NOS. 21-5299, 21-5304

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

NOVARTIS PHARMACEUTICALS CORP.,
Plaintiff-Appellee,

v.

CAROLE JOHNSON, in her official capacity as Administrator, U.S. Health Resources and Services Administration, *et al.*,
Defendants-Appellants.

UNITED THERAPEUTICS CORP.,
Plaintiff-Appellee,

v.

CAROLE JOHNSON, in her official capacity as Administrator, U.S. Health Resources and Services Administration, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, *amicus curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") makes the following disclosure: PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. But PhRMA's membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at https://phrma.org/About#members.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and *amici*. – Except for the present filers and Kalderos, Inc. (which has filed a motion for leave to participate as *amicus curiae*), all parties and *amici* appearing before the district court and in this Court are listed in the briefs for the appellees.

B. Rulings Under Review. – Reference to the rulings at issue appear in the briefs for the appellees.

C. Related Cases. – These cases have not previously been before this Court or any other, except for the district court where they originated. Appeals involving similar issues have been docketed in the Third and Seventh Circuits, and two cases involving similar legal issues are currently pending in the U.S. District Court for the District of Columbia. *See Sanofi-Aventis US LLC v. U.S. Dep't of Health & Hum. Servs.*, Nos. 21-3167, 21-3379 (3d Cir.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Hum. Servs.*, Nos. 21-3168, 21-3380 (3d Cir.); *AstraZeneca Pharmas. LP v. Sec'y U.S. Dep't of Health & Hum. Servs.*, No. 22-1676 (3d Cir.); *Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.); *See Kalderos, Inc. v. United States*, No. 21- cv-2608 (D.D.C.); *Boehringer Ingelheim Pharms., Inc. v. Becerra*, No. 21-cv-2826 (D.D.C.).

/s/ William J. Trunk
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Dated: June 15, 2022

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GLOSSARY

340B Program or Section 340B	Section 340B of the Public Health Services Act, codified at 42 U.S.C. § 256b
GAO	Government Accountability Office
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
MDRP	Medicaid Drug Rebate Program
OIG	Office of Inspector General
PhRMA	Pharmaceutical Research and Manufacturers of America

STATEMENT OF IDENTITY, INTEREST IN CASE, AND SOURCE OF AUTHORITY TO FILE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary nonprofit association that represents the nation's leading biopharmaceutical research companies. Through their participation in the 340B Program, which is at the heart of this appeal, PhRMA's members provide billions of dollars in discounts on outpatient drugs to many entities that provide healthcare to underserved and indigent patients. PhRMA's unique industry perspective warrants its filing this separate brief. *See* D.C. Cir. Rule 29(d).

PhRMA and its member companies support the 340B Program and wish to see the Program chart a sustainable path so that it can continue to support our nation's most vulnerable patients, as Congress intended. PhRMA submits this *amicus* brief to detail how the 340B Program operates and explain how the unchecked proliferation of contract pharmacies has distorted the 340B Program. The

[1] All parties have consented to the filing of this brief, and no party or party's counsel has contributed money intended to fund this brief's preparation or submission. Nor has any person—other than PhRMA, its members, or its counsel—contributed money that was intended to fund the preparation or submission of this brief. Appellee Novartis Pharmaceuticals Corp. is a member of PhRMA but did not directly contribute financially to the preparation or submission of this brief.

Appellee United Therapeutics Corp. is not a PhRMA member, but its counsel previously represented PhRMA as *amicus curiae* and offered similar briefs in related litigation pending before the Third and Seventh Circuits. Save to that extent, no party or party's counsel authored this brief in whole or in part.

drastic increase in those arrangements has expanded the 340B Program without adequate safeguards and, in the process, undermined its safety-net mission.

INTRODUCTION

Congress created the 340B Program in 1992 to permit certain healthcare facilities serving poor, uninsured, and otherwise vulnerable patients to purchase prescription drugs for those patients at steeply discounted prices—thereby reducing medical expenses and expanding care for those patients who need it most.

Sadly, however, today's 340B Program bears little resemblance to the one Congress designed. In recent years, the 340B Program has been coopted by large commercial pharmacies that have opportunistically lined up to serve as "contract pharmacies" to 340B-eligible facilities. Those pharmacies, which are not themselves eligible to participate in the 340B Program, have been acquiring large volumes of 340B-discounted drugs, dispensing them at a massive markup to patients who may or may not be 340B-eligible, and often pocketing a significant share of the difference—all at the expense of the very patients whom the Program was designed to protect.

The effects of this opportunistic behavior are unmistakable. Although the 340B Program has grown exponentially by nearly every metric over the past decade—participants, sales volume, dollar value, you name it—charity-care levels have remained paltry. Meanwhile, contract pharmacies have profited handsomely.

See United Therapeutics Br. at 17.

The Government Accountability Office ("GAO") and other watchdogs have sounded alarms for more than a decade about this contract-pharmacy abuse, including the heightened risk of statutory violations regarding duplicate discounts and diversion. In 2011, GAO stressed the need for better oversight precisely because "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."[2] In 2018, GAO again urged the Health Resources and Services Administration ("HRSA") to increase oversight over contract pharmacies, noting that "HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements."[3] Likewise, the Department of Health and Human Services' ("HHS") Office of Inspector General ("OIG") has maligned such contract pharmacy arrangements, citing the inconsistent and imprecise methods used by contract pharmacies to identify 340B drugs.[4]

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[2] GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement* at 28 (Sept. 2011), https://perma.cc/H6QX-ZQMV (2011 GAO Rep.).

[3] GAO, GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at Highlights (June 2018), https://perma.cc/TQW6-JTHN (2018 GAO Rep.).

[4] *See Examining Oversight Reports on the 340B Drug Pricing Program, Hearing of the S. Comm. on Health, Educ., Labor, & Pensions*, 115th Cong. 11 (May 15, 2018) (testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation & Inspections, Off. of Inspector Gen.) (2018 HHS IG Rep.); HHS Office of Inspector

Left to grapple with a federal program that bears little resemblance to its original design, Appellees here (among other manufacturers) adopted reasonable policies, consistent with their obligations under the 340B Program, to ensure that the benefits of the Program are not swallowed up entirely by the contract-pharmacy industrial complex. The precise contours of these policies differ somewhat from manufacturer to manufacturer, but *all* of them permit *all* covered entities to purchase 340B drugs at the statutorily discounted price for delivery directly to the covered entity. And, though the manufacturers' policies do not forbid the use of contract pharmacies, they have imposed commonsense terms to help stem abuse—for example, limiting (as HHS itself once did, *infra* at 7-8) covered entities to only a single contract pharmacy, as opposed to hundreds, to ensure that 340B-discounted drugs are not unlawfully diverted to ineligible patients or result in duplicate discounts. Such terms are fully consistent with Section 340B, which, as the district court correctly held, does not prohibit manufacturers from placing terms on their sales to covered entities.

The decision below should be affirmed.

STATUTES AND REGULATIONS

Relevant excerpts of the applicable statute are contained in the addendum to

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General, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 10-12 (JA850-52) (Feb. 4, 2014) (2014 HHS IG Rep.).

the Brief for Appellee Novartis Pharmaceuticals Corp.

BACKGROUND

A. The 340B Program

Congress created the 340B Program in 1992 to provide access to reduced-price pharmaceuticals to certain safety-net health facilities that serve indigent, uninsured, and otherwise vulnerable patient groups. *See* H.R. Rep. No. 102-384 (II), at 11-13 (JA86-88) (1992); Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943 (Nov. 4, 1992) (codified as amended at 42 U.S.C. §256b). In establishing the program, Congress tackled an unintended consequence of passage of the Medicaid Drug Rebate Program ("MDRP") in 1990, which disincentivized manufacturers from voluntarily offering these discounts to safety-net providers.[5] *See* United Therapeutics Br. at 6-7. Under the 340B Program, pharmaceutical manufacturers—if they want their drugs to be reimbursed under Medicaid and Medicare Part B—must charge such "covered entities" no more than a deeply discounted statutory "ceiling price" on certain outpatient prescription drugs. 42 U.S.C. § 256b(a)(1), (4) (directing HHS to "enter into [such] an agreement" with

[5] See Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 29 (2019). The MDRP included a new requirement for manufacturers to report their "Best Price" in order to calculate Medicaid rebates on their drugs. Before the MDRP, manufacturers had "regularly offered discounts to . . . hospitals and other safety-net providers" on a voluntary basis. *Id.* at 29.

manufacturers); *see also id*. § 256b(a)(5)(B).

Those discounts were not intended to be corporate handouts to pharmacies and their commercial partners. Rather, Congress intended for the discounts to reduce drug costs by restoring those discounts on outpatient drugs that safety-net providers had previously received. That is why Congress carefully defined the small subset of healthcare providers eligible to participate in the 340B Program, 42 U.S.C. § 256b(a)(4), with a focus on those entities "that provide direct clinical care to large numbers of uninsured Americans," H.R. Rep. No. 102-384 (II), at 10-13 (JA85-88).

Congress included other safeguards to ensure that 340B benefits were not diverted or lost. So, for example, Congress prohibited covered entities from engaging in "diversion"—*i.e.*, "resell[ing] or otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Congress likewise prohibited duplicate discounts or rebates so that manufacturers are not required to provide both a Medicaid rebate and a 340B discount on the same drug. *Id*. § 256b(a)(5)(A). To police those restrictions, both the manufacturer-sellers and HHS may audit the compliance records of covered entities. *Id*. § 256b(a)(5)(C).

A touchstone of the 340B Program has long been that covered entities should ensure that the Program's benefits reach its intended beneficiaries: *patients*. Early on, HRSA admonished that covered entities should "pass all or a significant part of

the discount to their patients," whether through discounted drugs or charity care. HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,551 (JA144) (Aug. 23, 1996).

B. Contract Pharmacies

Four years after the 340B Program launched, HRSA issued nonbinding guidance about covered entities' use of third-party pharmacies—so-called "contract pharmacies"—under the Program. *See* 61 Fed. Reg. at 43,549-56 (JA142-149). Acknowledging that the statute "[wa]s silent as to permissible drug distribution systems," *id*. at 43,549 (JA142), HRSA advised that covered entities *without access to in-house pharmacies* could contract with one (and only one) contract pharmacy to "facilitate program participation," *id*. at 43,551 (JA144). *See also Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1540 (JA150-153) (Jan. 12, 2007).

That single-contract-pharmacy rule was important, the agency recognized, to prevent duplicate discounts and drug diversion. *See, e.g.,* 61 Fed. Reg. at 43,550 (JA143) (one-contract-pharmacy rule designed to "decrease the drug diversion potential"). And HRSA understood that even this limited use of contract pharmacies should be accompanied by safeguards. Among other things, covered entities were directed to "retain[] title" to 340B drugs until they were sold to a patient. *Id*. at 43,553 (JA146). Contract pharmacies were also instructed to "provide the covered

entity with reports" and "establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity." *Id*. at 43,555-56 (JA148-149).

More than a decade later, HRSA changed its mind. *See Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (JA154-161) (Mar. 5, 2010). In 2010, HRSA issued revised guidance inviting covered entities to use an unlimited number of contract pharmacies, without regard to whether the covered entities already had access to in-house pharmacies. HRSA identified no textual support in the statute for its sudden about-face. And HRSA finalized this guidance in the face of warnings from manufacturers about a "heightened risk of drug diversion and duplicate discounts." *Id.* at 10,273 (JA155).

Just as night follows day, large commercial pharmacies leapt at the chance to boost their own profits. Between 2010 and 2020, contract pharmacy arrangements increased by more than 4,000%, to nearly 30,000 participating pharmacies. *See* Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program* at 4 (JA504) (Oct. 2020) (Vandervelde); *see also* Adam Fein, *Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, Drug Channels (June 15, 2021), https://perma.cc/X3UM-ZH8C (Fein) (estimating more than 140,000 contract-pharmacy arrangements as of June 2021). By 2020, covered-entity hospitals were using an average of 22 contract pharmacies, with the average distance

between hospital and contract pharmacy ballooning to 334 miles. Vandervelde at 7 (JA507).[6]

You might expect that, given the massive proliferation of contract pharmacies acquiring 340B-discounted drugs, the Program's benefits would now be reaching more patients in need. Unfortunately, that is not the case.

SUMMARY OF ARGUMENT

Today's 340B Program does not resemble the one Congress created thirty years ago. Established to reduce pharmaceutical costs for safety-net facilities and the vulnerable populations they serve, the Program has mutated into a profit generator for commercial pharmacies and others, which have developed increasingly creative mechanisms to wring from the Program as much money as possible.

While these contract pharmacy arrangements proliferate, patients receive little (or no) benefit. Contract pharmacies and their affiliates are swallowing up cost savings from the 340B Program as corporate profits instead of helping patients. Indeed, contract pharmacies routinely charge 340B-eligible patients *full price* for their supposedly "discounted" medications. Those profits are not being invested in reducing drug costs or increasing charity care, levels of which remain dismal. *See infra* at 17-21.

[6] This is despite the fact that many covered entities have their own in-house pharmacies zero miles away. *See*, *e.g.*, 2018 GAO Rep. at 30 n.46.

Spurred by these abuses, pharmaceutical manufacturers (like Appellees here) have crafted reasonable policies to enhance Program integrity while fully complying with their statutory obligation to offer discounted drugs to covered entities. None of these policies prevents a covered entity from purchasing 340B-discounted drugs for eligible patients, nor do they impede those patients from accessing these drugs. As the district court correctly held, nothing in the text, structure, or intent of the 340B Program precludes manufacturers from establishing terms for their sales to covered entities. The judgment below should be affirmed.

ARGUMENT

I. TODAY'S 340B PROGRAM BEARS LITTLE RESEMBLANCE TO CONGRESS'S DESIGN

The explosion in contract-pharmacy arrangements under the 340B Program has caused a seismic shift in who actually benefits under the Program. Rather than facilitating charity care and discounted drugs for vulnerable patient populations, as it once did, the Program has transformed into a black-box subsidization scheme for a handful of large commercial pharmacies and their commercial partners. This was not Congress's intent, nor is it in the statute Congress enacted.

A. The Spread Of Contract Pharmacies Has Been Fueled By The Promise Of Higher Profits

The reason Congress enacted the Section 340B program was "to reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B*

Drug Pricing Program, 57 Wm. & Mary L. Rev. 637, 638 (2015). That is why, in identifying the "covered entities" eligible to purchase 340B-discounted drugs, Congress intended to include those facilities that provide care to vulnerable populations. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (covered entities "include public hospitals and community health centers, many of them providers of safety-net services to the poor").

As a consequence, "covered entities" generally fall into two narrow categories. The first are those that receive a federal grant to support care, such as Black Lung clinics, Ryan White HIV/AIDS program grantees, and federal qualified health centers (which provide primary and preventative care services to medically underserved populations). *See* 42 U.S.C. § 256b(a)(4); GAO, GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 5-6 (Dec. 2020), https://perma.cc/7C25-9TMB (2020 GAO Rep.). The second are certain public or private non-profit hospitals that meet statutorily defined criteria, and have governmental powers or contract with state or local governments to provide care to low-income individuals not eligible for Medicare or Medicaid. *See* 42 U.S.C. § 256b(a)(4)(L)-(O).

Over the last two decades, however, the 340B Program's size and character has shifted dramatically. Although federal grantees and hospitals once accounted for roughly equal amounts of 340B sales volume—51 percent (grantees) vs. 49

percent (hospitals) in 2004—those days are a distant memory. In 2016, hospitals represented a staggering 87 percent of 340B sales volume. *See* PhRMA, *Chart Pack: Medicines in 340B* at 3 (Jan. 5, 2022), https://perma.cc/9RJR-3B2L (340B Medicines). What's more, upwards of 93% of such sales are to disproportionate share hospitals that are under no obligation "to use 340B savings to serve vulnerable populations." Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments* at 10, USC Schaeffer (Oct. 14, 2021), https://perma.cc/3SUN-QR5U (Mulligan).[7]

As participation by hospitals has skyrocketed, so too has the use of contract pharmacies (*see* 340B Medicines at 15):

[7] Although this "disproportionate share" metric was intended to capture safety-net hospitals treating a significant number of uninsured patients, the Medicare Payment Advisory Commission has concluded that the amount of Medicare DSH payments a hospital receives is "not a good proxy for the amount of uncompensated care" a hospital provides. *See MedPac, Report to the Congress, Overview of the 340B Drug Pricing Program* at 5 (May 2015), https://perma.cc/6U3T-DS94. Moreover, the composition of "disproportionate share hospitals" participating in the 340B Program has changed over time, with those joining since 2004 more likely to serve wealthier and more insured populations, "counter to the original intent of" the statute. *See* Mulligan at 10.

And this growth, as the Brief for Plaintiff-Appellee United Therapeutics Corp. explains (at 17), has primarily been among highly profitable chain pharmacies. Approximately 75 percent of 340B contract pharmacies are chain pharmacies, notwithstanding that chain pharmacies represent scarcely half of all pharmacies nationwide. *See* 2018 GAO Rep. at 20-21.[8]

This should come as little surprise. Contract pharmacies profit in multiple ways from these 340B arrangements. *First*, the contract pharmacy frequently collects a flat fee—according to one GAO study, generally from $6 to $15 per prescription, but as high as $1,750 for certain brand name drugs, depending on the contract. *Id.* at 26-27. *Second*, a contract pharmacy will, in some arrangements, receive a fee of as much as 20 percent based on revenues generated by each prescription. *Id.* This can be substantial, as contract pharmacies will bill a patient's third-party insurer—or even a cash-paying patient directly—at full price for a 340B drug that cost only a fraction of that.[9] One study concluded that the "average profit

[8] Moreover, several contract pharmacies are part of vertically integrated companies that also operate pharmacy-benefit managers (who manage and administer drug benefits on behalf of health plans), third-party administrators, and/or insurers. *See, e.g.*, Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, Drug Channels (Apr. 5, 2022) https://perma.cc/L2CR-AKYX. Thus, the 340B program "was originally intended to provide healthcare services to indigent populations but income from the program is now being captured by some of the largest corporations in the world." Vandervelde at 7 (JA507).

[9] A recent analysis of oncology treatment and supportive drugs found that the median markup charged by 340B hospitals to commercial insurers was "3.8 times

margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies." Vandervelde at 3 (JA503).

The fine print of these financial arrangements remains largely unknown, because there is no requirement they be disclosed. But suffice it to say that the 340B Program is a massive profit center for contract pharmacies. *See* United Therapeutics Br. at 16 (noting covered entities and contract pharmacies "generated an estimated $13 billion in gross profits from 340B prescriptions").[10]

B. Through Creative Accounting, Contract Pharmacies Have Expanded Their Claims for 340B-Discounted Drugs

Given the unmistakable profit incentives, the arrangements between contract pharmacies and covered entities have evolved to maximize the dispensing of 340B drugs. Contract pharmacies typically use a system specific to only 340B drugs

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their 340B acquisition costs." Aharon Gal, *Examining Hospital Price Transparency, Drug Profits, & the 340B Program* at 8 (Sept. 2021), https://perma.cc/264U-EQZ2. And for the past 5 years, non-profit and government hospitals' overall margins have been positive. *See* Yang Wang, et al., *COVID-19 and Hospital Financial Viability in the US*, JAMA Health Forum (May 13, 2022).

[10] Contrary to the government's assertion (at Br. 6), the use of contract pharmacies was not de rigueur at the Program's inception. Rather, it was only *after* the 340B Program was created that certain covered entities affirmatively sought to use contract pharmacies, which are plainly not contemplated by the statute's text. 61 Fed. Reg. at 43,550 (JA143) ("As early as 1993, several covered entity groups and a home care company came forward to assist the Department in developing a workable mechanism to use outside pharmacies.").

known as the "replenishment model," which has radically expanded the role of contract pharmacies under the 340B Program and, in the process, moved the Program even further afield from Congress's original design.

The replenishment model generally works like this: John, who may have no idea whether his provider is a 340B-covered entity, fills a prescription at a contract pharmacy. John's prescription generally will not indicate whether it is 340B-eligible, nor does the pharmacy even check. Rather, the pharmacy simply fills the prescription from its general inventory—which includes 340B-discounted drugs that, by law, can be dispensed only to patients of a covered entity. *See* 2018 HHS IG Rep. at 11 (testifying that "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory"). Then, only *after* the drugs are dispensed—at a steep markup—does the pharmacy attempt to sort out whether the prescription *was* 340B-eligible. If so, then the pharmacy simply orders new drugs at the 340B-discounted price to "replenish" its inventory. John, who already paid full price for the medication, sees not a penny of that discount. *See* 2014 HHS IG Rep. at 9, 14 (JA849, 854) (per the replenishment model, "contract pharmacies do not know to charge the discounted 340B price" and thus the patients "will have already paid the full non-340B price.").

The replenishment model thus often conflicts with the 340B statute's prohibition that "a covered entity 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)(B). By design, the model can route 340B drugs to persons who are not patients of the covered entity: The contract pharmacy may replenish its general inventory using 340B drugs, taking title to the drugs (which the covered entity relinquishes—contrary to HRSA's guidance that it must "maintain" title); and the contract pharmacy then dispenses the drugs to any patient that walks in, without regard to whether the person is a patient of the relevant covered entity.

Although GAO and similar watchdog groups have attempted to shine a spotlight on the replenishment model, the specific details of its actual operation remain largely hidden from view. What we do know, however, is that contract pharmacies rely on black-box "algorithm[s]" to retrospectively assess whether patients whose prescriptions have already been filled were eligible for 340B-discounted drugs *they may already have been sold*—albeit at full price. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp 3d 47, 61 n.19 (D. Del. 2021).

One struggles to reconcile any of this with the text or intent of the 340B statute. Among other things, the statute forbids the sale of 340B drugs to anyone "who is not a patient of the [covered] entity." 42 U.S.C. § 256b(a)(5)(B). In the replenishment model, however, such diversion is a feature and not a bug: By design, contract pharmacies are systematically selling 340B drugs to patients who may or not be eligible to receive them, and sorting out the details later—not to ensure that

eligible patients receive their discounts, but to ensure that the pharmacy's shelves remain stocked with medicine the pharmacy acquired at a discount.[11]

This was hardly the charitable mission Congress had in mind.

II. THE UNCONSTRAINED USE OF CONTRACT PHARMACIES UNDERMINES THE 340B PROGRAM

The 340B Program today bears little resemblance to the one Congress enacted. Contract pharmacies are not among the enumerated list of entities that Congress listed in the statute for participation in the Program, yet these pharmacies have gradually arrogated to themselves much of the Program's benefits—to the detriment of the very patients whom the Program was intended to help.

A. The Contract-Pharmacy Regime Offers Little (If Any) Benefit To Patients

Notwithstanding the significant profit that contract pharmacies and large hospitals enjoy trading in 340B drugs, contract-pharmacy arrangements offer little or no benefit to patients. In many instances, the profits are not passed on to patients in the form of drug savings. For example, one GAO survey found that 57 percent of hospital respondents reported providing *no* discounts to low-income uninsured

[11] One wonders how many statutory violations are being committed in furtherance of the replenishment model. Ominously enough, the user manual to one of the most common programs used to belatedly identify 340B-eligible patients cautions that "certain configurations [of the software] are associated with greater risk of noncompliance." *See* Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://perma.cc/WC8A-MXGE.

patients on the price of 340B drugs dispensed at contract pharmacies, and another 18 percent reported providing discounts at only some. 2018 GAO Rep. at 31. Thus, "[d]espite the 340B program's goal of increasing access and providing more comprehensive care," uninsured patients frequently pay full price for drugs and do "not directly benefit from the 340B discount on their prescriptions." HHS IG Rep. at 12.

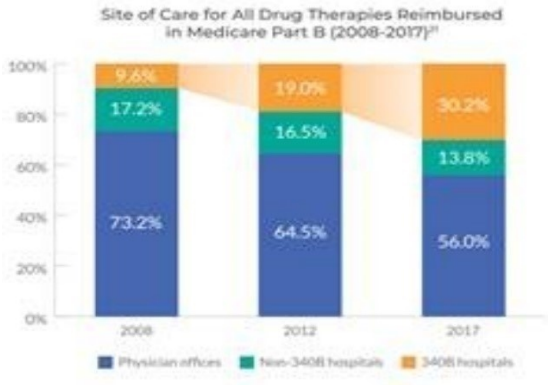
Nor are patients generally benefiting indirectly through increased levels of charity care or investment. Participation in the 340B Drug Pricing Program "has not been associated with increases in hospital-reported uncompensated care provision, bringing into question whether the program is achieving its stated goal of freeing up resources that are devoted to the care of low-income populations." Sunita M. Desai & J. Michael McWilliams, *340B Drug Pricing Program and Hospital Provision of Uncompensated Care*, The American Journal of Managed Care at 433 (Oct. 2021, Vol. 27, Issue 10), https://perma.cc/C2XV-PR7T; *see also* 340B Medicines at 6 (although disproportionate share hospitals represent more than 80 percent of 340B sales, 65 percent of such participating hospitals have charity care rates below the national average). And despite the massive growth in 340B sales, one recent study "found no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in

ways that would reduce mortality." Sunita M. Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. Engl. J. Med. 539, 546-47 (Feb. 8, 2018), https://perma.cc/6YFS-RT4R.

Far from improving patient care, the increase in contract-pharmacy arrangements has created perverse incentives that often harm patients. For one thing, the "savings available from discounted 340B drugs can incentivize hospitals and providers to change their behavior in order to reap financial benefits"—even when it is not in the "patients' best medical interests." Stephen T. Parente & Michael Ramlet, *Unprecedented Growth, Questionable Policy: The 340B Drug Program* at 6, https://perma.cc/GDL2-SJYL (Parente). So, for example, there is an incentive to prescribe more expensive (or unnecessary) pharmaceuticals even when a lower-cost option is available, because of the opportunity to profit from the difference between the sale and (discounted) purchase price, Mike McCaughan, *The 340B Drug Discount Program*, Health Affairs (Sept. 14, 2017), https://perma.cc/E2W3-RAKK. One study found that per-patient pharmacy spend at 340B disproportionate share hospitals is almost three times the spend of non-340B hospitals. Milliman, *Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals* (March 2018), https://perma.cc/6MSC-DEMS.

Evidence also indicates that the promise of increased profits has prompted 340B hospitals to acquire independent physician practices so that those practices

may likewise qualify for 340B discounts:



Eleanor Blalock, BRG, *Site-of-Care Shift for Physician-Administered Drug Therapies: Update* at 2-3 (2019), https://perma.cc/W97F-EUMX. That profit-driven consolidation, in turn, "ultimately end[s] up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings[.]" Parente at 7.

Put bluntly, the 340B Program has evolved "from [a program] that serves vulnerable patient populations to one that enriches hospitals." Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 Health Affairs 1786, 1786 (Oct. 2014), https://perma.cc/HFJ8-SAT7. The explosion in contract pharmacies has facilitated that unfortunate evolution.

This is not the program that Congress enacted.

B. Contract Pharmacies' Detrimental Effects On The 340B Program Are Well Documented

It is scarcely a secret that contract pharmacies have undermined the 340B Program's central mission to help low income patients who are in most need of affordable medicines. More than a decade ago, the GAO reported that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." 2011 GAO Rep. at 28. Sure enough, HRSA has since identified hundreds of instances of unlawful diversion—doubtless only the iceberg's tip. *See* 2018 GAO Rep. at 37; *see also id*. at 44 (diversion involving contract pharmacies).

The ever-growing number of contract pharmacies has likewise resulted in a more diffuse and unaccountable chain of 340B drug distribution, rendering it nearly impossible to enforce the 340B statute's mandate against duplicate discounts. As it is, both CMS and HRSA have been unable to police this requirement across all covered entities.[12] And here, again, the GAO has found that contract pharmacies

[12] *See* GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* at Highlights (Jan. 2020), https://perma.cc/YV7M-JGYC (noting that CMS "does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests"); *see also id*. (HRSA audits "are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply" with prohibition on duplicate discounts). Moreover, HRSA almost never terminates a covered entity's ability to participate in the 340B program for non-compliance. *See Examining HRSA's Oversight of the 340B Drug Pricing Program, Hearing Before the H. Subcomm. on Oversight & Investigations*, 115

only feed the problem. *See* 2018 GAO Rep. at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."); *id*. at 37 ("Weaknesses in HRSA's [a]udit [p]rocess [i]mpede [i]ts [o]versight of 340B [p]rogram [c]ompliance at [c]ontract [p]harmacies.").

Adding insult to injury, HRSA has refused to do anything to constrain the use of contract pharmacies and associated statutory violations of the 340B Program. HRSA's rationale for not stepping in is that "the 340B statute does not address contract pharmacy use."[13] True enough—but that is like saying you are powerless to remove someone from your birthday party because you never invited them in the first place. Contract pharmacies are, and always have been, statutory interlopers. Because the 340B statute never contemplated their involvement, it cannot be that those same strangers to the Program are entitled to siphon away its resources with impunity. Nothing in the statute's text forbids manufacturers from imposing terms designed to curb statutory abuses of the Program.

Cong. 63, 79 (July 18, 2017) (testimony of Krista M. Pedley, former Director of HRSA's Office of Pharmacy Affairs) (HRSA had "terminated one covered entity" as of 2017); *see also Genesis Health Care, Inc. v. Azar*, 2019 WL 6909572, at *2 (D.S.C. Dec. 19, 2019) (HRSA "vacated its decision to remove [covered entity] from the 340B Program and promptly reinstated [covered entity] into the 340B Program" after the covered entity initiated litigation) (citation omitted)).

[13] 2020 GAO Rep. at 15-16.

III. APPELLEES' CONTRACT-PHARMACY POLICIES ARE ENTIRELY CONSISTENT WITH THE STATUTORY TEXT

The explosive growth in the use of contract pharmacies and the parallel use of the replenishment model—principally benefiting for-profit pharmacies and large hospitals at the expense of patients—shows no signs of abating. HRSA has enabled 340B discounts to be siphoned to for-profit entities that Congress never intended to subsidize. And despite this, the agency has consistently refused to address these problems.[14] *See* United Therapeutics Br. at 18-20.

Spurred in part by years of contract-pharmacy abuses, Appellees and other manufacturers have independently implemented reasonable policies to restore some semblance of integrity to the 340B Program. The policies differ somewhat from manufacturer to manufacturer, but they generally require the submission of certain claims data or add reasonable terms on deliveries to contract pharmacies to mitigate unlawful diversions and duplicate discounts. *See, e.g.*, United Therapeutics Br. at 20-21 (describing policy); Novartis Br. at 14-15 (same). Notably, however, none of them places a limit on the quantity of 340B drugs that covered entities may acquire

[14] Indeed, PhRMA has repeatedly tried to engage with HRSA to improve the administration of the 340B Program. *See, e.g.*, PhRMA, *Petition for Rulemaking Regarding An Administrative Dispute Resolution Process For The 340B Drug Pricing Program* (Nov. 24, 2020), https://perma.cc/Z2R4-CUQS; PhRMA, *Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA)* (Oct. 27, 2015), https://perma.cc/T8G8-WK88. But PhRMA has repeatedly been rebuffed by the agency.

for eligible patients, nor impedes eligible patients from accessing drugs that are 340B-eligible. Quite to the contrary, many of the manufacturers' policies are designed to *prevent* 340B-discounted drugs from being diverted from those patients eligible to receive them.

These policies are thus fully consistent with the 340B statute, which by its plain text requires only that manufacturers "offer" their drugs to covered entities (not contract pharmacies) for "purchase" at or below the 340B ceiling price. 42 U.S.C. § 256b(a)(1). That is because, as the district court correctly recognized, nothing in the "plain language, purpose, [or] structure" of the statute prohibits manufacturers from establishing terms for their 340B-discounted sales to covered entities. JA 410. And the statute likewise does not speak to what distribution systems and requests manufacturers "must accept," which tells us the statute "does not compel any particular outcome with respect to covered entities' use of pharmacies." *Id.* at 403 (internal quotations omitted).

Put another way, the 340B statute does not command, through silence or otherwise, that manufacturers blithely accede to their customers' demands to ship discounted drugs to anyone, anywhere, on whatever terms they desire.

CONCLUSION

This judgment of the district court should be affirmed.

Dated: June 15, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 21(d)(1) because this brief contains 5,518 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Circuit Rule 32(e)(1).

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

/s/ William J. Trunk
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Dated: June 15, 2022

CERTIFICATE OF SERVICE

I certify that on June 15, 2022, I filed a copy of the foregoing document via the CM/ECF system of the United States Court of Appeals for the District of Columbia Circuit, which will send notice of this filing to all counsel of record.

/s/ William J. Trunk
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