendant has a policy under which it provides insulin at 340B prices through contract pharmacies but that policy requires that: 1) the covered entity provide the 340B price at

point of sale to all patients regardless of ability to pay; (2) the contract pharmacy not charge any dispensing fees; (3) no insurer or other payer is billed for the drug; (4) the covered entity provide claims level data to demonstrative compliance. The Lilly policy is completely unworkable. Contract pharmacies will not dispense drugs without charging a dispensing fee and there is no reason that covered entities should be required to submit claims level detail in order to take advantage of this program.

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

39) The U.S. Department of Health and Human Services ("HHS") has implemented a statutorily mandated Administrative Dispute Resolution ("ADR") process for 340B covered entities and manufacturers to resolve certain 340B program disputes. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.20-10.24. On February 4, 2021, Little Rivers filed an ADR petition against AstraZeneca. The Little Rivers ADR petition contends that AstraZeneca has violated the 340B statute by declining to ship 340B discounted drugs to Little Rivers' contract pharmacies.

40) If the injunction against enforcement of the ADR process against Defendant is lifted, Little Rivers will have the ability to bring an ADR petition against Lilly to request relief from its policy not to offer 340B pricing at contract pharmacies.

[*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 26th day of May 2021.

Respectfully submitted,

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

Exhibit E

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

	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

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

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

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

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ESPINOSA, Acting Administrator, Health Resources and Services Administration, et al., Defendants.	Case No. 1:21-cv-01479-DLF

CERTIFICATE REQUIRED BY LCVR 26.1 OF THE LOCAL RULES OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

The undersigned counsel of record for National Association of Community Health Centers, Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center (collectively the "Amici") certify that to the best of their knowledge and belief, there are no parent companies, subsidiaries, affiliates, or companies which own at least 10% of the stock of the Amici which have any outstanding securities in the hands of the public. All Amici are not-for-profit organizations and do not issue stock. These representations are made in order that judges of this Court may determine the need for recusal.

Respectfully submitted,

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Counsel for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc, and FamilyCare Health Center

Dated: July 2, 2021

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, Acting Administrator, Health Resources and Services Administration, et al., Defendants.	Case No. 1:21-cv-01479-DLF

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

The National Association of Community Health Centers, Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc., dba FamilyCare Health Center (collectively the "Amici"), have moved to file an Amicus Curiae brief in support of Defendants' Motion for Summary Judgment. Being duly advised, the Court now GRANTS Amici's request.

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

DATE: _____, 2021

_____
The Honorable Judge Dabney L. Friedrich
United States District Court
District of Columbia