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

Attorneys for Amici Curiae National Association of Community Health Centers, Ryan White Clinics for340B Access, Little Rivers Health Care, Inc., and WomenCare, Inc.

NOVO NORDISK INC., *et. al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY Civil Action No. 3:21-cv-806-FLW-LHG

BRIEF OF AMICI CURIAE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, RYAN WHITE CLINICS FOR 340B ACCESS, LITTLE RIVERS HEALTH CARE, INC., AND WOMENCARE, INC. IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Steven A. Haber
Obermayer Rebmann Maxwell & Hippel LLP
1120 Route 73, Suite 420
Mt. Laurel, NJ 08054
(856) 857-1422

Matthew Sidney Freedus
Rosie Dawn Griffin
Brendan Michael Tyler
Feldesman Tucker Leifer Fidell LLP
1129 20th St. NW, 4th Floor
Washington, DC 20036
(202) 466-8960
Counsel to Amicus Curiae NACHC

Ronald S. Connelly
Powers Pyles Sutter and Verville, PC
1501 M Street, Northwest, 7th Floor
Washington, DC 20005
(202) 872-6762
Counsel to Amici Curiae RWC-340B, Little Rivers Health Care, Inc, and WomenCare, Inc.

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RWC-340B v. Azar, No. 1:20-cv-02906 (D.D.C. Nov. 23, 2020) (stayed Jan. 13, 2021) 21

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15 U.S.C. §§ 13–13b 21

42 U.S.C. § 254b(a)(1) 13, 38

42 U.S.C. § 254b(e)(5)(D) 19

42 U.S.C. § 254b(k)(3)(A) 35

42 U.S.C. § 256b(a)(5)(A) 11

42 U.S.C. § 256b(a)(5)(B) 22

Public Health Service Act, Pub. L. 78-410, § 330(a), 58 Stat. 682, 704 (1944) 19

Special Health Revenue Sharing Actof 1975, Pub. L. 94-63, § 501, 89 Stat. 304, 342–43 (1975) 19, 20

Regulations

42 C.F.R. § 412.92 27

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Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) ..... passim

Other Authorities

American Diabetes Association, Diabetes Care, Insulin Access and Affordability Working Group: Conclusions and Recommendations, Jan. 2018, *available at* https://care.diabetesjournals.org/content/41/6/1299..... 28, 30

Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020), https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf.....15

Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf 21

GAO, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, at 28 (2011), https://www.gao.gov/assets/gao-11-836.pdf 8

H.R. Rep. No. 102-384(II) 22, 25, 37

HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp..9

HRSA, Bureau of Primary Health Care, *2018 Health Center Data: National Data, Other Data Elements* (2019) 39

HRSA, *Duplicate Discount Prohibition*, https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html 11

HRSA, *FAQs, What is a "ship to bill to" arrangement?*, *https://ww*w.hrsa.gov/opa/faqs/index.html/.....7

HRSA, *Health Center Program Data*, https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited June 25, 2021) ..43

HRSA, *Manufacturer Notices to Covered Entities* (July 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf 14

https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf 17

Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Senate Report, 6, *available at* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL).pdf.....28

Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020) 15

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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 15

Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020), https://bit.ly/3pNrfgZ.....16

Letter from Members of Congress to Alex M. Azar II at 1 (Sept. 14, 2020), ECF No. 36-4 at 1127 4

Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020), https://bit.ly/2NQlzpc 14

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.15

Letter from United States Senators to Alex M. Azar II at 1 (Sept. 17, 2020) 4

NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-11, http://www.nachc.org/wp-content/uploads/2020/01/Chartbook-2020-Final.pdf.39

Notice Regarding Limitation on Hospital Contract Pharmacy Distribution (Dec. 1, 2020), VLTR_007754-58 4

Rachel Gillett & Shay*anne Gal*, *One Chart Reveals How the Cost of Insulin Has Skyrocketed in the US, Even Though Nothing About it Has Changed*, Business Insider (Sept. 18, 2019), https://www.businessinsider.com/insulin-price-increased-last-decade-chart-201 29

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).....41

RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020) 38

Sara Rosenbaum *et al.*, *Cmty. Health Ctrs. Ten Years After the Affordable Care Act: A Decade of Progress and the Challen*ges *Ahead*, Geiger Gibson RCHN Community Health Foundation Research Collaborative (Mar. 2020), https://www.rchnfoundation.org/wp-content 32

U.S. Bureau of Labor Statistics, *CPI Inflation Calculator*, https://www.bls.gov/data/inflation_calculator.htm 29

WIBW, *Community HealthCare System in St. Marys to close emergency room doors, adjust services* (Apr. 28, 2021), https://www.wibw.com/2021/04/28/community-healthcare-system-in-st-marys-to-close-emergency-room-doors-adjust-services/ 41

INTRODUCTION

Plaintiffs ask this Court to radically revise the 340B drug discount program ("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 entities—including Amici Little Rivers Health Care, Inc. ("Little Rivers") and FamilyCare Health Centers ("FamilyCare") and many of the members of the National Association of Community Health Centers ("NACHC") and Ryan White Clinics for 340B Access ("RWC-340B")—can obtain 340B discounted drugs. Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively "Novo") attempt to create a boogeyman of for-profit contract pharmacy companies by misrepresenting how covered entities' 340B contract pharmacy arrangements actually work. No party to this litigation is a 340B covered entity. Amici, which are covered entities and their membership organizations, submit this brief to inform the Court of how contract pharmacy arrangements enable safety-net health care providers to receive critically necessary discounts on outpatient drugs. If Novo 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.

Novo 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 late 2020, Novo unilaterally reinterpreted 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, Novo has halted 340B contract pharmacy shipments only for purchases by hospitals participating in the 340B Program, and it continues to ship 340B drugs to contract pharmacies when the drugs are ordered by grantees, such as Amici.

Amici appreciate that Novo continues to honor its obligations to provide 340B pricing to Amici. Critically, however, Novo 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 if those drugs are distributed through a contract pharmacy. Thus, if the Court holds for Novo, Novo 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, which currently refuse to ship 340B discounted drugs to Amici's contract pharmacies. The nation's healthcare safety-net and countless underserved communities will thus continue to be significantly harmed if the Court supports Novo'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,[1] and with both houses of Congress unmistakably opposed to the unprecedented

[1] Email and letter from Farruq Jafery to Krista M. Pedley, and attached Notice Regarding Limitation on Hospital Contract Pharmacy Distribution (Dec. 1, 2020), VLTR_007754-58; HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, ECF No. 19-5 at 38–45 ("Advisory Op.") (withdrawn June 18, 2021).

actions by Novo and other drug companies,[2] Novo turned to the judiciary to condone its unlawful behavior.[3] Novo currently seeks to gut this vital federal drug pricing program by asking the Court to declare that the 340B statute does not require Novo to honor 340B prices on drugs shipped to contract pharmacies and to vacate and override a clear and well-reasoned HHS cease-and-desist letter finding that Novo is in violation of the 340B statute and commanding it to cease its unlawful behavior.[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, Novo 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. Novo cannot dismiss covered entities and their patients by

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[2] *See* Letter from Members of Congress to Alex M. Azar II at 1 (Sept. 14, 2020), ECF No. 36-4 at 1127; Letter from United States Senators to Alex M. Azar II at 1 (Sept. 17, 2020), ECF No. 36-4 at 1146; Letter from House Committee on Energy & Commerce to Alex M. Azar II at 1 (Sept. 3, 2020), ECF No. 36-4 at 1112.

[3] Novo's litigation strategy is not limited to this suit. *See, e.g.*, Notice of Motion and Motion to Intervene, ECF No. 62, *Am. Hosp. Ass'n, et al v. Azar*, 4:20-cv-08806-YGR, (N.D. Cal. Jan. 10, 2021) (case dismissed).

[4] Letter from Diana Espinosa to Farruq Jafery (May 17, 2021) ("May 17 letter"), ECF No. 40-2.

shining the spotlight on for-profit retail pharmacies. The truth is that Novo's unlawful acts damage covered entities that treat the nation's most vulnerable patients.

Novo would have the Court rewrite the 340B statute to exclude many covered entities from participating in the 340B Program and simultaneously deprive covered entities of their one and only statutory remedy against Novo. In essence, Novo wants the lucrative benefit of its Pharmaceutical Pricing Agreement with HHS—having its products covered under Medicare Part 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 Novo'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 to dismiss or, in the alternative, for summary judgment, ECF No. 37, and oppose Plaintiffs'

cross-motion for summary judgment ECF No. 45 ("Novo Mot. SJ"). Simply put: Amici urge the Court to protect the nation's safety-net as Congress intended.

ARGUMENT

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

Novo mischaracterizes the contract pharmacy model as an unconstitutional, massive forced giveaway to large, corporate chain pharmacies. Novo Mot. SJ at 2, 29-33. 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.

Novo 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. Novo alleges that growth in the 340B Program has led to "significant waste and abuse" and that "opportunities for unlawful distributions to non-patients and other abuses have increased" because many contract pharmacies rely on the replenishment model for distributing 340B drugs. Novo Mot. SJ at 10-11 (citing GAO, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, at 28 (2011).[6] Contrary to Novo'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.

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[5] https://www.hrsa.gov/opa/faqs/index.html/
[6] https://www.gao.gov/assets/gao-11-836.pdf.

Moreover, Novo mischaracterizes the relationship between covered entities and contract pharmacies, alleging that a covered entity "never takes title to…the 340B discounted drug." Novo Mot. SJ at 11. In fact, covered entities maintain title to the drugs 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."). Thus, 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

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

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 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.

Novo's misunderstanding about the replenishment model extends to its impact on Medicaid duplicate discounts. Novo Mot. SJ at 11. 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 the prescription is filled. Since replenishment—when appropriate—occurs well after the point of sale, the covered entity by then has updated information on its patients' Medicaid status. The replenishment model thus 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 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.

[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.*

1, 3-4 (1976). The Supreme Court *recommended* a replenishment system in which providers manage their inventories according to general accounting principles by adjusting inventories at a later date. *Id*. at 20-21.

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

Novo not only asks this Court to set aside the HHS May 17 letter, but also to declare that Novo is not required 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 Novo from its legal and contractual obligations, run counter to Congress's intentions for covered entities, and significantly damage the viability of the nation's health care safety net. Until Novo 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

[9] 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).

savings and revenue to fund crucial aspects of their safety-net operations.

Despite honoring contract pharmacy arrangements for at least twenty-four years, in December of 2020, Novo sent letters to covered entities informing them of its new contract pharmacy policy under which it would no longer offer 340B discounts on drugs purchased by 340B hospitals and dispensed through the hospitals' contract pharmacy arrangements, effective January 1, 2021. *See* Letter from Novo Nordisk Inc. to Covered Entities (Dec. 1, 2020);[10] Notably for Amici, which are eligible for the 340B Program by virtue of receiving a federal grant or subgrant, Novo has exempted federal grantees and sub-grantees from its unlawful policy. Although Amici and other federal grantees continue to receive 340B pricing on Novo's drugs dispensed at contract pharmacies, a decision by this Court in favor of Novo would impact all covered entity types by setting a dangerous precedent that may encourage Novo to revoke this exemption and implement the more restrictive policies of other manufacturers.

Apparently in concert, Novo joined five other drug companies that had already taken strikingly similar actions to halt 340B pricing on drugs shipped to contract pharmacies, effective during September and October 2020. *See* HRSA,

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

Manufacturer Notices to Covered Entities (July 2020);[11] Eli Lilly & Co., *Limited Distribution Plan Notice for Eli Lilly and Company Products* (Sept. 1, 2020) ("Lilly LDP");[12] Letter from Gerald Gleeson, Vice President & Head, Sanofi US Market Access Shared Services, SanofiAventis U.S. LLC (July 2020);[13] Letter from Odalys Caprisecca, Exec. Dir., Strategic Pricing & Operations, AstraZeneca PLC (Aug. 17, 2020);[14] Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Aug. 17, 2020);[15] Letter from Kevin Gray, Senior Vice President, Strategic Operations, United Therapeutics Corporation (Nov. 18, 2020).[16] 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 Novo and its like-minded peers if the May 17 letter is invalidated.

HHS, through its Health Resources and Services Administration ("HRSA"),

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[11] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

[12] https://www.rwc340b.org/wp-content/uploads/2020/12/Eli-Lilly-and-Company_Limited-Distribution-Plan_Public-Notice_Sept-1-2020.pdf

[13] https://www.rwc340b.org/wp-content/uploads/2020/12/Sanofi-340B-Program-Integrity-Initiative-Notification-7.2020.pdf.

[14] http://www.avitapharmacy.com/blog/wp-content/uploads/2020/09/AstraZeneca-Retail-Communication-340B-Final.pdf.

[15] Novartis has since retreated, in part, by shipping to federal grantees' contract pharmacies and to hospital contract pharmacies within a 40-mile radius. Letter from Daniel Lopuch, Vice President Novartis Managed Mkts. Fin., Novartis Pharmaceuticals Corp. (Oct. 30, 2020).

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

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 Novo, 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."[17]

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

[17] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novo-nordisk-covered-entities.pdf.

> 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").

Novo argues that the agency relationship between covered entities and their contract pharmacies is a fiction. Novo Mot. SJ at 28-29. But Novo and other manufacturers are currently selling drugs to covered entities to be distributed through their 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 Novo and other manufacturers that have adopted policies similar to Novo's. Other hospital covered entities, however, continue to purchase drugs from Novo and those other manufacturers for shipment to contract pharmacies, but at much higher, non-340B prices. Novo, 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").[18] *See* Federal Trade Commission, University of Michigan Advisory Op., Letter to Dykema Gossett (Apr. 9, 2010).[19] 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

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[18] 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 by exempting "purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" from the Robinson-Patman Act's prohibitions against price discrimination. *Id.* § 13c.

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

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 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.

Novo 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. Novo 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 Novo's Motion for Summary Judgment Would Set a Dangerous Precedent and Will Inflict Significant Harms on All Covered Entity Types and Their Patients and Compromise Vital Safety-Net Services Throughout the Nation

Novo relies on a press release from its drug manufacturer trade association, PhRMA, and a letter from Adam Fein, a consultant for the pharmaceutical industry, to support its assertion that "allowing contract pharmacies to participate in the 340B program has not benefitted patients." Novo Mot. SJ at 9-10. This statement is false and severely misconstrues how the 340B contract pharmacy program operates. Covered entities provide vast uncompensated or undercompensated safety-net services by virtue of 340B savings and revenue, much of which is attainable only through 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. Novo seeks to upend the 340B Program through a ruling that it is not obligated to ship to any covered entity's contract pharmacy. If it succeeds, Novo 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, Novo's and other 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 Novo will signal to other drug companies that they are authorized to stop shipping covered entity-purchased drugs to contract pharmacies. Such an outcome could cause many safety-net providers to shut their doors. These outcomes would be tragic at any time, but they are unconscionable in the midst of the now 15-month battle that is being 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.[20] 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).[21] Springhill Medical Center ("Springhill"), a not-for-profit, 58-bed

[20] The following declarations are included in the Administrative Record filed by Defendants on May 11, 2021, ECF No. 36 (May 11, 2021): Declaration of Craig Glover, MBA, MA, FACHE, CMPE, President and CEO of FamilyCare (ECF No. 36-8 at 1880, "Glover Aff."); Declaration of Peter Johnson, RPh, Chief of Pharmacy and Ancillary Services at Springhill Medical Center (ECF No. 36-8 at 1892, "Johnson Aff."); Declaration of James D. Duck, Owner of The Corner Drug Store, (ECF No. 36-8 at 1898, "Duck Aff."); Declaration of Terri S. Dickerson, CFO of WomenCare, Inc., dba FamilyCare Health Center (ECF No. 36-8 at 1888, "Dickerson Aff."). The 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).

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

hospital located in Springhill, Louisiana that is designated by the Centers for Medicare and Medicaid Services as a sole community hospital,[22] 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, 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 inability of financially needy patients to access drugs at 340B prices is particularly problematic for insulin-dependent diabetics, whose survival depends on daily access to insulin and who are faced with increasing insulin prices. The astronomical increase in the price for insulin products in recent years is well documented. *See, e.g.*, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Senate Report, 6 ("The WAC [wholesale acquisition cost]

[22] Sole community hospital status is granted to rural hospitals that meet certain criteria to demonstrate that they are the sole source of inpatient care within a particular geographic area. 42 C.F.R. § 412.92.

prices of long- and short-acting insulins have risen steeply.”);[23] American Diabetes Association, Diabetes Care, Insulin Access and Affordability Working Group: Conclusions and Recommendations, Jan. 2018 (“The average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013”).[24] For example, between 2009 and 2019, the list price for a 10-milliliter vial of NovoLog®, a fast-acting insulin produced by Novo, rose from $93 to almost $290, a 212% increase. Rachel Gillett & Shayanne Gal, *One Chart Reveals How the Cost of Insulin Has Skyrocketed in the US, Even Though Nothing About it Has Changed*, Business Insider (Sept. 18, 2019).[25] During the same period, U.S. inflation was only 22%. U.S. Bureau of Labor Statistics, *CPI Inflation Calculator*.[26]

Many covered entities offer patient assistance programs under which, prior to Novo’s new policy on contract pharmacies, a financially needy diabetic patient was able to fill a prescription for NovoLog® at a local contract pharmacy based on the 340B pricing. Now, when a financially needy patient receives an insulin prescription from a hospital, the patient may have to travel long distances to the

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[23] *Available at* https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL).pdf
[24] *Available at* https://care.diabetesjournals.org/content/41/6/1299.
[25] https://www.businessinsider.com/insulin-price-increased-last-decade-chart-2019-9.
[26] https://www.bls.gov/data/inflation_calculator.htm ($1 in January 2009 for buying power in December 2019).

hospital's in-house pharmacy or pay a price that is thousands of times higher and will continue to rise if insulin prices continue on their current trajectory. Novo is increasing the price for insulin at the same time it refuses to offer 340B discounts to hospital covered entities that choose to dispense insulin to their patients through contract pharmacies. Novo's policy is not only financially harmful; it can impact a patient's health. The American Diabetes Association has reported that the high cost of insulin may impact patients' health because patients faced with these high costs "may be less adherent to recommended medication dosing and administration, resulting in harm to their health." American Diabetes Association, Diabetes Care, Insulin Access and Affordability Working Group: Conclusions and Recommendations, Jan. 2018.[27]

This is particularly concerning because Novo is one of only three manufacturers that distribute insulin products in the U.S. The other two manufacturers, Eli Lilly and Sanofi, also restrict access to 340B prices at contract pharmacies, which has resulted in patients leaving the pharmacy without their medications. The affidavit from Optimus Health Care Inc. provides just a few examples of the negative impact Lilly's actions have already had on covered entity patients. Spinelli Aff. ¶ 12. One Optimus patient, who is visually impaired and does not speak English, previously paid only $15 a month for Lilly insulin prior to

[27] *Available at* https://care.diabetesjournals.org/content/41/6/1299.

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. The owner of The Corner Drug Store, a contract pharmacy for Springhill, submitted an affidavit in Amici's lawsuit against Defendants. In the affidavit, The Corner Drug Store stated that several patients were no longer able to afford Sanofi's insulin product, Lantus, because Sanofi no longer allowed the drug to be purchased with 340B discounts. Duck Aff. ¶¶ 4-12. At least two patients who had been paying a 340B price of $17.30 for Lantus were charged $1,360.57 because Sanofi had cut off Springhill's access to 340B pricing for drugs shipped to The Corner Drug Store. Duck Aff. ¶¶ 8, 11. Because of the significant price increase, these patients left the pharmacy without purchasing Lantus.[28] Duck Aff. ¶¶ 4-12. Covered entities like Optimus

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

and Springhill have absorbed these increased costs to date, but they cannot afford to do so indefinitely.

Through contract pharmacies, uninsured and under-insured covered entity patients fill prescriptions at convenient locations, often at a greatly reduced or no cost. 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% (from 115,421 to 191,717), patients with substance use disorders increased 80% (from 506,279 to 908,984), and patients with depression, mood and anxiety disorders increased by 72% (from 2,740,638 to 4,724,691). Sara Rosenbaum et al., *Cmty. Health Ctrs. Ten Years After the Affordable Care Act: A Decade of Progress and the Challenges Ahead*, Geiger Gibson RCHN Community Health Foundation Research Collaborative (Mar. 2020).[29]

With discounted drugs no longer available at covered entities' contract pharmacies, many covered entity patients lost access to lifesaving medications. Some drug manufacturers have made a tiny concession to allow covered entities to use *one* contract pharmacy if they do not operate their own in-house pharmacies, but this exception to their policies does little to aid many indigent covered entity

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

patients who cannot access that one pharmacy.[30] Covered entities serving remote or rural areas in particular have lost access to discounted drugs over large geographic areas, making it nearly impossible for their patients to access affordable medications.[31] *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.");

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[30] Moreover, covered entities must submit documentation to the manufacturers which as caused implementation of these exceptions to take several months for some covered entities.

[31] The following declarations, which are attached to this brief as exhibits, 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. *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. (Ex. B "Simila Aff."); Declaration of Lee Francis, Erie Family Health Center (Ex. C "Francis Aff."); Declaration of Kimberly Christine Chen, North County HealthCare, Inc. ("NCHC") (Ex. D "Chen Aff."); Declaration of Ludwig M. Spinelli, Optimus Health Care Inc., (Ex. E "Spinelli Aff."); Declaration of J.R. Richards, Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus (Ex. F "Richards Aff."); Declaration of Heather Rickertsen, Crescent Community Health Center (Ex. G "Rickertsen Aff."); and Declaration of Jackson Mahaniah, Lynn Community Health Center (Ex. H "Mahaniah Aff.").

Johnson Aff. ¶ 18 (a patient treated at the Springhill outpatient department will have to drive 38 miles to have his or her prescription filled at Springhill's one designated contract pharmacy).

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.[32] 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).

[32] The Declaration of D. Tucker Slingerland, M.D. is submitted as Exhibit I to this brief (Ex. I, "Slingerland Aff.")

Meeting that obligation is logistically impossible if only one pharmacy serves a large service or "catchment" area.

Moreover, in response to 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 presents an unanticipated strain on covered entity staffing, removing resources from day-to-day patient care.

Another distressed covered entity, 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 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 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 program income, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992). Many of the programs and services 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 the prevention of exacerbation or deterioration that would require more costly care. Glover Aff. ¶¶ 15, 27; *see also* NACHC, *Community Health Center Chartbook 2020* (Jan. 2020), Figs. 1-11 (number of health center patients diagnosed with a chronic health condition grew 25% from 2013 to 2017), 1-10 (21% of FQHC patients have diabetes compared to the national rate of 11%).[33]

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 Center Data: National 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).

[33] http://www.nachc.org/wp-content/uploads/2020/01/Chartbook-2020-Final.pdf.

Drug companies' deprivation of 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 annually 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 manufactures 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 $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).[34]

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* 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.

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 (indicating likely elimination of clinical pharmacists and closure of one or more rural clinic

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

locations); Richards Aff. ¶ 25 (significant financial loss will result in reduction in clinical and patient services); Slingerland Aff. ¶ 23 (noting that 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 revenues 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. If Novo revokes its exemption, 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 Center Program Data*.[35] Per patient costs will increase dramatically if these providers are burdened with covering the full price of Novo's drugs. Many covered entities, including Amici Little Rivers and FamilyCare, lack the financial resources necessary to bear the additional costs of drugs for indigent patients. Auclair Aff. ¶ 38.

CONCLUSION

Granting Novo's motion would significantly harm covered entities, their patients, their staff, and the health care safety-net community by freeing Novo and other drug companies from their obligations under the 340B statute, upending an over two-decades-long status quo upon which all covered entity types depend. HHS's May 17 letter describes what Novo has understood for decades—drug companies that choose to participate in the 340B federal drug pricing program are

[35] https://data.hrsa.gov/tools/data-reporting/program-data?grantNum=H80CS06658 (last visited June 25, 2021).

required to offer to covered entities 340B pricing, regardless of where the drugs are dispensed to the covered entity's patients. For the above reasons, Amici respectfully request that the Court grant HHS's motion to dismiss and motion for summary judgment and deny Novo's cross-motion for summary judgment.

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Respectfully submitted,

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

/s/ Matthew S. Freedus
Matthew Sidney Freedus*
D.C. Bar No. 475887
Rosie Dawn Griffin
D.C. Bar No. 1035462
Brendan Michael Tyler
D.C. Bar No. 1672687
FELDESMAN TUCKER LEIFER FIDELL LLP
1129 20th St. NW, 4th Floor
Washington, DC 20036
T: (202) 466-8960
F: (202) 293-8103
mfreedus@ftlf.com
rgriffin@ftlf.com
btyler@ftlf.com
Counsel for Amicus Curiae National Association of Community Health Centers

/s/ Ronald S. Connelly
Ronald S. Connelly*
D.C. Bar No. 488298
POWERS PYLES SUTTER & VERVILLE, PC
1501 M Street, N.W., 7th Floor
Washington, DC 20005
Tel. (202) 466-6550
Fax (202) 785-1756
Ron.Connelly@PowersLaw.com
Counsel for Amici Curiae Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc, and FamilyCare Health Center

* *Pro hac vice applications forthcoming*

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

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

NOVO NORDISK INC., et. al., Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*., Defendants.	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY Civil Action No. 3:21-cv-806-FLW-LHG

INDEX OF EXHIBITS TO BRIEF OF AMICI CURIAE OF DEFENDANTS' MOTION TO DISMISS AND MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT[1]

Exhibit A Declaration of Gail Auclair, M.S.M.-H.S.A., B.S.N., R.N, CEO of Little Rivers Health Care Inc ("Little Rivers").

Exhibit B Declaration of Donald A. Simila, CEO of Upper Great Lakes Health Center, Inc.

Exhibit C Declaration of Lee Francis, President and CEO of Erie Family

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

Health Center.

Exhibit D Declaration of Kimberly Christine Chen, Director of Pharmacy at North County HealthCare, Inc. ("NCHC").

Exhibit E Declaration of Ludwig M. Spinelli, CEO of Optimus Health Care Inc.

Exhibit F Declaration of J.R. Richards, CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus.

Exhibit G Declaration of Heather Rickertsen, PharmD, Director of Clinical Pharmacy Services, Crescent Community Health Center.

Exhibit H Declaration of Kiame Jackson Mahaniah, CEO of Lynn Community Health Center.

Exhibit I The Declaration of D. Tucker Slingerland, M.D., CEO of Hudson Headwaters Health Network ("HHHN").

Exhibit A

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]

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[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 B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Declaration of Donald A. Simila

I, Donald A. Simila, declare as follows:

1. I am Chief Executive Officer at Upper Great Lakes Family Health Center, Inc. ("Upper Great Lakes"), and I have held this role since on or about October 1, 2009. As Chief Executive Officer, I am responsible for oversight of all services, including pharmacy services. To fulfill my job duties, I have access to all pharmacy-related transactions generated by prescriptions written by our physicians. Additionally, Upper Great Lakes has a dedicated analyst and 340B/pharmacy committee that reviews program activity, and educates me, as well as the board, staff, and patients, on the program. To prepare this declaration, I reviewed wholesaler invoices, pharmacy contracts, and pharmacy invoices.

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

3. Upper Great Lakes is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide primary health care and related services across a 10,000 square mile service area at 11 distinct and dispersed clinic sites, 20 congregate care facilities, and various school-based clinics.

4. Upper Great Lakes has been in business as an FQHC since approximately May 2010, and is a member of the National Association of Community Health Centers.

5. On an annual basis, Upper Great Lakes provides approximately 25,000 unique patients with 80,000 clinical visits for comprehensive primary care, OB/GYN, Behavioral Health including Medication Assisted Treatment for Opioid Use Disorder, and preventative and restorative dental services. As a rural community, Upper Great Lakes' target population is significantly underserved, aging, and impoverished. Sixty percent of Upper Great Lakes patients are either on Michigan Medicaid or on Medicare. Seventy percent of our patients

are at or below 200% of the federal poverty level ("FPL"), and 25% are at or below 100% of the FPL.

6. Upper Great Lakes is a "covered entity" for purposes of the 340B Drug Program ("340B Program). As a covered entity, Upper Great Lakes can purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

7. Upper Great Lakes has been a covered entity since in or around 2010 and, as required, annually recertifies its locations as 340B eligible sites with the Health Resources and Services Administration ("HRSA").

8. As a covered entity, Upper Great Lakes is permitted to choose how it will deliver pharmacy services to its patients. Upper Great Lakes—across its 10,000-mile service area—maintains contractual arrangements with local retail pharmacies to support its patients by ensuring local access to reduced price medications for those who meet federal poverty guidelines.

9. Upper Great Lakes requests HRSA approval for each of its contracted pharmacy partners. Once approved, Upper Great Lakes enters into a contractual relationship with the individual pharmacy's wholesaler under which Upper Great Lakes purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to the contract pharmacy. The health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible Upper Great Lakes patients.

10. When an Upper Great Lakes provider writes a prescription, it is electronically transmitted to a local pharmacy where the prescription is filled by the retail pharmacist; a third-party application identifies patients who qualify to purchase medications at 340B pricing, as well as claims that are submitted to insurance plans.

11. The "virtual inventory" owned by Upper Great Lakes is tracked by an Upper Great Lakes 340B analyst through real-time data reporting from third-party administrator software. Reconciliations occur each month.

12. Upper Great Lakes carves in a select few pharmacies that bill a single managed Medicaid plan for most claims; as required, Medicaid is not billed for outpatient medications. The retail pharmacy directly submits claims to Medicaid for medications purchased at retail pricing from non-340B inventory.

13. Upper Great Lakes passes its 340B savings directly to eligible patients who meet federal poverty guidelines.

14. Savings generated through claims made to commercial insurance and other third-party payers ensure that Upper Great Lakes can continue to provide essential health care services to its underserved rural community.

15. With its 340B savings, Upper Great Lakes is able to provide its vulnerable patient population access to a board-certified addiction medicine physician for treatment of Opioid

Use Disorder—the only Addiction Medicine Specialist in the entire Upper Peninsula of Michigan, which encompasses 15 counties and approximately 17,000 square miles—and is able to support the training of an additional 4 physicians to meet DEA licensing requirements for Medication Assisted Treatment. The approximate annual cost to support the addiction services above and beyond reimbursement is $200,000.

16. Additionally, as the only dental provider that accepts Medicaid in large volumes in the service area, Upper Great Lakes is able, due in part to 340B savings, to maintain a dental service at two locations with combined annual operating losses of approximately $450,000.

17. 340B savings also support OB/GYN services in a 4-county area with a population of approximately 45,000. The approximate annual operating loss of this service for the community exceeds $225,000 annually. Without this service, women in our service area and target population would be required to travel more than 100 miles one-way for access to OB/GYN care.

18. Clinic locations in rural counties such as Ontonagon, Iron, and Menominee all carry annual operating losses as the cost of employing physicians and operating a clinic exceed reimbursement from Medicaid, Medicare, and private insurance. In total, clinic services for these counties add up to an annual operating loss of more than $600,000.

19. Federal grant money falls far short of covering the operating losses outlined in the preceding paragraphs. 340B savings help to fill these gaps.

20. Finally, as an organization, Upper Great Lakes has completed over 10,000 COVID-19 tests in local communities through mobile services and walk-up or drive-up testing. Funds from 340B savings have supported the costs associated with standing up testing teams, purchasing test kits, and underwriting coordination of this service. Our health center has been the only source of community testing in most communities we serve. In addition, Upper Great Lakes has been instrumental at two local Universities commencing face-to-face instruction; at those institutions, we conduct random COVID-19 surveillance testing for students and employees daily, providing approximately 600 tests per week. This service enabled the Universities to bring 6,700 students back to campus. Without the safe integration of students into these communities, the economic impact to the greater community would be dire.

21. Upper Great Lakes follows HRSA requirements and the 340B statute to ensure all contract pharmacies are engaged in a binding contractual agreement with the Health Center. Each pharmacy has executed a contract with Upper Great Lakes prior to registering and obtaining approval for including the pharmacy in Upper Great Lakes' approved network.

22. Upper Great Lakes designed its contract pharmacy network to ensure that all patients across the 10,000-mile, 11-county rural service area have access to discount medications. In addition to being located in the communities we serve, most contract pharmacies have expansive hours of operation that many of our patients need.

23. Our annual operating margin is approximately 1-2% on a budget of $22 million. The average salary for a primary care physician in this region is approximately $240,000 plus benefits of about $50,000. Without 340B savings, all our primary care practices lose money. On an annual basis, across all 11 locations, Upper Great Lakes' drug sales through the 340B Program at all contract pharmacies amounts to approximately $6 million dollars. After administrative fees, ingredients costs, and dispensing fees, the health center nets approximately $250,000 to $300,000 per month (or approximately $3 million to $3.6 million annually).

24. Beginning on or about September 1, 2020, I became aware that certain drug manufacturers, including Eli Lilly, Sanofi, and AstraZeneca would cease providing outpatient prescription drugs at 340B prices to Upper Great Lakes' contract pharmacies.

25. Because of these actions by the drug manufacturers, health center patients, staff, and the community Upper Great Lakes serves will be significantly and irreparably harmed both clinically and economically.

26. Although Eli Lilly at least appeared to offer us the option of selecting one single contract pharmacy through which 340B-priced medications could be dispensed to eligible patients, a single pharmacy for all our patients would severely limit our patients' access to life saving medications.

27. The travel distance between our northern most and southern most clinical delivery sites is 200 miles. The Upper Peninsula of Michigan is a roughly 17,000 square mile region that is sparsely populated with approximately 300,000 individuals. Only one 90-mile stretch of interstate highway exists in the region, running north and south on the Peninsula's extreme eastern edge. Most of the population is served by two-lane state and county highways. As a region, the Peninsula will receive annual snowfalls in excess of 200 inches. Some areas receive more than 300 inches annually. Given the geographic and weather realities here, travel is hampered nine months of any given year.

28. The drug manufacturers' decisions were seemingly made without regard for the narrow margins on which safety net providers like Upper Great Lakes operate, or for the immediate and unplanned-for financial losses that result from these actions. Since September 1, 2020, and on a monthly basis, Upper Great Lakes has lost and will lose anticipated revenues in excess of approximately $50,000 from Eli Lilly's actions alone. Annualized, this amounts to approximately $600,000 from Eli Lilly alone.

29. As a result of this loss, we are currently planning major reductions in services, which will include closure of access points/service delivery sites, termination of employees, reductions in health center providers, and likely closure of OB/GYN (for which we have already reduced staffing), dental, and mental health services.

30. The ultimate result of the manufacturers' actions will be a significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community with chronic health conditions that require ongoing care.

31. Additionally, as a major employer in the region with a monthly payroll in excess of approximately $1.2 million, a likely necessary staff reduction of about 50% will have a direct economic impact on our communities of approximately $7.2 million annually.

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

Donald A. Simila, MSW, FACHE

Executed on ___12/03/2020_____ By_____

Donald A. Simila
Chief Executive Officer, Upper
Great Lakes Health Center, Inc.

Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Declaration of Lee Francis, MD, MPH

I, Lee Francis, MD, MPH, declare as follows:

1. I am the President and CEO of Erie Family Health Center, Inc. ("Erie"), located in and around Chicago, Illinois. I joined Erie in 1991 and have held the role of President and CEO since 2007. As President and CEO, I am charged with enacting Erie's strategic vision of serving as a national leader in the provision of community-based health care. I am responsible for the overall health of the organization, including financial stability, operational success, and clinical quality.

2. Regarding the 340B Drug Pricing Program ("340B Program"), as President and CEO, I have regular access to 340B financial and operational updates. I also receive regular updates on the 340B Program from Erie's Chief Financial Officer, who serves as the federal OPAIS Authorizing Official. As part of my regular duties, I am also made aware of provider and staff feedback related to 340B successes and barriers. Additionally, in my role as an Internal Medicine physician at Erie, I am keenly aware of the benefit the 340B Program offers for my own patients. To prepare this declaration, I have reviewed 340B Program metrics and feedback from providers and staff.

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

4. Erie is a Federally-qualified health center, and a member of the National Association of Community Health Centers. The health center receives federal funding under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population residing across over 185 zip codes in the Chicagoland region.

5. Erie is an approximately 63-year-old primary healthcare provider that delivers integrated and affordable medical, dental, and behavioral health care for patients of all ages. We also encourage good health in our underserved patient population through ongoing health education, case/care management, strong hospital partnerships, and community outreach.

6. Motivated by our belief that high-quality health care is a human right, Erie serves more than 80,000 patients per year at 12 locations throughout Chicago and the surrounding suburbs, regardless of patient insurance status, immigration status, or ability to pay for Erie's services. Almost all of Erie's patients are low income, and approximately 27% of Erie's patients are uninsured. Approximately 71% of patients are Hispanic and about 44% are best served in a language other than English.

7. Erie is a "covered entity" for purposes of the 340B Program. Erie has been registered with the Health Resources and Services Administration ("HRSA") as a 340B covered entity since on or about January 1, 1997. As required, we maintain accurate management of our clinic registrations within HRSA's OPAIS database. We recertify our 340B covered entity status annually, and most recently recertified for all twelve of our participating 340B locations on or about February 18, 2020. A list of our covered entity locations, downloaded from HRSA's 340B OPAIS database on October 7, 2020, is attached as Exhibit A.

8. The 340B Program allows Erie to purchase significantly discounted outpatient prescription drugs for pharmacy dispensing and as clinic-administered drugs. We acquire 340B discounted drugs for pharmacy dispensing through wholesaler AmerisourceBergen; we are also in the process of adding Cardinal Health as another 340B wholesaler account. For clinic-administered medications, we have 340B drug purchasing accounts with Allergan, Henry Schein, Paragard Direct, Theracom, and R&S Northeast, LLC.

9. Erie's participation in the 340B Program allows us to help our low-income uninsured and underinsured patients afford their medications. Without 340B discounts, critical medications—including, among many others, insulin, asthma inhalers, blood pressure medications, Pre-Exposure Prophylaxis (PrEP) for HIV, Suboxone and Narcan to treat opioid use disorder—would be unaffordable and inaccessible for these patients. 340B contract pharmacies enable our patients to access, and many other medications.

10. As required by federal law and regulations, and in keeping with our mission, we reinvest 100% of 340B savings and revenue from third-party reimbursement into expanding access for our underserved patients. For example, this money is used to cover costs associated with comprehensive care, a Medication-Assisted Treatment Program for opioid use disorder, and telemedicine and electronic population health tools, which enable Erie to serve patients at greatest risk for missing health screenings or services.

11. Many Erie patients have chronic conditions exacerbated by social challenges. Improving health outcomes depends on Erie providing: 1:1 Care Management, Maternal and Child Case Management, HIV/AIDS Case Management, Health Coaching, Referrals support,

Care Coordination and Outreach, Public Benefits navigation, Resource navigation, and PrEP navigation services. Because robust comprehensive care and case management are not usually reimbursed by third-party payers, Erie would not be able to offer these services without 340B savings.

12. As a covered entity, Erie is permitted to choose how it will deliver pharmacy services to its patients. While we use drugs purchased at 340B pricing for a select portion of our in-clinic medication supply, Erie contracts with local pharmacies to dispense all other 340B medications to its patients. We do not own or operate our own pharmacies. We currently contract with many local Walgreens pharmacy stores and one independent community pharmacy, Allcare Discount Pharmacy, which is co-located within one of our clinic sites.

13. Erie has a written agreement with Walgreens to dispense the 340B drugs we purchase to eligible Erie patients. We first contracted with Walgreens in or around 2011 and received HRSA approval for our first Walgreens contract pharmacy location on or about August 22, 2011. In the intervening years—following guidance from HRSA and Apexus—we have registered additional Walgreens locations. Our current Pharmacy Services Agreement with Walgreens—which applies to of all our active Walgreens pharmacy locations and all of our active covered entity locations, as registered in HRSA's 340B OPAIS database—was executed on or about April 4, 2017.

14. Erie likewise has a written agreement with Allcare Discount Pharmacy to dispense 340B drugs to eligible patients. We first contracted with Allcare Discount Pharmacy in or around September 2010; HRSA approved the pharmacy arrangement on or about May 23, 2011. Our current Pharmacy Services Agreement with Allcare Discount Pharmacy was executed on or about August 7, 2019.

15. As described in our Pharmacy Services Agreements, Erie purchases 340B drugs from wholesalers and directs those drugs to be shipped to the contract pharmacy as part of a "bill-to, ship-to" arrangement. Under this arrangement, Erie maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services to our eligible patients. Some of our contract pharmacies use a precise accumulation software to dispense a retail pharmacy product to patients and perform a careful 340B eligibility assessment; if the dispense meets all eligibility criteria, the accumulator will be replenished with an Erie-purchased 340B drug for that dispense.

16. Understanding that 340B compliance falls squarely on Erie, we have multiple compliance safeguards in place and perform extensive auditing, including an audit of all contract pharmacy 340B dispenses for patient and provider eligibility and audits to verify that Medicaid Fee-For-Service was not billed for any contract pharmacy 340B claim (to avoid prohibited duplicate discounts). All audits are completed on a monthly basis and reported out quarterly to our 340B Compliance Committee. We also commission an annual external 340B audit. Our most recent external audit, in January 2020, yielded positive feedback on Erie meeting HRSA 340B compliance standards.

17. Our contract pharmacies dispense over 115,000 340B discounted prescriptions annually to our eligible patients. On average, Erie spends approximately $470,000 on 340B drug products monthly for dispensing through our contract pharmacies.

18. The critical benefit the 340B drug discount to patient outcomes is illustrated in an email from an Erie pediatrician attached as Exhibit B. In the email, the pediatrician explains how one of her patients benefited from access to affordable insulin through the 340B Program. The patient turned 18 this year, moved out to live independently, started working, and lost his Medicaid coverage. Previously, the patient's Type 1 diabetes had been managed by providers at the local children's hospital. During this transition to adulthood, he was unable to stay with his care team and could no longer afford the insulin he was prescribed. The Erie pediatrician was able to work collaboratively with the patient's previous provider to assume care for his diabetic condition and prescribed an affordable Lantus pen (a Sanofi product) through the 340B Program. Aligning the patient with access to the affordable 340B drug helped to keep his sugars under control, keep him out of diabetic ketoacidosis, and keep him out of the hospital until he was able to get his insurance reinstated. The 340B Program helped this young adult access life-saving medicine and avoid hospitalization.

19. Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships.

20. Our contracts with local pharmacies to dispense 340B medications allow our patients to receive their critical 340B medication at a pharmacy close to their home. Erie patients generally experience multiple barriers to accessing care, including significant transportation barriers. Even though Erie has twelve clinic locations, some Erie patients still have significant travel times to attend their visit at the health center. The trip for some patients requires multiple segments on public transportation, as well as walking. Providing medication access near a patient's home supports that patient's ability to take their medication regularly, without potentially dangerous gaps around refills.

21. Many of our patients are hourly wage-earners, essential workers, work long hours, hold multiple jobs, or have care-giving responsibilities during the business day, and most will not get paid to take time away from work to obtain medications. Our contract pharmacy partners include 24-hour pharmacies and those with home delivery capabilities, providing crucial access to our patients, both day-to-day and in times of crisis.

22. Beginning on or about July 7, 2020, I became aware that certain drug manufacturers—starting first with Eli Lilly and its Cialis products and now including Eli Lilly, Sanofi, and AstraZeneca, Merck, and Novartis—had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Erie's contract pharmacies.

23. Eli Lilly's notification affecting all products made or distributed by the company was implemented without advance notice on September 1, 2020, which did not allow Erie adequate time to respond to protect our patients' access to Lilly medication. Sanofi, Merck, and Novartis, for their parts, have requested that covered entities enroll in an unsanctioned and burdensome data collection platform called 340B ESP. Erie will not be participating in this data collection; our patients have thus lost access to Sanofi products. To date, Novartis has not yet followed through on threats to block 340B price access at contract pharmacies.

24. Because of these actions, our ability to provide patients with affordable medications has been dramatically reduced—Erie patients who were regularly receiving a 340B drug made by Eli Lilly, Sanofi, or AstraZeneca no longer have access to that medication at the discounted 340B price. Without the 340B discount, these medications are inaccessible for an Erie patient paying out-of-pocket. The following table provides Erie's average annual 340B prescription volumes prior to the manufacturers' actions:

Medication Impacted	**Medication Type**	**Average number of Erie 340B prescription fills annually at contract pharmacies, prior to recent manufacturer limitations**
Eli Lilly		
Basaglar	Insulin (diabetes)	840
Humalog	Insulin (diabetes)	1080
Humulin	Insulin (diabetes)	240
Trulicity	GLP-1 Agonist (diabetes)	120
Sanofi		
Admelog	Insulin (diabetes)	300
Lantus	Insulin (diabetes)	2400
AstraZeneca		
Brilinta	Antiplatelet (heart, circulation)	120
Bydureon	GLP-1 Agonist (diabetes)	240
Byetta	GLP-1 Agonist (diabetes)	480
Farxiga	SGLT2 Inhibitor (diabetes)	180
Symbicort	Inhaler (LABA+ICS) (asthma)	840

25. Erie is in communication with AstraZeneca regarding designating one exception contract pharmacy. This process is not finalized, and at present, our contract pharmacies are unable to purchase 340B priced AstraZeneca drugs. Even if the AstraZeneca exception process comes to fruition, it would only allow 340B access at one of our contract

pharmacies. To provide just one example of how unworkable this will be for our patients, patients of our Erie HealthReach Waukegan clinic would need to travel nearly three hours one-way on public transportation to arrive at our one remaining contract pharmacy in the Humboldt Park neighborhood of Chicago.

26. Erie is actively assessing opportunities to switch patients to affordable alternative medications. But I know as a medical provider that it is neither easy nor seamless to switch patients from one product to another. Many medication alternatives require a medical provider to review the patient chart, consider comorbidities, and assess appropriate dosing for the substitute medication. Several of the impacted diabetic treatments have very different dosing—for example daily versus weekly dosing—which requires extensive patient education and provider troubleshooting.

27. Language barriers add another layer of difficulty for patients who proceed to the pharmacy to pick-up their 340B refill and are told the price will potentially be hundreds of dollars more than it was last month. Forty-four percent of Erie patients are best served in a language other than English, and in 2019 Erie, through our interpretation service, provided care in 77 unique languages.

28. Erie has teams of Diabetes Educators who help teach patients how to use their insulin, diabetes medications, and glucose monitoring systems. As an Erie clinician, I directly see how important it is for my patients to thoroughly understand how to use their medication as directed. Frequent and/or rushed switching between medication formulations increases the opportunity for medication errors.

29. The loss of 340B savings and revenue—100% of which is reinvested into expanding access for our underserved patients—threatens Erie's ability to (1) provide comprehensive care to existing patients and (2) expand services to reach more individuals in its underserved target population. During the COVID-19 pandemic especially, 340B savings have been critical to our ability to continue serving patients and to maintain capacity to provide future services.

30. We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue. Erie is proud of the work of our care managers, case managers, health educators, and patient navigators, who provide personalized services that address social determinants of health and help Erie patients navigate their chronic health conditions. Without 340B savings, we would not have the capacity to fund these unreimbursed comprehensive care programs.

31. Erie is exploring all available options, but there is no action we can take to promptly remedy the drug manufacturers' refusal to provide 340B discount pricing. Erie has always used contract pharmacy partnerships to provide 340B medication access to patients. We do not have the pharmacy infrastructure to participate in the 340B program as an in-house pharmacy, and creating that infrastructure would involve a lengthy and expensive endeavor. Our patients cannot wait, they need access to affordable medications now.

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

Dated: _____

By: _____ December 2, 2020
Lee Francis, MD, MPH, President and CEO
Erie Family Health Center, Inc.

Exhibit D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
Plaintiff,	)	
	)	Civil Action No. 1:20-cv-03032
v.	)	
ALEX M. AZAR II, et. al	)	

Declaration of Kimberly Christine Chen

I, Kimberly Christine Chen, declare as follows:

1. I am the Director of Pharmacy at North Country HealthCare, Inc. ("NCHC") in Flagstaff, Arizona and have held this role since July 2012. As the Director of Pharmacy, I am responsible for oversight of our 340B compliance program, our in-house pharmacy programs, our contract pharmacy partnerships, and our clinical pharmacy services. I am also part of our management team, and to fulfill my job duties have access to financial and strategic planning information, including information related to the application of pharmacy revenue to other areas of the organization. My role reports directly to the Chief Financial Officer (CFO), who in turn reports to the Chief Executive Officer (CEO).

2. To prepare this declaration, I met with my pharmacy management team—which includes the pharmacy manager, pharmacy business manager, and clinical pharmacist representative—met with our CEO and CFO, and reviewed relevant internal data and reporting. I also met with my clinical pharmacists to discuss general patient impact and specific patient cases in which recent changes to our access to 340B discount pricing have impacted patient care.

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

4. NCHC, a member of the National Association of Community Health Centers, is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. NCHC has its historical roots in a free health clinic model that transitioned to FQHC status upon community health center funding in 1996. The center has approximately 500 employees, approximately 85 of whom are medical providers.

5. Our primary clinic site and administrative hub is located in Flagstaff, Arizona, a population center with Medically Underserved Population (MUP) designation.

6. We also provide primary care services at behavioral health centers and homeless shelters, and operate satellite clinics targeting uninsured patients in Seligman, Winslow, Holbrook, Round Valley, Show Low, Williams, Grand Canyon, Dolan Springs/Kingman, Bullhead City, Lake Havasu City, and Payson communities. All, excluding Lake Havasu City, are designated Medically Underserved Areas (MUA's) and Health Professional Shortage Areas (HPSA's). These communities vary in distance from Flagstaff, primarily across the Interstate 40 corridor of Northern Arizona. The table below indicates the approximate distance and direction of these communities from our Flagstaff location.

Site (PCA)	Distance from Flagstaff (miles)	Direction from Flagstaff
Seligman	70	W
Winslow	60	E
Holbrook	90	E
Round Valley	180	SE
Show Low	140	E
Williams-Grand Canyon	35	NE
Dolan Springs/Kingman	143	W
Bullhead City	184	W
Lake Havasu City	208	W
Payson	115	SE

7. NCHC's services include diagnosis, treatment and referral for all illnesses, chronic disease management, prenatal/perinatal and delivery care, well woman checks, well child services/immunizations, pharmacy, laboratory and radiology services, preventive care/health education, oral health services, and integrated behavioral health. We also provide significant health promotion/disease prevention and enabling programs.

8. The Center has grown rapidly over the past twenty-five years, providing approximately 164,000 patient visits in calendar year ending December 31, 2019 to approximately 52,000 unduplicated users who call NCHC their "medical home."

9. The current payer mix from our most recent financials show that approximately: 7.2% of our patients are uninsured; 38% are Medicaid; 19.1% are Medicare; and 32.8% are commercially insured. The Medicare user population is expected to continue growing as few local providers accept new Medicare assignment.

10. According to the three Medicaid Managed Care plans in our service areas, diabetes, hypertension, and cardiovascular issues are the top three medical issues among that population. NCHC sees these issues similarly reflected in their patient population regardless of payer type.

11. NCHC has three in-house pharmacies situated within our Flagstaff, Grand Canyon, and Kingman locations. Our Grand Canyon and Kingman pharmacies are tele-pharmacies, staffed by pharmacy technicians (with Flagstaff-based pharmacists performing all

pharmacist's duties, oversight, and counseling). These tele-pharmacies were the first in Arizona—approved by special waiver from the Arizona Board of Pharmacy in 2010—and represent two of only a handful across the state. Tele-pharmacies help address the critical and unique needs in rural health care.

12. NCHC is a "covered entity" for purposes of the 340B Drug Program ("340B Program") and has been registered as such with the Health Resources and Services Administration (HRSA) since July 1, 1998. As required, NCHC recertifies all its eligible locations annually with HRSA. A current covered entity listing pulled from HRSA's Office of Pharmacy Affairs Information System (OPAIS) 340B database is attached as Exhibit A.

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

14. NCHC uses a combination of both in-house and contract pharmacies to meet our patients' pharmaceutical needs. In addition to NCHC's three in-house pharmacies, NCHC utilizes 52 contract pharmacies in 12 different communities. Specific contract pharmacies, contract dates, HRSA OPA registration dates, and active dates are included as Exhibit B.

15. NCHC works with both McKesson and Cardinal distributors in a "bill-to/ship-to" replenishment model for providing 340B medications to eligible patients. The 340B medications are purchased after the prescription has been filled at a contract pharmacy and it has been confirmed that the prescription is (1) eligible for the 340B Program and (2) is not a Medicaid claim.

16. Our claims are managed by a third-party administrator (TPA) and audited by NCHC compliance staff. The TPA matches the prescriptions to patient, provider and encounter files to "carve in" those claims as 340B eligible. Depending on the TPA, there are also additional mechanisms to ensure accuracy, such as embedded coding in electronic prescriptions from our electronic medical record and bar coding on printed prescriptions. Once the TPA has "carved in" a prescription, a record of that eleven-digit national drug code (NDC) is recorded. When the TPA identifies that a full package of a medication (11-digit NDC match required) has been dispensed to eligible patients, an order is generated for that medication. The drug is purchased by NCHC (aka "bill-to") and provided to the contract pharmacy where the medication was originally filled (aka "ship-to"). At no point in this process can the contract pharmacy order 340B medications directly or see the 340B drug pricing.

17. All claims the TPA "carves in" are communicated to NCHC and audited to ensure compliance. No such claims are billed to Medicaid—the TPA is provided with all Bank Identification Numbers (BIN) and Processor Controller Number (PCN) listed on Arizona's Medicaid Exclusion File and NCHC audits all carved in claims to additionally ensure that all prescriptions were eligible and that none were billed to Medicaid.

18. NCHC also achieves compliance through (1) ongoing internal and external audits of both in-house pharmacy and contract pharmacy claims; and (2) extensive staff training.

19. NCHC providers prescribe roughly 280,000 prescriptions annually. Of those prescriptions, only about 13.97% were filled by NCHC's in-house pharmacy; approximately 65.33% were filled by NCHC contract pharmacies. However, of the prescriptions sent to the contract pharmacies, only about 26% were ultimately applied to the 340B Program. The other 74% were either Medicaid or otherwise not eligible for the 340B Program.

20. Contract pharmacy agreements are critical to provide our most vulnerable patients access to affordable medications for several reasons.

21. First, NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel (one-way trip), to reach the closest of NCHC's in-house pharmacies:

Service Areas	Pharmacy Locations		
	Flagstaff Pharmacy	Kingman Pharmacy	Grand Canyon Pharmacy
Seligman	70	74	
Lake Havasu		60	
Bullhead City		37	
Williams	35		59
Winslow	50		
Payson	115		
Holbrook	90		
Show Low	140		
Round Valley	180		

22. Traveling such tremendous distances to access affordable medications is not feasible for our patients, especially in northern Arizona where inclement weather is a significant factor during the winter months.

23. Our contract pharmacy agreements provide our patients access to affordable medications within their communities.

24. Second, our contract pharmacies, unlike our in-house pharmacies, are open on nights, weekends, and holidays. Even in the communities where we have an in-house pharmacy, contract pharmacies are critical to provide medication access outside regular business hours.

25. Finally, our homeless populations are best served by community pharmacies near where they are located to increase their adherence and reduce their significant barriers to care.

26. NCHC's participation in the 340B Program allows us to provide our uninsured and underinsured patients—including low-income workers and homeless individuals—access to affordable or no-cost medications. All our contract pharmacies provide a modified sliding fee scale pricing to our patients who are 200% or more below the federal poverty level.

27. Additionally, revenue from prescriptions filled for our insured patients is used in furtherance of our mission and federal grant project.

28. For example, 340B Program proceeds support our clinical pharmacy program, in which pharmacists work in the clinics as members of interdisciplinary care teams to optimize medication regimens, promote adherence, generate medication alternatives and provide both group and individual patient education. Clinical pharmacists are critical on teams that provide chronic disease management, anticoagulation services, and pain management. Clinical pharmacy services expand patient access to care, improve patient outcomes, decrease medical providers' workloads, and improve provider satisfaction. This service is not reimbursable by CMS or commercial insurance, and would not be possible without the 340B Program.

29. Revenue generated from the 340B contract pharmacy environment is also used to support our most rural clinics. Without this subsidy, these clinics, which have lower patient volumes, would not be sustainable. Without this funding source, NCHC may be forced to close as many as six of our locations and lay off approximately 100 staff and providers.

30. Beginning in or around June 2020, I became aware that certain drug manufacturers, including Merck (notified June 29, 2020), Sanofi (notified July 31, 2020), AstraZeneca (notified August 20, 2020; position since modified to permit limited use of contract pharmacies) and Eli Lilly (notified September 1, 2020) had unilaterally decided, without government approval, to cease providing most or all outpatient prescription drugs at 340B prices to most or all of NCHC's contract pharmacies.

31. These actions significantly and negatively impact our patients.

32. Without contract pharmacies, only three of the twelve communities NCHC serves would have access to pharmacy.

33. Without contract pharmacies, patients will not be able to afford their medications at commercial pricing and most will not be able to travel the great distances required to procure their medication from our in-house pharmacies.

34. For example, Symbicort, made by AstraZeneca, is the only approved first line medication in the treatment of asthma according to the 2020 guidelines by Global Initiative for Asthma (GINA). NCHC has multiple patients who are homeless who were tried and failed on other alternative treatments. The clinical pharmacist was able to switch them to Symbicort and the patients experienced marked improvement in their asthma, decrease in their exacerbations, and quality of life due the medication change. Many of these patients can no longer use a contract pharmacy for Symbicort and instead must find a way to access the medication through an NCHC in-house pharmacy. Although NCHC identified and implemented workarounds for these patients, there is a limit to what we can do, and inevitably patients' health outcomes will be negatively impacted by limits on medication access.

35. An uninsured, Type 1 diabetic patient of our Show Low clinic, which is located approximately 280 miles from our closest in-house pharmacy, was taking Novartis-produced Novolin N, an insulin medication, but was experiencing frequent hypoglycemia (low blood sugar). Our clinical pharmacy staff worked with this patient to switch him to Sanofi-produced Lantus, on which he was able to keep his blood sugars stable. On or about October 1, his Lantus was no longer available through the contract pharmacy. Additionally, even if he could tolerate being switched back to Novolin N, the product and its comparable product made by Eli Lilly (Humulin N) are also not available at 340B pricing.

36. This patient's body is unable to make insulin. Without it he will die. Insulin is not a choice. Type 1 diabetes is not a choice.

37. I would also add that with the loss of contract pharmacy revenue, the clinical pharmacist who was able to get this patient on a stable, healthy insulin regimen targeted to his particular needs is potentially in jeopardy of losing their job, leaving this patient and all the others like him struggling to manage chronic diseases and navigate access to affordable mediations.

38. While this is just one patient story, all our diabetic patients face similar terrible outcomes. In the short term, switching insulins on stable patients can increase weight gain, reduce adherence due to formulations that require more frequent dosing throughout the day, and increase the risk of hypoglycemia, which can lead to seizures, coma, and even death. Insulin changes are difficult to titrate and require frequent contact with a clinical pharmacist, whose jobs are hanging in the balance. In the long term, these patients face higher risk for renal damage, retinopathy and blindness, and cardiovascular events.

39. Our patients are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications. Our providers are being forced to deviate from the standards of care based on a patient's payer type.

40. These changes have caused immediate harm and will cause additional harm the longer this is allowed to continue. Due to our geographical barriers, NCHC has had to scramble to get couriers in place at our various clinics and establish other workarounds for access to affordable care. We have also placed additional staffing burdens on our pharmacy team to identify those patients most impacted by these manufacturer's actions and to determine what treatment options may be available that the patient can both afford and access. Our pharmacy team has also had to create and support new processes for these deliveries and solutions for managing the influx of changed prescriptions. Our clinic staff has scrambled to navigate processes to allow patients to pick up medications in our clinics, a process that many front office clinic staff have never had to do before.

41. These additional burdens come at a time when health care across the nation is trying to adapt to the global pandemic.

42. If these actions continue, NCHC will have to make crucial decisions on what will need to be cut to compensate for the reduction in program income derived from our participation in the

340B Program. We will likely have eliminate our clinical pharmacists and determine which rural clinic location would need to be the first of possibly multiple clinic closures.

43. Last fiscal year, NCHC's in-house pharmacy wrote off more than $3.2 million in direct patient medication costs. As an FQHC, NCHC does not have the capacity to continue to provide the scope and depth of our services to patients if these attacks on the 340B Program continue.

44. NCHC has done its best to protect our patients during this crisis, but our solutions fall short.

45. For example, the courier deliveries we have established occur weekly and cannot address acute patient needs. If a patient realizes that they will run out of their insulin after the courier has left the clinic, they will not be able to access their medications for another week, putting the patient in danger of significant medical emergency that may require hospitalization or even result in death. Additionally, in northern Arizona, where severe snowstorms can occur on short notice during the winter months, it is common for couriers to have to cancel deliveries. The resulting delays in therapy are detrimental for patients and pose significant costs and burdens to the healthcare system.

46. Mailing prescriptions to patients poses challenges as well. Many of our patients do not have consistent addresses, our homeless patients have no addresses at which they can receive mail, our insurance contracts prohibit mailing beyond individual patient exceptions, and even if we were to secure mail-order status, all mail in our region is routed through Phoenix, where summer heat exceeds manufacturer recommendations for safe medication storage. Safely and legally mailing medications would involve significant expense and would still fail to help many of our most vulnerable patients.

47. A longer-term solution to consider is expanding our tele-pharmacy program. These pharmacies are very expensive to maintain, and the Arizona Board of Pharmacy requirements state that the pharmacy technician that staffs these locations must have a minimum of 1,000 hours of technician experience prior to working in tele-pharmacy. This is a huge barrier due to the rural nature of these locations. Staffing in these locations by skilled, credentialed team members is an ongoing issue and this would also be the problem for tele-pharmacy. Additionally, due to the parameters of operation, these pharmacies do not demonstrate a high capture rate of prescriptions for those patients who have insurance, making the model not financially sustainable without outside funding.

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

Executed on: December 3, 2020

By: Kimberly Chen

Kimberly Christine Chen
Director of Pharmacy
North Country HealthCare, Inc.

Exhibit E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Declaration of Ludwig M. Spinelli

I, Ludwig M. Spinelli declare as follows:

1. I am the Chief Executive Officer at Optimus Health Care Inc ("Optimus"), which serves approximately 50,000 patients in the Bridgeport and Stamford regions of Connecticut. In this position, which I have held since in or around September 1983, I am ultimately responsible to the Board of Directors for health center performance and patient care.

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

3. Optimus is a Federally-qualified health center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. Optimus is a member of the National Association of Community Health Centers.

4. Optimus has been in operation since approximately December 1976, and presently offers some 210,000 annual visits to approximately 50,000 unduplicated patients at our 35 service locations. Our target population is low-income residents in our southwestern Connecticut service area that ranges from western New Haven county to the New York border.

5. Approximately 22% of our patients have no insurance and are thus placed on a sliding fee scale based on their income. Some 60% of our patients qualify for Medicaid and approximately 8% for Medicare.

6. We have around 7,000 patients with diabetes, hypertension, and asthma, and we provide comprehensive support to approximately 500 HIV positive patients.

7. Optimus is a covered entity for purposes of the 340B Drug Pricing Program ("340 Program") and has been for some 10 years. Optimus recertifies its covered entity status

annually with the Health Resources and Services Administration (HRSA) in keeping with HRSA's Office of Pharmacy Affairs guidelines and directives.

8. The 340B Program allows Optimus to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. Optimus purchases drugs at 340B pricing from two main wholesalers: Cardinal Health and McKesson. We purchase approximately $1.4 million in prescription medications from our 340B wholesalers every year.

9. Optimus dispenses the drugs it purchases at 340B pricing to eligible patients via contracted pharmacy partners. These contracted pharmacies include Walgreens, CVS, Walmart, Rite Aid, and three local pharmacies in our service area: Slavins, Cornerstone, and Bridgeport Pharmacy.

10. From a patient perspective, these pharmacies are accessible and conveniently located. Many also have home delivery options, which help out patients to obtain their medications and remain compliant with medication regimens.

11. Optimus has written agreements with each contract pharmacy that detail how the program works. In compliance with 340B rules, each of these pharmacies was registered with and approved by HRSA, before any 340B medications were dispensed to any of our patients. The approximate date of approval for each pharmacy is as follows:

    - Walgreens Pharmacies executed on 8/24/2011
    - Rite Aid Pharmacies executed on 7/1/2014
    - Slavins-Hancock Pharmacy executed on 1/1/2013
    - Cornerstone Pharmacy executed on 9/18/2013
    - Bridgeport Pharmacy executed on 4/4/2019
    - Wal-Mart Pharmacy (Stratford CT) executed on 4/1/2019
    - CVS Pharmacies executed on 7/22/2019

12. With the exception of Walgreens, our 340B operations are managed by our Third-Party Administrators ("TPAs") CaptureRx and Wellpartner. Through the services provided by the TPAs, we ensure 340B Program compliance including:

    - Patient, prescriber and covered entity eligibility
    - Exclusion of Medicaid prescriptions to prevent duplicate discounts
    - Purchasing and tracking inventory
    - Reports for auditing

13. Although the TPAs assist us in fulfilling these responsibilities, we know that Optimus is ultimately accountable for adherence with 340B Program requirements. Our Finance Department tracks the activity overseen by our in-house pharmacist, who helps to manage the program and is a resource to the contract pharmacies and the patients. Our 340B Committee and our Compliance Department are actively involved in ensuring that we meet all relevant HRSA and program requirements.

14. At the pharmacy level, each prescription is verified for eligibility in accordance with 340B rules. Patient eligibility, covered entity and prescriber eligibility, and all other 340B criteria must be met. We achieve this through our TPA's, CaptureRx, WellPartner, and Walgreens. If a prescription does not meet any of the qualifying criteria, it is excluded from our 340B Program. This applies to both insured and uninsured patients.

15. Optimus' participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Uninsured patients get 100% of the savings at our partner (contract) pharmacies, as explicitly spelled out in our agreements with these pharmacies, and pharmacists do not mark-up our 340B medications. In addition to the 340B cost of the medication, a reasonable, pre-negotiated dispensing fee is charged to patients who can afford it. For our patients who cannot afford the dispensing fee, we cover the entire cost of their prescription.

16. Any net revenue we derive from the 340B Program also goes directly to our patients. Our Dental, Podiatry, and Clinical Nutrition departments are excellent examples of how we provide enhanced patient care with 340B dollars. In our geographical area, we are one of the only sites to offer dentures and other procedures at deep discounts.

17. Similar to dentistry, our Podiatry and Clinical Nutrition Departments are supported by 340B dollars. These departments reach some of our most needy patients, including those with diabetes, for whom podiatry and clinical nutrition services can be crucial to overall wellbeing.

18. Optimus has a robust 340B Program with approximately 3,200 unique patients participating. Of these, about 1,500 patients have no prescription insurance. The remaining 1,700 some odd patients have prescription insurance; however, they may still need additional assistance affording their medications. Through our partnerships with contract pharmacies, our patients receive approximately 17,000 prescriptions every year.

19. At Optimus, pharmacy services are an integral part of comprehensive health care. In addition to 340B dispensing services, our community pharmacy partners provide pharmacy-based health care to our patients and support to our clinical staff. Some of these services include chronic disease state monitoring, medication adherence programs, medication therapy management services, and timely feedback to our clinicians. The strong communication link between our providers and pharmacists allows for easy communication and delivery of patient care.

20. Convenient locations and service hours, coupled with culturally competent staff, make our 340B partner pharmacies the best choice for our patients. To accommodate patient care priorities, we do not require patients to change pharmacies for 340B pricing. Instead, we expand 340B access to the patients' pharmacies of choice.

21. Beginning on or about July 23, I became aware that certain drug manufacturers, including Eli Lilly, AstraZeneca, and Sanofi had unilaterally decided, without government approval,

to cease providing outpatient prescription drugs at 340B prices to most or all of Optimus' contract pharmacies. These restrictions have impacted our uninsured patients' ability to acquire life-saving and life-improving medications. We have determined the impact from these three manufacturers alone to be as follows:

- Uninsured patients will lose access to approximately 773 affordable prescription medications for their chronic health conditions. Our records show that before COVID-19, annually 1,610 unique (unduplicated) patients received one or more medications made by one of these three manufacturers. The need for affordable medications in underserved communities has been amplified by the pandemic and the economic fall-out that resulted. Access to insulin, asthma controllers, and other essential medications are cut off when people need them the most. Patients that were paying about $12 to $15 for three months' supply of these medications will now have to pay about $300 to $600 per month to continue their treatment.

- Our health center will lose over $560,000 a year in 340B revenue, this does not include the impact from Merck and other manufacturers who have also announced plans to restrict access to 340B pricing but have not implemented their plans to date. If the current trend is allowed to continue, we believe this figure will be much higher. 340B is a vital revenue stream that allows us to expand primary care to patients who need it the most. As a result, vital programs like Dental, Podiatry, Clinical Nutrition, and others will be at risk of losing their funding. Without 340B revenue, our expanded dental services would become an expense we could not afford to cover.

- To limit the loss to our patients, we are actively searching for suitable alternatives for medications made by Eli Lilly, AstraZeneca, and Sanofi. Please see the attached list of recommendations developed by our Clinical Pharmacist to help support our providers and patients.

22. There is significant harm done to our patients due to the sudden discontinuation of 340B pricing of maintenance medications. As pharmaceutical companies continue to exclude more medications from the 340B Program, we are quickly running out of options for our patients.

    - The sudden discontinuation of 340B pricing did not allow time to notify patients and work out an effective strategy.

    - Providers are forced to change medication therapies without adequate time to evaluate the health outcome of new therapies to their patients.

    - In the case of the "one contract pharmacy only" requirement imposed by certain manufacturers, providers are put in the uncomfortable (and sometimes inappropriate) position of telling patients which pharmacy they can go to for their medications.

23. Patients who rely on our 340B Program for their medications have been harmed directly. Mrs. P. is an uninsured patient. Since 2017 her diabetes has been controlled on insulin

made by Eli Lilly, for which she paid $15 a month. On September 4, 2020, she went to the pharmacy and she was asked to pay $270. Without any prior notice or a reasonable alternative, she was left without her medication. To complicate matters more, Mrs. P. is a visually impaired patient who does not speak English. She depended on the 340B Program to access her medication at a local pharmacy that accommodates her needs. She has been let down.

24. Mrs. A. has a similar story. She is followed in our ob-gyn practice in Stamford for gestational diabetes. While her pregnancy is high risk, she has been managed well on an insulin product made by Eli Lilly. However, 27 weeks into her pregnancy, she was asked to pay full price for her insulin, $320 which she could not afford. Like many of our patients, Mrs. A. is not eligible for discount programs sponsored by pharmaceutical companies due to her undocumented immigrant status.

25. Many of our asthmatic patients are also affected by Astrazeneca's restriction on 340B priced medications. Mr. O. can be cited as an example. He suffers from severe asthma. While his illness has been difficult to control, he and his doctor have worked closely together to manage his condition and stabilize him on the right medication. Mr. O. paid $15 a month and visited the local pharmacy frequently since 2014. In October 2020, his medication therapy was interrupted due to Astrazeneca's policy change. Mr. O. could not afford to pay $315 a month for his inhaler. He is now starting treatment on a new medication, uncertain how well it will control his asthma. Even more uncertain of what might happen to him if more pharmaceutical companies block access to the 340B Program.

26. These patient experiences demonstrate the challenges uninsured individuals face to pay for their medications. The pandemic has worsened the problem with additional health problems and a lack of jobs to pay for these medications. At a time of dire need, access to 340B priced medications is being restricted by some pharmaceutical companies.

27. The harms listed above are in addition to the financial burden levied on Optimus to continue to provide comprehensive health services, without the vital dollars to reach more patients. To fill the gap created by the 340B loss, Optimus anticipates a $1.5 million budget reduction. At risk are our patients who receive free and reduced-cost care, many of the same patients who lost their 340B savings at the pharmacy.

28. Optimus is coming out of the last fiscal year with an overall loss caused by COVID-19. We did participate in the Payroll Protection Program, but our revenue remains below that of the pre-COVID period. Our visits are down approximately 20%, and many patients are reluctant to visit Optimus for routine care due to recent COVID-19 positive spikes in the population.

29. We are working with some drug manufacturers that will ship our drug purchases to one contract pharmacy, but our service area is approximately 25 miles wide. It is impossible to expect all of our patients to travel to one single pharmacy given the significant practical barriers that stand in the way such as time and transportation availability.

30. Additionally, many patients are hesitant to use mail order pharmacies, and those pharmacies are not part of our 340B Program. Thus, this option does not improve access to needed medications.

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

Executed on: 12/8/20

By: Ludwig M Spinelli

Ludwig M. Spinelli
Chief Executive Officer
Optimus Health Care Inc

Exhibit F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Declaration of J.R. Richards

I, J.R. Richards, declare as follows:

1. I am the CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus ("MAP") and have held this role since in or around January 2015. As CEO, I am responsible for overall operations and implementation of the policies of the Board of Directors. I supervise a senior leadership team consisting of the Chief Operations Officer, the Chief Financial and Business Development Officer, the Chief Medical Officer, the Chief Information Officer, the Chief Compliance Officer, and the Satellite Operations Administrator. I am also responsible for oversight of all departments within the organization, including the Pharmacy Department, whose members have regular access as part of their job duties to all information related to pharmacy operations. To prepare this declaration, I consulted with all members of the senior management team, as well as our Director of Pharmacy Operations, and reviewed relevant data and information.

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

3. MAP is a Federally Qualified Health Center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in Augusta, Georgia and surrounding areas, including in Richmond, Burke, and Jefferson counties. MAP has served this patient population regardless of patient insurance status or ability to pay since in or around 1997.

4. MAP estimates it will serve over 25,000 patients in 2020, over 5,000 of whom are uninsured and below 200% of the federal poverty level. MAP currently provides primary care, woman's health, dental, pediatrics, behavioral health, diabetes management, pharmacy, endocrinology, pulmonary, dermatology, infusion therapy, and infectious disease services for our patients and community.

5. In 2019 alone, MAP provided over $8,000,000 in uncompensated care to patients who could not, either through insurance or independently, cover some or all the costs for their care.

6. MAP is a "covered entity" for purposes of the 340B Drug Pricing Program ("340B Program") and first received Health Resources and Services Administration (HRSA) approval to participate in the 340B Program in or around 2008. MAP recertifies its status annually with HRSA to maintain that approval.

7. The 340B Program allows MAP to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. MAP purchases these discounted medications for dispensing at its in-house pharmacies, clinics, and contract pharmacies from several wholesalers, including Cardinal, McKesson, Henry Schein, and other independent companies. MAP currently spends an estimated $410,000 per month—close to $5 million per year—in 340B drugs for its patients.

8. MAP uses a combination of in-house pharmacy and contract pharmacy arrangements to provide all-inclusive access to its patients for their prescription needs. Due to several patient-related factors, MAP is only able to serve about 40% of its patients through in-house pharmacies. Most of MAP's patients thus rely on our contract pharmacy network to fulfill their prescription needs. All contract pharmacy arrangements are memorialized in written agreements between MAP and the pharmacy. Dispensing is available through contract pharmacies only after an agreement is finalized and approved by HRSA's Office of Pharmacy Affairs (OPA).

9. Our contract pharmacy network expands our ability to offer 340B savings and reach more of our vulnerable patients to fulfill their pharmacy needs. Because of 340B, MAP is able to provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all.

10. Six of our eleven sites do not have an in-house pharmacy and MAP's patients who rely on these sites for care strictly rely on contract pharmacies to meet their prescription needs at affordable prices. Additionally, because our in-house pharmacies are only open during clinic hours—weekdays from 8AM to 5PM—our contract pharmacy network allows our patients to access 340B discounted drugs outside of these hours. A lack of available time during the traditional workday is a significant barrier for our patient population.

11. An optimized network of contract pharmacies also allows MAP to generate additional revenue by increasing its "capture rate," which in turn enables MAP to retain more 340B savings and therefore support more services for its patients. As required, we reinvest all 340B savings and revenue in services that expand access for its medically underserved patient population.

12. Our participation in the 340B Program further allows us to provide services to vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families.

13. MAP does not and legally cannot refuse to see an individual based on his or her inability to pay for services. We offer all our services on a sliding fee scale for those that are 200% below the poverty level, and many patients receive services for free. This means that a patient can see a provider for a primary care medical visit valued at $175 including lab work, for as little as $25, or for free depending on their family's income and size.

14. MAP also uses 340B Program savings and revenue to provide patient services that could not be offered without these funds. These services include behavioral health, dental, mobile van services, a patient assistance program, and free prescription delivery services, which annually entail an estimated 6,000 free prescription deliveries to our underserved community to overcome major transportation barriers to care.

15. Across all pharmacies, MAP currently fills an average of approximately 7,500 prescriptions per month, and approximately 90,000 prescriptions per year.

16. All our contract pharmacies operate on a virtual inventory model, which means pharmacies dispense medications from their retail stock, identify qualified 340B claims, and replenish their stock with 340B medications. The claim matching process is handled by Third-party Administrators (TPAs) and goes through several filters before a claim is deemed eligible for 340B pricing. MAP pays a fee to the contract pharmacies (for providing dispensing services) and TPAs (for qualifying claims and ordering medications).

17. As required by HRSA, MAP does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount. MAP views compliance of contract pharmacies very seriously and has hired a pharmacist who is a 340B Apexus Certified Expert (340BACE) to audit and reconcile inventories on all contract pharmacy claims. In or around July 2020, MAP underwent a 340B HRSA Audit where there were no findings.

18. Beginning on or about July 22, 2020, I became aware that certain drug manufacturers including Eli Lilly, Sanofi, and AstraZeneca had unilaterally decided to cease providing outpatient prescription drugs at 340B prices to MAP's contract pharmacies.

19. Because of this action, many of MAP's patients can no longer fill their prescriptions for life-saving and life-sustaining medications through MAP's contract pharmacy network.

20. MAP currently has no access to Eli Lilly or Sanofi medications at 340B pricing to be dispensed through its contract pharmacies.

21. MAP likewise has no access to AstraZeneca drugs at 340B pricing at most of its contract pharmacies. After its initial announcement, AstraZeneca indicated it would ship drugs purchased at 340B prices to certain contract pharmacies. On or about October 14, 2020, MAP requested that AstraZeneca approve six of its contract pharmacies for this exception. MAP received notice on or about November 30, 2020, that AstraZeneca would continue to ship drugs at 340B pricing to three of the six requested pharmacies. MAP is currently working with its TPA to implement 340B purchases and dispensing for these pharmacies.

22. We have been working to switch patients to alternate medications and to convince our patients, where possible, to fill their prescriptions at our own, in-house pharmacies where they will still have access to discount pricing.

23. Both efforts have challenges. Even for patients who don't face significant barriers to filling their prescriptions at one of MAP's in-house pharmacies, many are reticent to switch because of familiarity and comfort. Switching patients to alternate formulations to avoid paying full price for these medications may cause patients to become unstable and potentially cause adverse health consequences. For example, a patient whose diabetes was fully controlled by Humalog (an Eli Lilly insulin) may be forced to switch to Novolog (a Novo Nordisk insulin) since Eli Lilly has banned or restricted shipments of its products at 340B pricing to our contract pharmacies. This patient's diabetes may become uncontrolled or the patient may experience adverse effects from switching. In 2019, approximately 19% of MAP's patients were diabetics compared to the State and National averages of 12% and 9%, respectively.

24. Additionally, MAP estimates we will lose up to approximately $350,000 in annual net revenue as a result of these manufacturer's actions. MAP receives grant dollars to help serve its patients, but these grants only cover about 28% of MAPs total expenses, and MAP depends on its 340B Program savings and revenue to help support approximately 41% of the remaining expenses, which include underfunded and unfunded programs and services such as behavioral health and dental services.

25. This significant financial loss, if not prevented or recovered, will also result in reduction in other clinical and/or patient services, increased work for clinicians, and increases in costs where MAP is covering costs for its uninsured patients and/or patients who are unable to pay.

26. MAP has actively tried to find ways to mitigate the negative financial consequences of the manufacturers' actions. We have considered eliminating or charging a fee for our current free prescription delivery program, increasing per-provider patient volume, and making reductions in some clinical services. Each of these options, however, ultimately negatively impacts patient care and still falls short of an adequate remedy.

27. These restrictions from manufacturers, and MAP's inability to access an administrative remedy through HRSA, will drastically impact our health center's operations and could severely alter our ability to provide access to low-cost services to our underserved community, which is the premise of the FQHC program.

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

Executed on: DECEMBER 9, 2020

By: _____
J.R. Richards, MPA
Chief Executive Officer

Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Declaration of Heather Rickertsen

I, Heather Rickertsen, PharmD, declare as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Exhibit H

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. _____
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Kiame Jackson Mahaniah

I, Kiame Jackson Mahaniah, declare as follows:

1. I am CEO at Lynn Community Health Center ("LCHC") in Lynn, Massachusetts and have held this role since October 2017. As CEO, I am responsible for overall compliance and adherence to all HRSA requirements, including requirements related to our participation in the 340B Program. To prepare this declaration, I reviewed relevant internal patient and prescribing data with Kim Macleod, our CFO, and discussed the current situation and its challenges in depth with my executive team, the Board of Directors, and most of our external stakeholders.

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. LCHC is a nonprofit community health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide healthcare and related services to a medically underserved population in the city of Lynn, Massachusetts regardless of patient insurance status or ability pay. We have been designated as a federally qualified health center (FQHC) since 1993.

4. Since 1971, LCHC that has served as the primary source of healthcare services in Lynn, Massachusetts, a dense, urban community with high rates of poverty. In 2019, LCHC provided approximately 286,980 medical, behavioral health, vision, and dental visits to approximately 41,115 patients.

5. Over 94% of our patients live at or below 200% of the federal poverty level, over 83% are racial/ethnic minorities, and about 59% are best served in a language other than English. Close to 60% of LCHC patients are on Medicaid, 9% are on Medicare, and 12% are uninsured.

6. The COVID-19 emergency is having a severe impact on Lynn and our patients. As of November 30, 2020, Lynn had 7,537 cases and 134 deaths in a city with 94,655 residents.

7. Lynn Community Health Center is a "covered entity" for purposes of the 340B Program. Our participation in the 340B Program, which provides us discount pricing on outpatient prescription drugs, began in or around 1999. We certify our covered entity status annually with the Health Resources and Services Administration (HRSA).

8. LCHC has contracted with pharmacies—principally Walgreens and CVS—to provide dispensing services to our eligible patients. We purchase drugs at 340B pricing from wholesalers McKesson, Cardinal, and AmeriSource Bergen and direct those drugs to be shipped to our contract pharmacies on a replenishment basis. LCHC maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies. LCHC's contract pharmacies undergo an annual certification process with HRSA's Office of Pharmacy Affairs.

9. One of the consistent barriers our patients face to accessing healthcare, including filling prescriptions, is transportation. In addition, we have a growing number of elderly patients for whom ambulation is also difficult. Contracting with pharmacies close to where our patients resides ensures convenient access, increases medication adherence, and provides opportunities for education within established patient-pharmacist relationships. Although always difficult to measure, this type of preventative and community-oriented care ultimately benefits total cost of care.

10. LCHC's average number of monthly 340B prescriptions is 14,000. Although that number is astounding, LCHC has one of the lowest ER use rates of any outpatient institution in Massachusetts.

11. Our annual purchases of pharmaceuticals at 340B pricing is approximately $4 million.

12. We ensure 340B Program compliance—including compliance with prohibitions on diversion and duplicate discounts—through a monthly reviews and independent third-party compliance testing.

13. LCHC's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients.

14. We are a national leader in integration of behavioral health (BH), Substance Use Disorder (SUD) treatment, and primary care. BH in particular does not have payment parity: providing psychopharmacologic services for children would simply be impossible without the margin provided by 340B discount pricing.

15. Support services, though vital to our patients, are generally not reimbursed. We use 340B savings and revenue to fund:
    - foreign language interpretation/translation services, which are currently provided in 30+ languages, with the top five languages accounting for 85% of our patients;

- social services, including assiduous screening for social determinants of health and a referral system through which we coordinate access to various services in the area (such as housing services coordinated through our relationship with the Massachusetts Coalition for the Homeless);
- recovery coaches and case management for our highest risk tier of patients, which includes patients suffering from homelessness, serious mental illness, and social isolation.

16. We respond to the needs of our most vulnerable constituents. Although we maximize our efficiency through lean management practices, we have limited flexibility given that we cannot choose our market, but instead simply answer identified community needs.

17. Without 340B discount pricing, we could not cover the cost of the programming listed above. With our care and services, there is a way forward for the most vulnerable in our underserved patient population. Our patients' needs will not disappear in the absence of such services, they will instead be pushed onto law enforcement, the schools, and/or the courts.

18. In September 2020, I became aware that certain drug manufacturers, including Eli Lilly and Sanofi, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of LCHC's contract pharmacies.

19. Because of this action, we estimate an approximate loss of $6 million from our roughly $8 million budget.

20. As a result of this loss, we are preparing for the permanent layoff of about 5% of our employees, or about 35 people. This includes all data management capabilities (3 FTE) that allow us to use our funding in the most efficient way possible; a dramatic scaling back of our mental health team, particularly in the psychopharmacology realm, to include our recovery coaches and most of our case managers.

21. We will also have to cut services, most of which are exactly those that heighten our efficiency and our ability to deliver targeted services: case management for vulnerable patients, programs targeting mentally ill folks suffering from homelessness, and therapy provided in our patients' native languages.

22. As a health center, we are used to operating very close to bare bone. Two years ago, for the first time in decades, we were ecstatic to realize a margin above 2%. A good month is one in which we clear $200,000. We normally have 4 good months a year.

23. LCHC would simply cease to exist as we now know it without our ability to purchase prescription drugs for our patients at 340B discount pricing. We would retrench to very basic care.

24. Crucially, our most vulnerable and marginalized patients would suffer the most. These patients will suffer untreated mental illness, lack of access to substance use disorder/addiction treatment, and lack of support services. I fear that the gains we have made in tackling some of the most profound problems in our community will be lost.

25. There are no good strategies we could employ to mitigate the drug manufacturers' actions. We could certainly develop a mail-in pharmacy program, yet we already have a 20% mail rejection rate. Trusting life-sustaining medication to this process seems unwise. Could we act as a wholesaler? Perhaps, but we currently don't have our own pharmacy and to expand in that way would require the development of a complex process that clearly lies outside our current services. It would take precious funds and bandwidth away from areas that cannot afford to spare either money, time, or expertise. There is no reasonable alternative to the 340B Program in its current iteration.

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

Executed on: 12/3/2020

By: _____
Dr. Kiame Jackson Mahaniah
CEO
Lynn Community Health Center

Exhibit I

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 Stroperland, 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

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

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

NOVO NORDISK INC., *et. al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY Civil Action No. 3:21-cv-806-FLW-LHG

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

Ryan White Clinics for 340B Access ("RWC-340B"), Little Rivers Health Care, Inc. ("Little Rivers"), WomenCare, Inc., dba FamilyCare Health Center ("FamilyCare") (collectively the "Amici"), and National Association of Community Health Centers have moved to file an Amicus Curiae brief in support of Defendants' Motion to Dismiss and Motion for Summary Judgment and in Opposition to Plaintiff's 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 to Dismiss and Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment is granted, and the Amicus Curiae brief attached to Amici's motion is hereby deemed filed with the Court in this case.

DATED:

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

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

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

NOVO NORDISK INC. et al, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*., Defendants.	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY Civil Action No. 3:21-cv-00806-FLW-LHG

CERTIFICATE OF SERVICE

I, Steven A. Haber, Esquire, hereby certify that I electronically filed the Unopposed Motion to File Amicus Curiae Brief in Support of Defendants' Motion to Dismiss and for Summary Judgment and in Opposition to Plaintiffs' Cross Motion for Summary Judgment with the Clerk of Court, using the CM/ECF filing system, which will send notification of the filing to all counsel of record.

Dated: June 29, 2021

s/ Steven A. Haber
Steven A. Haber