Nos. 21-5299 & 21-5304

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

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff-Appellee,

v.

CAROLE JOHNSON, ET AL.,
Defendants-Appellants,

UNITED THERAPEUTICS CORPORATION,
Plaintiff-Appellee,

v.

CAROLE JOHNSON, ET AL.,
Defendants-Appellants,

On Appeal from the United States District Court
for the District of Columbia
Nos. 21-cv-1479 & 21-cv-1686, Hon. Dabney L. Friedrich, U.S. District Judge

BRIEF OF AMICI CURIAE STATES OF CONNECTICUT, ARKANSAS, COLORADO, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, ILLINOIS, KANSAS, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, NEBRASKA, NEVADA, NEW JERSEY, NEW MEXICO, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, UTAH, VERMONT, IN SUPPORT OF DEFENDANTS-APPELLANTS

WILLIAM TONG
Attorney General of Connecticut
CLARE KINDALL
Solicitor General of Connecticut
MICHAEL K. SKOLD
Deputy Solicitor General

LYNN D. WITTENBRINK
Assistant Attorney General
165 Capitol Avenue
Hartford, CT 06106
Telephone: 860-679-1114
Email: lynn.wittenbrink@ct.gov

Attorneys for the State of Connecticut

Additional Counsel on Signature Page

May 16, 2022

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

(A) Parties and Amici to Instant and Consolidated Case:

In the consolidated appeals to this court, 21-5299 and 21-5304, captioned on the cover to this amicus brief, there are the following parties and amicus:

1) Novartis Pharmaceuticals Corporation (Plaintiff-Appellee)
2) Carole Johnson, in her official capacity as Administrator, Health Resources and Service Administration (Defendant-Appellant)
3) Xavier Becerra, in his official capacity as Secretary, United States Department of Health and Human Services (Defendant-Appellant)
4) United Therapeutics Corporation (Plaintiff-Appellee)
5) United States Health Resources and Services Administration (Defendant-Appellant)

In addition, the following appeared before the District Courts in the underlying matters:

6) Diana Espinosa, Acting Administrator of U.S. Health Resources and Services Administration (Defendant-Appellant)
7) U.S. Dept. of Health and Human Services (Defendant-Appellant)
8) American Hospital Association (Amicus)
9) 340B Health (Amicus)
10) America's Essential Hospitals (Amicus)
11) Association of American Medical Colleges (Amicus)
12) Children's Hospital Association (Amicus)
13) American Society of Health-System Pharmacies (Amicus)
14) National Association of Community Health Centers (Amicus)
15) Ryan While Clinics for 340B Access
16) Little Rivers Health Care, Inc.
17) Womencare, Inc.

(B) Third Circuit: *Sanofi v. HHS; Novo Nordisk v. HHS; Astra Zeneca v. Secretary United States Department of Health and Human Services*:

In the consolidated cross-appeals and now joined appeals to the US Court of Appeals, 3rd Circuit, **21-3167, 21-3168**, **21-3379 and 31-3380, and 22-1676,** there are the following parties:

1) Sanofi Aventis US LLC (Plaintiff- Appellant), (Plaintiff-Appellee)
2) United States Department of Health and Human Services (Defendant-Appellant), (Defendant-Appellee)
3) Secretary of the United States Department of Health and Human Services (Defendant-Appellant), (Defendant-Appellee)
4) General Counsel of the United States Department of Health Human Services (Defendant Appellant), (Defendant-Appellee)
5) Health Resources Services Administration (Defendant-Appellant), (Defendant-Appellee)
6) Administrator of the Health Resources and Services Administration (Defendant-Appellant), (Defendant-Appellee)
7) Novo Nordisk, Inc. (Plaintiff-Appellant), (Plaintiff-Appellee)
8) Novo Nordisk Pharma, Inc. (Plaintiff-Appellant), (Plaintiff-Appellee)
9) AstraZeneca Pharmaceuticals LP (Plaintiff-Appellee), (Amicus Appellant), (Amicus Appellee)
10) Pharmaceutical Research and Manufacturers of America (Amicus Appellant)
11) Kalderos (Amicus Appellant), (Amicus Appellee)

(C) Seventh Circuit: *Eli Lilly and Company v. Xavier Becerra*:

In the appeal and cross-appeal to the US Court of Appeals, 7th Circuit, **21-3128 and 21-3405,** there are the following parties:

1) Eli Lilly and Company (Plaintiff-Appellant), (Plaintiff-Appellee)
2) Lilly USA, Inc. (Plaintiff-Appellant), (Plaintiff-Appellee)
3) United States Department of Health & Human Services (Defendant-Appellant), (Defendant-Appellee)
4) Health Resources and Services Administration (Defendant-Appellee)
5) Diana Espinoza, in her official capacity as Acting Administrator of the Health Resources and Services Administration (Defendant-Appellant), (Defendant-Appellee)
6) Xavier Becerra in his official capacity as Secretary of Health & Human Services, Office of the Secretary (Defendant-Appellant), (Defendant-Appellee)
7) Daniel J. Barry in his official capacity as Acting General Counsel of Health & Human Services (Defendant-Appellant), (Defendant-Appellee)

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

STATUTES

United States Code, Title 42

TABLE OF AUTHORITIES
(continued)

Page

FEDERAL REGULATIONS

TABLE OF AUTHORITIES
(continued)

Page

OTHER AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page

COURT RULES

INTERESTS OF AMICI CURIAE

Amici States, Connecticut, Arkansas, Colorado, Delaware, District of Columbia, Hawaii, Illinois, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Utah and Vermont, submit this brief, pursuant to Federal Rule of Appellate Procedure 29(a)(2), in support of defendants-appellants, administrators of the Health Resources and Service Administration and the Department of Health and Human Services. Drug manufacturers' refusal to offer safety-net healthcare providers discounted prices on critical prescription drugs, as required by the 340B Drug Pricing Program (the 340B Program or Program), threatens the interests of Amici States. As a result of the manufacturers' refusals and restrictions, numerous federally qualified health centers (FQHCs) and other safety-net providers operating in our States are unable to provide vulnerable patients with affordable prescription drugs and expanded healthcare services. Amici States have a strong interest in protecting the health and well-being of our residents and in ensuring that our most vulnerable residents have access to affordable prescription drugs.[1] Reduced health outcomes and more expensive

[1] *See* State Attorneys General Letter to Health & Human Services Secretary Azar (Dec. 14, 2020), https://portal.ct.gov/-/media/AG/Press_Release/2019/340B-Multistate-Letter-12142020_Final1.pdf

care—often borne by the States—result when patients cannot access or afford the medications or services they need.

SUMMARY OF THE ARGUMENT

For nearly two years, United Therapeutics Corporation (UT) and Novartis Pharmaceuticals Corporation (Novartis), among other drug manufacturers participating in the 340B Program of the Public Health Service Act, 42 U.S.C. § 256b, have flouted their statutory obligation to offer safety-net providers 340B-discounted prices on critical prescription drugs. These drug manufacturers have either limited 340B covered entities to using a single retail community pharmacy,[2] (contract pharmacy), or conditioned the use of multiple contract pharmacies on intrusive audits of healthcare providers' confidential, proprietary claims data.[3] Drug manufacturers allege that imposing conditions that restrict the use of contract pharmacies is appropriate because the term "pharmacy" is not in the text of the 340B statute and that such conditions are necessary to prevent drug diversion and duplicate

---

[2] The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the public at retail prices. 42 U.S.C. § 1396r-8(k)(10).

[3] Hospital Associations Letter to Health & Human Services Secretary Azar (August 20, 2020), https://www.ashp.org/-/media/assets/advocacy-issues/docs/GRD-Letter-to-HHS-Secretary-Azar-Regarding-340B-Contract-Pharmacy?utm_source=GRDBreakingNews-090320&utm_campaign=GR?loc=ceoblog-05252021.

reimbursement claims. But permitting manufacturers to unilaterally change the 340B Program is in direct contravention of the statute and policies long established by Congress and advanced by the States.

Since its inception in 1992, the 340B Program has advanced the federal government's continued desire to rein in rising drug prices and protect patients' access to affordable prescription medicines. Congress enacted the 340B Program to enable "covered entities"—select hospitals, clinics, and health centers that serve a disproportionate share of poor patients in urban and rural areas—"to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] The 340B Program requires that drug manufacturers provide steep discounts on prices of outpatient drugs sold to these safety-net providers, allowing covered entities the benefits of (1) Program savings from the discounts on drug prices and (2) Program revenue generated from the prescription sales that patients' third-party payors such as insurance companies reimburse beyond the 340B-price. Thus, by Congress' design and for nearly 30 years, the 340B Program has successfully yielded significant savings and revenue for safety-net providers, many of which use contract pharmacies to dispense critical medications to patients served by these covered entities.

[4] H.R. Rep. No. 102-384, pt. 2, at 12 (Sept. 22, 1992).

The goal of the 340B Program is to aid covered entities that serve disproportionate levels of medically underserved patient populations. It is fundamental to § 340B that Congress credited covered entities for their ability to "provide direct clinical care to large numbers of uninsured Americans," regardless of a patient's ability to pay.[5] To increase access to affordable prescription drugs and expand healthcare services, Congress assigned the 340B Program's savings and revenue benefits solely to covered entities. 42 U.S.C. § 256b(a)(5). To achieve these goals, covered entities rely on a growing network of contract pharmacies to make affordable drugs *accessible* to a wider patient population across the country. The resulting increase in patients served under this statutory arrangement has allowed covered entities to generate significant revenue, which funds their ability to expand healthcare services in their communities and further supports Amici States' public health efforts. Finally, to ensure that covered entities continue to receive 340B discounts and generate critical revenue, Congress designated the Administrative Dispute Resolution (ADR) Process as the appropriate forum in which manufacturers and covered entities can resolve disputes involving claims of

[5] H.R. Rep. No. 102-384, pt. 2, at 12 (Sept. 22, 1992). Pursuant to 42 U.S.C. § 254b(k)(3)(G)(iii)(I), FQHCs are required to "assure that no patient will be denied health care services due to an individual's inability to pay for such services." Thus, FQHCs must use any non-grant or program income to stretch their resources to offset any uncompensated care.

overcharges or duplicate reimbursements "fairly, efficiently, and expeditiously." *Id.* § 256b(d)(3)(B)(ii)-(iv).

Novartis and United Therapeutics' attempt to upend the 340B Program's reliance on contract pharmacies runs counter to these goals and is unjustified. Nothing in the statute or the legislative history allows drug manufacturers to unilaterally place industry-wide restrictions on covered entities' use of contract pharmacies for their prescription dispensing needs. Contract pharmacy arrangements as a dispensing mechanism are consistent with § 340B, and manufacturers' new policies are an improper way to remedy any disputes regarding duplicate reimbursements or drug diversion. Novartis and United Therapeutics must not preemptively deny patients' access to affordable prescription drugs at the expense of the Amici States' public health when they have a remedy through the ADR Process. Amici States thus support HHS's issuance of the May 17, 2021 Violation Letters to Novartis and United Therapeutics for refusing to ship drugs to contract pharmacies absent restrictions in contravention of § 340B. JA35-36; 65-66; 552-553; 590-591; 595-596. This Court should reverse the decision below.

ARGUMENT

I. THE HISTORY OF THE 340B PROGRAM SHOWS THAT ITS PURPOSE IS TO PROTECT VULNERABLE POPULATIONS FROM PRICE INCREASES

Congress created the 340B Program as a pathway for covered entities to be eligible to purchase drugs at a significant discount after drug manufacturers raised

drug prices for community health clinics and veterans, among other vulnerable groups, in the early 1990s.[6] This price increase came as a result of the 1990 Medicaid Drug Rebate Program, which required drug manufacturers to sell their drugs to state Medicaid programs at the *best price* given to any purchaser in the country on each drug.[7] To compensate, drug manufacturers refused to offer any "best prices" below the Medicaid price and "promptly cancelled discount contracts, terminated special-price practices, and raised the prices they charged public hospitals."[8] They also eliminated a list of drugs available to other federal purchasers at lower prices previously negotiated with the Department of Veterans Affairs (DVA) and other FQHCs.[9]

Once drug manufacturers imposed higher drug prices for veterans and other vulnerable patient groups, Congress understood that it "cannot continue to allow the DVA, [f]ederally-funded clinics, and their patients to remain unprotected against manufacturer price increases."[10] As a remedy, Congress enacted the Public Health Service Act, which created the 340B Program and required drug manufacturers to participate as a condition of having their outpatient drugs covered under Medicaid

---

[6] H.R. Rep. No. 102-384, pt. 2, at 10-11 (Sept. 22, 1992).

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

and Medicare Part B. 42 U.S.C. §§ 1396r-8(a)(1), (a)(5). Through Pharmaceutical Pricing Agreements (PPAs) between manufacturers and HHS, Congress required manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." *Id.* §§ 256b(a)(1), 1396r-8(a)(1).

II. THE PROVISION OF OUTPATIENT CARE RELIES ON A NETWORK OF CONTRACT PHARMACIES

Contract pharmacies are vital to covered entities and the success of the 340B Program because contract pharmacies are the vehicle by which many covered entities dispense affordable prescription drugs for outpatient treatment and recovery, particularly for patients who continue to face significant barriers to care. The 340B Program was primarily concerned with patients' access to prescription drugs for recovery outside the traditional hospital settings—namely, at home. Thus, § 340B imposes ceilings on prices that drug manufacturers may charge only for *outpatient drugs* sold to covered entities. *Id.* § 256b(b)(2).[11] With few exceptions, outpatient drugs are generally drugs "which may be dispensed only upon prescription" by a physician or authorized provider. *Id.* §§ 256b(b)(2), 1396r-8(k)(2).[12] And ten of the

[11] *See also* Ass'n. of Am. Med. Colls., *340B Helps the Most Vulnerable Patients* (Mar. 3, 2019), https://www.aamc.org/news-insights/340b-helps-most-vulnerable-patients.

[12] Outpatient drugs covered under the 340B Program may include prescription drugs approved by the Food and Drug Administration (FDA), certain over-the-counter drugs provided as prescriptions, biological products, other than vaccines, that can be dispensed only by a prescription, and insulin approved by the FDA. Notably, when payment for an outpatient drug is bundled with payment for other services, the drug

sixteen covered entities enumerated in the 340B statute deal primarily with *outpatient care*; six categories include hospitals that provide inpatient services and ten are categories of entities tied to federal grant programs that deal primarily with outpatient care (such as FQHCs). *See id.* § 256b(a)(4)(A)-(L). Therefore, the statute explicitly limits discounts to outpatient drugs for covered entities and the vast majority of covered entities do not provide inpatient care.

These statutory limitations reinforce that Congress was concerned with patients' access to medicines outside of traditional hospital settings and not necessarily with inpatient care where patients benefit from the administration of drugs in an in-patient setting. One purpose of outpatient care has always been to keep Americans out of costly hospital beds, which is costly for everyone, including patients and Amici States. Today, by serving millions of Americans nationwide through a network of more than 12,000 covered entities with more than 46,000 contract pharmacy arrangements and about 20,000 contract pharmacies, the 340B Program is effective in reaching patients nationwide.[13] But the drug manufacturers'

---

is not covered by the 340B Program. *340B Drug Pricing Program Omnibus Guidance*, 80 Fed. Reg. 52,300 (Aug. 28, 2015).

[13] Equiscript, *The 340B Program in One Sentence* (2022), https://www.equiscript.com/blog/the-340b-program-in-one-sentence; Gov't Accountability Off., *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight* (July 18, 2017), https://www.gao.gov/assets/gao-17-749t.pdf. The American Association of Medical Colleges noted: "The 340B Program is one of the most effective healthcare programs . . . . There is no cost to

new conditions seeking to limit the use of multiple contract pharmacies attempt to circumvent congressional efforts to address high drug prices and expand healthcare access. Manufacturers should not be allowed to unilaterally restrict covered entities' use of contract pharmacies and thereby eliminate the significant revenue benefit Congress assigned to safety-net providers.

A. Use of Multiple Contract Pharmacies Is Well-Established and a Necessary Feature of Federal Assistance Programs

Congress has a history of enacting federal legislation in which contract pharmacies play an integral part of the statutory scheme. Congress understood that covered entities commonly use multiple contract pharmacies, particularly in federal assistance programs. While it is true that § 340B is silent as to the use of contract pharmacies, JA403 (District Court Opinion p. 13), the same is true of *any* type of drug distribution system for covered outpatient drugs purchased by covered entities.[14] The statute's "silence" is certainly not a prohibition. Nothing in the text of § 340B *requires* a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself or through a single contract pharmacy.[15] Still, the context

---

taxpayers, and it allows hospitals to provide lifesaving programs to their most vulnerable patients and communities." Am. Ass'n. of Med. Colls., *supra* note 12.

[14] In its 1996 Guidance, HHS recognized that § 340B "is silent as to permissible drug distribution systems." *See* Notice Regarding Section 602 Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

[15] JA403 (District Court Opinion p. 13).

in which Congress acted informs its legislative intent regarding the use of contract pharmacies.

Congress did not need to expressly authorize the use of contract pharmacies because it legislated with the understanding that the contract pharmacy networks were already in place and operating to facilitate prescription-dispensing services to patients.[16] In 1996, four years after the statute's inception, only 4% of covered entities maintained in-house pharmacies. JA394 (Op. at p. 4). The Court should not assume that Congress intentionally structured the Program so that only 4% of covered entities would be able to fully participate.

In addition, other laws enacted during this period emphasized the use of contract pharmacies, underscoring Congress' understanding that contract pharmacies are a vehicle by which public health was and is administered. In 1990, Congress stressed the role of community pharmacists in the drug delivery system by including patient prescription counseling by pharmacists as one of the components of the Drug Utilization Review requirements incorporated into the Medicaid program. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 1927(g), 104 Stat. 1388 (codified in divers sections of 42 U.S.C.). In response to

---

[16] *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000)(As Congress affirmatively acted to address the issue and created a distinct scheme to regulate "it is hardly conceivable that Congress . . . was not abundantly aware of what was going on").

prescription drug-related illnesses, Congress sought to minimize the risk by requiring states to implement a drug use review program "for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results." *Id.* § 1927(g)(1)(A). To accomplish this, Congress turned to states to establish standards for providing drug information to consumers in the form of prescription counseling at retail community pharmacies, i.e. contract pharmacies. *Id.* § 1927(g)(2)(A)(ii).

Congress enacted § 340B two years later in 1992 with the same understanding: contract pharmacies are the common drug delivery system for outpatient drugs.[17] In formally allowing use of contract service agreements between covered entities and retail pharmacies (i.e., contract pharmacies) in its 1996 Guidance, HRSA appropriately reasoned that "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." Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996). Indeed, it recognized that, even by 1996, "contract pharmacies are used by a number of large organizations, such as the American Red

[17] *See United Steelworkers of Am. v. Weber*, 443 U.S. 193, 201 (1979) (Congressional acts must "be read against the background of the legislative history . . . and the historical context from which the Act arose").

Cross, several community health centers, and the New York Blood Consortium." *Id.* at 43,550.

Use of multiple contract pharmacies is not new. It is a primary method for dispensing prescriptions. Section 340B's omission of the term "contract pharmacies" from the statute should carry little weight when it is contrary to this "contextual evidence of congressional intent." *Burns v. United States*, 501 U.S. 129, 136 (1991).

B. Contract Pharmacy Arrangements Sufficiently Protect Against Drug Diversion and Duplicate Discounts

Contract pharmacies have long been established in federal regulations and have provided sufficient protection against drug diversion and duplicate discounts. Since 1996, for over twenty-six years, HRSA encouraged the use of contract pharmacies "to facilitate [P]rogram participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." 61 Fed. Reg. at 43,555 (August 23, 1996). To provide assurance and protections against drug diversion, HRSA also provided guidance on model contract pharmacy agreement formats. *Id.* To this day, covered entities submit contract pharmacy agreements to HRSA's Office of Pharmacy Affairs (OPA), and "dispensing is available only after an agreement is finalized and approved" by OPA. JA278 (Richards Declaration p. 2). As one covered entity in Michigan explains, once approved by OPA, it "enters into a contractual relationship with the individual pharmacy's wholesaler under

which [it] purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to the contract pharmacy." JA281 (Simila Declaration p. 2).

Under these agreements, covered entities usually pay a fee both to the contract pharmacy (for providing the dispensing services) and to the third-party administrator (TPA) (for qualifying claims and ordering medications). JA729 (Richards Declaration p. 3). Importantly, the claim matching process, often handled by TPAs, goes through several filters before a claim is deemed eligible for 340B pricing. *Id.*; JA304 (Chen Declaration p. 3)(a covered entity in Arizona explains that at "no point in this [claim matching] process can a contract pharmacy order 340B medications directly or see the 340B drug pricing"). The most significant feature of this arrangement is that "the health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services" to the covered entity's eligible patients. *Id.*; JA281 (Simila Declaration p. 2); JA298 (Mahania Declaration p. 1)(a covered entity in Massachusetts explains that in addition to retaining title to the drugs, its "contract pharmacies [also] undergo an certification process" with the OPA). They maintain auditable records and inventories.[18]

And contrary to any claim that profits generated by the sale of manufacturers' drugs will somehow enrich for-profit commercial pharmacies, covered entities "never enter into an agreement with contract pharmacies where [the covered entity]

[18] Ass'n. of Am. Med. Colls., *supra*, note 12.

does not retain much of the savings from the 340B discount." JA279 (Richards Declaration p. 3). This is a critical point. Any profits, or revenue, from the sale of manufacturers' drugs cannot in practice enrich contract pharmacies because revenue can only be generated by the spread between the ceiling price and any reimbursement at or above that price from third-party payers including the Medicare Program, Medicaid managed care organizations, or patients' private insurance carriers.[19] The benefit of this difference between the ceiling price and the eventual reimbursement is claimed only by covered entities. *Id*. This is because eligibility to participate in the 340B Program is regulated by which covered entities are eligible to receive drug discounts. That determination is not necessarily dependent on a patient's eligibility based on their individual financial need. The 340B Statute allows covered entities to purchase drugs at the 340B price for all their patients, regardless of a patient's income or insurance status. 42 U.S.C. § 256b(a)(5)(B). In this way, covered entities can generate significant revenue when a particular patient's insurance reimbursement for a drug exceeds the 340B price. For example, critical medications and products like insulin and inhalers can be priced at about $900 to $1,800 for a three-month supply, while covered entities, entitled to 340B discounts, can purchase

[19] Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC Schaeffer (Oct. 14, 2021), https://healthpolicy.usc.edu/research/the-340b-drug.pricing.program-background-ongoing-challenges-and-recent-developments/.

the same product amounts for $12 to $15. JA311 (Spinelli Declaration p. 3). Not only are these medications lifesaving for uninsured patients living with diabetes or chronic obstructive pulmonary disorders, but the price difference—when it is subject to reimbursement—is also what enables covered entities to generate revenue from the spread between the discounted price and reimbursement and use it to offer additional services to medically underserved communities.

C. Contract Pharmacies Enable Covered Entities to Satisfy their Statutory Obligations to Provide Care to All Patients, Regardless of their Ability to Pay

The 340B statutory scheme is particularly beneficial because covered entities' participation in the 340B Program generates both savings and revenue at no cost to taxpayers. The savings and revenue, in turn, enable covered entities to make healthcare affordable and accessible to more patients.

This is critical since § 330 of the Public Health Service Act obligates the FQHC covered entities to use any non-grant or program income—e.g. revenue generated through public or private reimbursement for services—in furtherance of their healthcare safety-net mission. 42 U.S.C. § 254b(e)(5)(D). As a result, FQHCs and other safety-net providers are uniquely qualified to provide high-quality care to medically underserved and diverse populations, using the cost savings from the discounted drugs and the revenue generated from the reimbursement received from third-party payors. *Id.* § 254b(a); JA278 (Richards Declaration p. 2)(in 2019 alone,

a covered entity in Georgia provided over $8 million in uncompensated care); JA324 (Starkey Declaration p. 1)(in a rural community of Oklahoma, there is only one 340B provider in the area and 61% of its patients are below 200% of the FPL); JA248 (Lees Email p. 2)(patients served at a covered entity in rural New York tend to present "sicker", require more costly care, and need financial assistance to afford critical services and medications").

Thus, any revenue generated from the use of contract pharmacies and available reimbursements enables covered entities across Amici States to deliver on their statutory commitments.

III. THE 340B PROGRAM'S PARTNERSHIP WITH STATES ALIGNS WITH HHS'S READING OF § 340B

The 340B Program is designed to work in partnership with Amici States and in support of their public health efforts, allowing the States and the federal government to stretch resources in a cost-efficient manner. Covered entities' reinvestment of 340B revenue supports the public health efforts of Amici States. But the new conditions unilaterally imposed by drug manufacturers reverse those gains and upset the role of the States in the administration of the 340B Program.

A. The Revenue Generated Through Contract Pharmacies and Reimbursements Supports Key Public Health Efforts

As discussed above, the 340B Program allows covered entities to yield significant revenue. Across multiple contract pharmacies, a covered entity in

Michigan can reach $6 million annually in drug sales through the 340B Program, approximately $3 million to $3.6 million of which is net revenue, after administrative fees, ingredient costs, and dispensing fees. JA283 (Simila Declaration p. 4). With the potential for revenue in the millions of dollars, this is a critical feature of the 340B Program, since many covered entities are FQHCs operating with slim profit margins. For instance, the same covered entity in Michigan that accrues up to $3.6 million annually in revenue has an annual operating margin of about 1-2% on a budget of $22 million. *Id*. Thus, the revenue achieved by this covered entity through its use of multiple contract pharmacies is crucial to its continuing operation and increasing access to healthcare for this underserved population.

Section 340B revenue helps fill gaps left by slim profit margins and limited federal grants, thereby enabling covered entities to provide care to their respective patient populations. JA747 (Simila Declaration p. 3). For instance, while a covered entity in Georgia receives grant dollars to help serve its patients, "these grants only cover about 28% of [its] total expenses," making the covered entity dependent "on its 340B Program savings and revenue to help support approximately 41% of its remaining expenses, which include underfunded and unfunded programs and services." JA280 (Richards Declaration p. 4). A covered entity's ability to generate revenue from larger volumes of 340B-discounted drugs (as a result of reaching more

patients through different contract pharmacy locations) is not a glitch in the Program, but a critical feature that helps providers augment the number of patients they serve and the types of services they can offer.

For example, 340B revenue allows covered entities to open new locations to improve access for low-income patients and offer OBGYN services, dental services, language translation services, behavioral healthcare, vaccinations, and case management and care coordination. *See* JA747 (Simila Affidavit p. 3); JA753 (Rickertsen Declaration p. 4); JA298-99 (Mahania Declaration p. 1-2). This revenue also allows covered entities to expand services for patients suffering from substance use disorders and create new initiatives to meet the needs of specific patient populations (such as cancer and heart disease treatments due to excessive radiation exposure). *Id*. Because FQHCs can never turn patients away due to inability to pay, this revenue also helps offset the losses resulting from uncompensated care costs incurred from treating patients who are uninsured and cannot pay. These are critical services to communities whose primary interaction with the healthcare system is at their local FQHC. For example, with 340B savings and revenue, many covered entities are able to increase access by providing transportation subsidies, improving call centers, centralizing referrals, hosting community education programs, and delivering mobile clinics to remote areas. JA787 (Castle Declaration p. 3); JA299 (Mahania Declaration p. 2).

These contributions are made possible by the vast networks of covered entities—including that of their affiliated contract pharmacies—operating in Amici States. While the ability to distribute larger volumes of 340B-priced prescriptions can supplement covered entities' slim budgets, the option to have multiple contract pharmacies is also a vital component of ensuring access to 340B drug pricing for patients who continue to face significant barriers to care. As Amici States know too well, state agencies and other components of our respective health delivery systems are often overwhelmed. But through covered entities' contractual relationships with a network of pharmacies, patients have the option of accessing affordable prescription drugs beyond the traditional workday hours and at geographically convenient locations. JA278 (Richardson Declaration p. 2). An Illinois covered entity notes many of its 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." JA759 (Francis Declaration p. 4). Contract pharmacies, particularly "24-hour pharmacies and those with home delivery capabilities," provide "crucial access" to patients. *Id.*

The services provided by covered entities were also essential during the beginning of the COVID-19 public health emergency and critical to Amici States' efforts to slow the spread of the virus and alleviate the burdens on our hospital

systems. In Michigan, covered entities supported the state's efforts to combat COVID-19 by utilizing 340B-generated funds to set up mobile and drive-up testing sites, employ additional personnel, and purchase test kits that allowed them to complete over 10,000 COVID-19 tests in local communities. JA282 (Simila Declaration p. 2). In addition, the covered entities were "instrumental to two local [u]niversities commencing face-to-face instruction" by conducting "random COVID-19 tests for students and employees, providing approximately 600 tests per week," which "enabled the [u]niversities to bring 6,700 students back on campus." *Id.* In this and many other ways, covered entities have proven to be integral to Amici States' public health efforts, which often result in healthier communities and positive economic impacts. Unlike Amici States and our covered entities, drug manufacturers have largely been insulated from the financial burden of combatting COVID-19, while health care providers have suffered the brunt of the economic harm." In early 2021, Eli Lilly's stock rose 11 percent.[20]

[20] Business Insider, *Stock Alert: Eli Lilly And Company Jumps 11%* (Jan. 11, 2021), https://businessinsider.com/news/stocks/stock-alert-eli-lilly-and-company-jumps-11-1029956099. Notably, 340B sales account for a small part of the $433 billion in national drug sales—1.4 percent. 340B Health, *New Independent Study Confirms 340B is a Small Share of U.S. Drug Market* (Aug. 08, 2018), https://340binformed.org/2018/08/new-independent-study-confirms-340b-is-a-small-share-of-u-s-drug-market/.

Drug manufacturers' restrictions on covered entities' use of contract pharmacies reverse public health gains by causing dramatic increases in the price of patients' life-sustaining medications used to treat common, chronic conditions including diabetes, cardiovascular and respiratory diseases.[21] Most importantly, the harm to patients' health from being deprived of access to affordable medicines is incapable of remediation because covered entities cannot retroactively provide, and their patients cannot retroactively benefit from, critical health care and enabling services that must be reduced or eliminated due to manufacturers' noncompliance with 340B pricing requirements. The 340B Program is undeniably critical to Amici States' public health efforts.

B. Manufacturers' New Conditions Upset the Role of the States in the 340B Program and Its Operation Across Public Health Systems

Amici States play a significant role in the operation of the 340B Program. Relevant provisions in § 340B demonstrate how the anticipated use of contract pharmacies facilitates the Program's operation within the Amici States' health systems. Novartis and United Therapeutics' restrictions on the use of contract pharmacies undermine this state and federal partnership, and the States' significant interests.

[21] Ass'n. of Am. Med. Colls., *supra,* note 12.

Congress reserved a pivotal role for the States' participation within the 340B Program by giving deference to state laws and ascribing to states certain responsibilities for the Program's implementation. For instance, § 340B authorizes discounts for certain "over-the-counter" drugs when those drugs are also prescribed by an authorized provider under state law. 42 U.S.C. § 256b(a)(2)(B)(ii). The statute also defines the scope of the Program to include drugs covered by Medicaid under a state's Medicaid plan. *Id.* § 256b(a)(3). And § 340B's defined covered entities include hospitals and clinics that are funded or operated by state or local government. *Id.* § 256b(a)(4)(K)-(L).[22] Further, § 340B forbids duplicate discounts by prohibiting a covered entity from billing a state Medicaid plan for a drug already purchased at the 340B-discounted price. *Id.* § 256b(a)(5)(A)(i). Moreover, the statute assigns states certain implementation responsibilities; it requires that states submit reports as a condition of certifying certain entities, indicating which covered entities are in fact operated by or receiving funds from a state or a local government. *Id.* § 256b(a)(7)(D). Lastly, § 340B contemplates a supporting role for oversight by states in requiring HHS to notify both manufacturers and individual state agencies about any covered entity that violates its compliance obligations or is no longer

[22] 340B covered entities also include "disproportionate share" hospitals which "serve a significantly disproportionate number of low-income patients." 42 U.S.C. §§ 256b(a)(4)(L)-(O); *see also* Health Res. & Servs. Admin. *Disproportionate Share Hospitals,* (May 2018), https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html.

eligible under statute. *Id.* § 256b(a)(9). These statutory provisions demonstrate that Congress accounted for the 340B Program's implementation within different systems of public health providers across Amici States.

Pursuant to these provisions, many States enacted laws in response to the 340B Program. For example, Illinois statutorily acknowledges that covered entities and pharmacies can enter into agreements independently as part of the 340B Program. *See* 305 Ill. Comp. Stat. Ann. 5/5-36 (clarifying that "outpatient pharmacy services provided by a health care facility registered as a covered entity pursuant to 42 U.S.C. § 256b or any pharmacy owned by or contracted with the covered entity" need not seek approval by its Department of Healthcare). In setting its own program integrity standards, Arizona recognizes that covered entities must use contract pharmacies by providing that the state "may not reimburse any contracted pharmacy for drugs dispensed as part of the 340B drug pricing program." Ariz. Rev. Stat. § 36-2930.03(A)(2)-(3).

In New York, state law defines a "covered entity" as "an entity that…causes claims for payment for drugs covered…either directly or through an authorized contract pharmacy." N.Y. Soc. Serv. Law § 367-a(9)(b)(iii). Similarly, Ohio law defines a covered entity as "an entity described in section 340B(a)(4) of the 'Public Health Service Act,'" 42 U.S.C. 256b(a)(4), and includes any pharmacy under contract with the entity to dispense drugs on behalf of the entity. Ohio Rev. Code §

5167.01(A). In Oregon, state law utilizes the term "340B pharmacy" to mean "a pharmacy that is authorized to purchase drugs at a discount under 42 U.S.C. § 256b." Or. Rev. Stat. § 735.530(15). The flexibility afforded to the States is further exemplified by Tennessee's state law establishing an FQHC pilot project using "telepharmacy services" to reach its patients so long as the central pharmacy site is licensed by the state and is "located within a [FQHC] that is connected through computer link, videolink, and audiolink to one (1) or more satellite clinics." Tenn. Code § 63-10-601.

These examples underscore that the 340B statute is primarily a drug pricing statute that does not control—and could not control—dispensing practices or health system arrangements across Amici States. Instead, § 340B is meant to operate in tandem with state laws to account for different systems of public health providers, Medicaid state plans, and state pharmacy laws. Novartis and United Therapeutics' restrictions on the use of contract pharmacies not only undermine § 340B but undermine state laws that allow for the use of contract pharmacy services. The partnership established by the 340B Program allows the states to exercise their authority to regulate prescription and dispensing practices within their borders. *See Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) (holding that regulation of matters of health and safety are undoubtedly within the States' historic police powers); *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 475 (1996)

(states have "great latitude under their police powers to legislate as to the protection of lives, limbs, health, comfort and quite of all persons"); *Gonzalez v. Oregon,* 546 U.S. 243, 270 (2006)(same).

IV. DRUG DIVERSION AND DUPLICATE DISCOUNTS DO NOT JUSTIFY MANUFACTURERS' NEW, UNLAWFUL CONDITIONS

The 340B statute specifically provides adequate remedies and a process by which drug manufacturers can seek to resolve claims of drug diversion or duplicate discounts without depriving covered entities and their patients of access to critical prescription drugs. Congress explicitly prohibits covered entities from requesting duplicate rebate payments from state Medicaid programs and the reselling or otherwise transferring of drugs purchased to other persons not patients of the covered entity. 42 U.S.C. § 256b(a)(5)(A)-(B).[23] The 340B Statute has protections and remedies to resolve any disputes over duplicate discounts resulting from the use of multiple contract pharmacies. As a condition of participating in the 340B Program, covered entities must allow HHS and the manufacturer to conduct audits to determine whether the covered entity is complying with the prohibitions on drug diversion and duplicate discounts from Medicaid. *Id.* § 256b(a)(5)(C). Moreover,

[23] The statute explicitly provides that, "[a] covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act" and "shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(A)-(B).

340B assigns primary oversight of the 340B Program to HHS, including both "manufacturer compliance" and "covered entity compliance." This allows HHS to conduct selective audits of manufacturers or wholesalers, including the imposition of sanctions, among other measures. *Id.* §§ 256b(d)(1), (2)(B)(ii)-(iv). Moreover, 340B also includes an ADR Process establishing the appropriate forum for manufacturers and covered entities to resolve claim disputes, "fairly, efficiently, and expeditiously." *Id.* § 256b(d)(3)(B)(ii)-(iv).

Congress enacted these protections to ensure compliance by both covered entities and manufacturers while also protecting patients' access to critical medicines. Indeed, manufacturers, while fully entitled to subject covered entities to individual audits when conditions warrant, must do so at their own expense, *id.* § 256b(a)(5)(C), and "as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity." *Id.* § 256b(d)(3)(B)(iv).

Amici States do not dispute that Novartis and United Therapeutics are entitled to conduct such audits on certain occasions, but what they cannot do is simply put the cart before the horse. Section 340B does not permit manufacturers to replace the statutory audit process with a process of their own choosing, i.e., to subject covered entities to intrusive auditing at the entities*' own expense and penalize them* for using contract pharmacies before there is any basis to suspect duplicate claims or ADR

proceedings against them have even commenced. This runs counter to the process and protections put in place by Congress.

If the drug manufacturers truly seek to prevent reimbursement abuses, they can avail themselves of the 340B statute's procedures governing such claims. Instead, the manufacturers' conditions bypass the statutory checks and balances and interfere with HHS's adjudication of complaints under its ADR process.

Lastly, for decades, drug manufacturers themselves have voluntarily agreed to participate in the 340B Program and thus fully understand the various ways in which the statute governs compliance disputes. *Id.* §§ 256b(a)(1), 1396r-8(a)(1) (discussing PPA contracts used nationwide between HHS and manufacturers). There is no basis for now disputing the use of contract pharmacies without at least engaging in the ADR process as intended by Congress. Novartis and United Therapeutics have long understood the requirements for participating in the 340B Program and the remedies long afforded to them to address any diversion or duplicate claims—they cannot now unilaterally modify a federal statute. The manufacturers in this instance are simply left with no basis for their reading of the statute.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's vacatur of HHS's Violation Letters to Novartis and United Therapeutics.

Dated: May 16, 2022

Respectfully submitted,

/s/ Clare E. Kindall

WILLIAM TONG
Attorney General of Connecticut
CLARE KINDALL
Solicitor General of Connecticut
MICHAEL K. SKOLD
Deputy Solicitor General
LYNN D. WITTENBRINK
Assistant Attorney General
165 Capitol Avenue
Hartford, CT 06106
Telephone:
Email: Clare.Kindall@ct.gov
Attorneys for the State of Connecticut

Additional Counsel on Next Page

ADDITIONAL COUNSEL

LESLIE RUTLEDGE
Attorney General of Arkansas
Office of the Arkansas Attorney General
323 Center Street, Suite 200
Little Rock, Arkansas 72201

PHILIP J. WEISER
Attorney General of Colorado
Attorney General's Office
1300 Broadway, 10th Floor
Denver, CO 80203

KATHLEEN JENNINGS
Attorney General of Delaware
Delaware Department of Justice
820 N. French Street
Wilmington, DE 19801

KARL A. RACINE
Attorney General for the District of Columbia
Office of the Attorney General
400 6th Street, NW, Suite 8100
Washington, D.C. 20001

HOLLY T. SHIKADA
Attorney General of Hawaii
Department of the Attorney General
425 Queen Street
Honolulu, Hawaii 96813

KWAME RAOUL
Attorney General of Illinois
Office of the Attorney General
100 W. Randolph St.
Chicago, IL 60601

DEREK SCHMIDT
Attorney General of Kansas
Office of the Kansas Attorney General
120 SW 10th Avenue, 2nd Floor
Topeka, Kansas 66612-1597

JEFF LANDRY
Attorney General of Louisiana
Louisiana Department of Justice
1885 N 3d St,
Baton Rouge, LA 70802

AARON M. FREY
Attorney General of Maine
Office of the Maine Attorney General
6 State House Station
Augusta, ME 04333

BRIAN E. FROSH
Attorney General of Maryland
Office of the Attorney General
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202

MAURA HEALEY
Attorney General of Massachusetts
Office of the Attorney General
One Ashburton Place
Boston, MA 02108

DANA NESSEL
Attorney General of Michigan
Department of Attorney General
PO Box 30212
Lansing, MI 48909

KEITH ELLISON
Attorney General of Minnesota
Office of the Attorney General
102 State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

LYNN FITCH
Attorney General of Mississippi
Mississippi Attorney General's Office
P.O. Box 220
Jackson, MS 39205

DOUGLAS J. PETERSON
Attorney General of Nebraska
Nebraska Department of Justice
2115 State Capitol
Lincoln, NE 68509

AARON D. FORD
Attorney General of Nevada
Nevada Attorney General's Office
100 North Carson Street
Carson City, NV 89701

MATTHEW J. PLATKIN
Acting Attorney General of New Jersey
New Jersey Office of the Attorney General
Richard J. Hughes Justice Complex
25 Market Street
Trenton, NJ 08625

HECTOR BALDERAS
Attorney General of New Mexico
Office of the Attorney General
408 Galisteo Street
Santa Fe, NM 87501

JOSHUA H. STEIN
Attorney General of North Carolina
North Carolina Department
Of Justice
114 W. Edenton Street
Raleigh, N.C. 27602

ELLEN F. ROSENBLUM
Attorney General of Oregon
Oregon Department of Justice
1162 Court Street NE
Salem, OR 97301

JOSH SHAPIRO
Attorney General of Pennsylvania
Office of the Attorney General
Strawberry Square
Harrisburg, PA 17120

PETER F. NERONHA
Attorney General of Rhode Island
Office of the Attorney General
150 S. Main Street
Providence, RI 02903

SEAN D. REYES
Attorney General of Utah
350 N. State Street, Suite 230
P.O. Box 142320
Salt Lake City, UT 84114-2320

THOMAS J. DONOVAN, JR.
Attorney General of Vermont
Office of the Vermont Attorney General
109 State Street
Montpelier, Vermont 05609

CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMIT, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and the rules of this Court, because it contains 6,086 words (as determined by the Microsoft Word 365 word-processing system used to prepare the brief), excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6). The brief was prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font.

/s/ Clare E. Kindall
Clare E. Kindall
Solicitor General

Dated: May 16, 2022

CERTIFICATION OF SERVICE

I hereby certify that on this 16th day of May, 2022, a true and correct copy of the foregoing brief was timely filed electronically with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

/s/ Clare E. Kindall
Clare E. Kindall
Solicitor General