THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

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

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INTERESTS OF AMICI CURIAE

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ARGUMENT

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

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

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

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

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

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

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

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

The alternative to the replenishment model is for the pharmacy to maintain a supply of drugs that the covered entity has pre-purchased at 340B discounts. *See* 2014 HHS-OIG Report at 5 (discussing "pre-purchased inventory model"). The pre-purchased inventory model, however, is a poor fit for most 340B contract pharmacy arrangements for at least two reasons. First, a pre-purchased inventory is just that—an expense to the covered entity in advance of a potential prescription. Such inventory would go to waste if it expires and is never dispensed. Second, the pharmacy often does not know whether the individual who presented the prescription is a patient of a covered entity at the time the prescription is dispensed. Without that real-time information, the pharmacy cannot effectively use a pre-purchased 340B inventory. Even if that information were available, a pre-purchased inventory model introduces an element of risk because it

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

requires a busy pharmacist or technician to select the correct inventory when dispensing. In contrast, under the replenishment model, the pharmacy fills all prescriptions from its inventory, and that inventory is replenished with 340B drugs purchased by the covered entity only to the extent that the contract pharmacy filled prescriptions for the covered entity's own patients, as determined outside the bustle of the pharmacy environment.

Novartis's misunderstanding about the replenishment model extends to its impact on Medicaid duplicate discounts. Novartis Mot. PI at 9. The replenishment model actually helps *prevent* duplicate discounts. The 340B statute protects manufacturers from providing a 340B discount and a Medicaid rebate on the same drug. 42 U.S.C. § 256b(a)(5)(A). To comply with this requirement, some covered entities "carve out" Medicaid patients, which means that these covered entities do not dispense 340B discounted drugs to any Medicaid patients. *See* HRSA, *Duplicate Discount Prohibition*.[8] Patients are often retroactively enrolled in Medicaid, and an individual's Medicaid status may not be known at the time a prescription is filled. Because replenishment occurs after the point of sale, the covered entity by then has updated information on its patients' Medicaid status. Far from being a "scheme," the replenishment model helps ensure that manufacturers are protected from paying duplicate discounts.

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

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

through group purchasing organizations are consistent with federal antitrust law, which permits certain health care providers to purchase discounted drugs for some patients (as does 340B). *Abbott Laboratories v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1, 3-4 (1976). The Supreme Court *recommended* a replenishment system where providers manage their inventories according to general accounting principles by adjusting inventories at a later date. *Id*. at 20-21.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Denying 340B pricing is antithetical to Congress's design of the 340B Program, which is

intended to expand care to patient populations served by safety-net providers. Without 340B savings, covered entities cannot possibly "reach[] more eligible patients and provid[e] more comprehensive services" to those patients. H.R. Rep. No. 102–384(II), at 12 (1992). Indeed, drug manufacturers' deprivation of 340B Program benefits has already harmed covered entities, their patients, and their broader communities, because covered entities have had to reduce critical services supported with 340B-derived funding. Eliminating 340B contract pharmacy arrangements will directly and indirectly harm our nation's most vulnerable communities by denying them affordable medications, critical health care, and related services that covered entities are able to provide through 340B Program participation. A decision favorable to Novartis will signal to it and other drug companies that they are authorized to stop shipping covered entity-purchased drugs to contract pharmacies. Just the day before this filing, drug manufacturer Boehringer Ingelheim Pharmaceuticals, Inc., became the most recent manufacturer to announce its policy to ignore contract pharmacy arrangements under its own unilateral rules and exceptions. Such an outcome could cause many safety-net providers to shut their doors. These outcomes would be tragic at any time, but are unconscionable in the midst of the now 15-month battle led by covered entities against the COVID-19 pandemic.

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

The 340B Program enables covered entities to offer discounted drugs to financially needy patients. For example, FamilyCare, a West Virginia-based FQHC, has a drug discount program that allows indigent patients to pay only FamilyCare's cost for the drug. Glover Aff. ¶ 17.[11]

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

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

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

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

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

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

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

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

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

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

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

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

FamilyCare serves a very large area in rural West Virginia and uses contract pharmacy arrangements across its service area to meet its patients' pharmaceutical needs. Glover Aff. ¶ 19 (noting that its contract pharmacy network enables FamilyCare to provide patients discounted drugs near their homes); *see also* Simila Aff. ¶ 26 ("a single pharmacy for all our patients would severely limit our patients' access to life saving medications"). Hudson Headwaters Health Network ("HHHN"), an FQHC based in upstate New York, provides care to over 90,000 patients across a 7,000 square-mile area that HHS designated as a Health Professional Shortage Area. Slingerland Aff. ¶ 10. HHHN's service area has only one major road that traverses from north to south, other roads are often impassable in the winter, and the service area is generally not served

by public transport. Slingerland Aff. ¶ 10.[15] HHHN uses contract pharmacies to minimize the many "geographic and logistical barriers" that its patients face to access affordable medications. Slingerland Aff. ¶ 10. FQHCs have an obligation to ensure that all patients have equal access to services. 42 U.S.C. § 254b(k)(3)(A). Meeting that obligation is logistically impossible if only one pharmacy serves a large service or "catchment" area.

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

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

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

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

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

Covered entities use 340B Program savings to subsidize the cost of important and life-saving health care services. For insured patients, covered entities benefit from the difference between the 340B price and the insurer's payment for the drug. Covered entities use these funds to supplement their federal grants and other income, thereby "reaching more eligible patients and providing more comprehensive services" as Congress intended. H.R. Rep. No. 102-384(II), at 12 (1992). Many of the programs and services that covered entities support with 340B savings are critical to treating the whole patient, but are not reimbursed by public or private insurance, and are often most needed by patients who lack insurance altogether. Auclair Aff. ¶¶ 21-22; Glover Aff. ¶ 15; Johnson Aff. ¶ 10; Simila Aff. ¶ 18; Slingerland Aff. ¶ 7. Congress designed the 340B Program to provide a funding stream for just these sorts of programs and services.

Covered entities provide, among other services, case management to assist patients with transportation, insurance enrollment, links to affordable housing resources, food access, patient care advocacy, in-home support, health screenings, and education for chronic health care conditions. Auclair Aff. ¶¶ 12–16, 22 (noting provision of behavioral health services at local public schools for students and families); Glover Aff. ¶¶ 11, 14–15; Slingerland Aff. ¶ 7 (noting that 340B savings are used to "improve infrastructure, renovating facilities, and expanding services into underserved communities in Northeastern New York who otherwise would have limited or

no local access to care"); Johnson Aff. ¶ 10 ("Springhill provides many services to its community including participation in community health fairs at which it provides free health screenings."). Case management and care coordination are particularly critical for homeless and indigent individuals, who require these services to encourage their use of necessary primary and other health care services. Auclair Aff. ¶ 17; Glover Aff. ¶ 26; *see also* 42 U.S.C. § 254b(a)(1) (designating the homeless as one of four patient populations served); RWC-340B, *Value of Ryan White Providers and Impacts Associated with Resource Reduction*, 2–3 (Oct. 2020) (Ryan White patients are more likely to be homeless than general HIV/AIDS population). Education and in-home assistance for patients with chronic health conditions are also vitally important for disease management and prevents exacerbation or deterioration that would require more costly care. Glover Aff. ¶¶ 15, 27; *see also* NACHC, *Cmty. Health Ctr. Chartbook 2020* (Jan. 2020), Figs. 1-11 (health center patients diagnosed with a chronic health condition grew 25% from 2013 to 2017), 1-10 (21% of FQHC patients have diabetes compared to the national rate of 11%), http://www.nachc.org/wp-content/uploads/2020/01/Chartbook-2020-Final.pdf.

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

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

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

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

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

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

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

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

CONCLUSION

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

Dated: July 2, 2021

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