Nos. 21-3128 & 21-3405

In The United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY AND LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,
v.
XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION,
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division
Case No. 1:21-cv-00081-SEB-MJD
The Honorable Sarah Evans Barker

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PLAINTIFFS-APPELLANTS

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June 1, 2022

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CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128 & 21-3405

Short Caption: Eli Lilly and Company et al. v. Xavier Becerra, et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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Pharmaceutical Research and Manufacturers of America ("PhRMA")

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

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ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

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Attorney's Signature: /s/ Philip J. Perry Date: June 1, 2022

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Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** X **No** ___

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Attorney's Signature: /s/ Cherish A. Drain Date: June 1, 2022

Attorney's Printed Name: Cherish A. Drain

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ___ **No** _X__

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Attorney's Signature: /s/ Gregory B. in den Berken Date: June 1, 2022

Attorney's Printed Name: Gregory B. in den Berken

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

ADMINISTRATIVE MATERIALS

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*[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 center of this appeal—PhRMA's members provide billions of dollars in discounts on drug purchases to many entities that provide healthcare to underserved and indigent patients. 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. In line with that interest, PhRMA submits this

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[1] All parties have consented to the filing of this brief, and no party or party's counsel authored this brief in whole or in part or 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. PhRMA's members are listed at https://phrma.org/About#members. Appellants are members of PhRMA but did not directly contribute financially to this brief's preparation or submission.

Undersigned counsel for PhRMA currently represent United Therapeutics Corporation (UT), a non-PhRMA member, in related litigation pending before the D.C. Circuit. *See United Therapeutics Corp. v. Espinosa*, No. 21-5304 (D.C. Cir.). UT did not contribute financially to this brief's preparation or submission.

amicus brief to detail how the 340B Program operates and to explain how the explosion of contract pharmacy arrangements has distorted the Program. The drastic increase in those arrangements has artificially expanded the Program without adequate safeguards to ensure compliance with statutory prohibitions and without contributing to its safety-net mission.

INTRODUCTION

Congress created the 340B Program in 1992 to help certain types of healthcare facilities serving poor, uninsured, and otherwise vulnerable patient groups by requiring discounts on drugs purchased for those patients, thus enabling these facilities to care for and provide more aid to the patients that need it most. Manufacturers used to provide these discounts voluntarily, but the enactment of the price-reporting requirements in the Medicaid Drug Rebate Program in 1990 disincentivized doing so. Congress created the 340B Program in 1992 in response to this unintended consequence, thereby restoring these discounts. But today's 340B Program bears little resemblance to the one Congress designed. As the Government Accountability Office (GAO) and the U.S. Department of Health and Human Services (HHS) Office of

Inspector General (HHS IG) have indicated, flawed guidance and weak oversight have fundamentally altered the 340B Program.

Today, the 340B Program too often serves to enrich large hospitals and pharmacy chains (which operate as "contract pharmacies" to the hospitals), as well as specialized consultants and other intermediaries, without benefiting the vulnerable patient populations that Congress intended to help. The text of the 340B statute does not contemplate contract pharmacies participating in the 340B Program—much less the creation of an economic windfall for those for-profit entities or the associated siphoning of funds that were intended to support healthcare for indigent patients. Indeed, the effects of opportunistic behavior by those seeking to profit from 340B discounts can be clearly identified: Although the 340B Program has grown exponentially by nearly every metric over the past decade—participants, sales volume, dollar value, the list goes on—charity-care levels have remained low and stagnant. Meanwhile, two of this nation's largest pharmacy chains have publicly reported that profits from 340B discounts are material to their finances. *See infra* at 18. In short, large hospitals and their pharmacy partners

are retaining 340B discounts as sizeable profits at the expense of the vulnerable patients the Program was intended to serve.

The unrestrained use of contract pharmacy arrangements has been a key factor contributing to the current situation. The number of contract pharmacy arrangements skyrocketed after 2010, when the U.S. Health Resources and Services Administration (HRSA)—the agency that administers the 340B Program—issued non-binding guidance purporting to allow covered entities to enter into unlimited contract pharmacy arrangements. But as those arrangements have proliferated, so have Program abuses. GAO and other watchdogs have been flagging these issues for over a decade. Shortly after HRSA issued its 2010 guidance, for example, GAO issued a report stressing the need for better oversight because "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." GAO, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement* at 28 (Sept. 2011), https://bit.ly/3KJAmKL. GAO again in 2018 urged HRSA to step up its oversight with respect to contract pharmacy arrangements, concluding that "HRSA does not have a reasonable assurance that

covered entities have adequately identified and addressed noncompliance with 340B Program requirements." GAO, GAO-18-840, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at Highlights (June 2018), https://bit.ly/3vKXcxg (2018 GAO Rep.).

The HHS IG has similarly voiced concerns about contract pharmacy arrangements, citing the inconsistent and imprecise methods used by contract pharmacies to claim 340B drug discounts. *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 General, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 10-12 (Feb. 4, 2014), https://bit.ly/3LzQj6g (2014 HHS IG Rep.). Those concerns arise from the use of multiple such methods, but especially from what is known as the "replenishment model," which in part involves the identification of previously unidentified 340B discounts by specialized consultants through data mining well after a drug is dispensed.

But nothing has changed. Faced with a misguided agency and a federal program that is now unmoored from its statutory roots, Appellants here and numerous other drug manufacturers adopted reasonable policies aimed at curbing the contract pharmacy-related abuses of the 340B Program while still abiding by their statutory obligations. The exact contours of these policies differ from manufacturer to manufacturer, but—consistent with the 340B statute—each permits every covered entity to purchase 340B drugs at the 340B-discounted price for delivery directly to the covered entity. But many of the manufacturers' policies require additional procedures for or limit orders by contract pharmacies to mitigate unlawful diversion and duplicate discounts.

Appellants' policy here provides that they will continue to offer and deliver 340B-discounted drugs for orders by and to any covered entity, and, in the event a covered entity does not have an in-house pharmacy, Appellants will also deliver 340B drugs to a single contract pharmacy designated by the covered entity. Decl. Heather Dixson in Supp. of Pl.'s Mot. for Prelim. Inj. and Mot. for Summ. J. ¶ 6, ECF No. 129-2 (Dixson

Decl.).[2] Appellants' policy, and those of other manufacturers, continues to allow covered entities to access 340B pricing directly. Appellants' policy is also generally aligned with guidance HRSA itself issued when it first implemented the 340B statute more than 20 years ago, which limited covered entities to using a single contract pharmacy. *See, e.g.*, *United Therapeutics Corp. v. Espinosa*, Nos. 21-cv-1479, 21-cv-1686, 2021 WL 5161783, at *6, 8 (D.D.C. Nov. 5, 2021) (explaining that two manufacturers' policies are more permissive than HRSA's 1996 guidance, which allowed each covered entity to use one contract pharmacy).

The district court acknowledged that no provision of the statute actually addresses contract pharmacies or "explicitly prohibit[s]" manufacturers imposing restrictions on shipments to them, but held that this statutory silence "leaves no room" for manufacturers to impose their policies. *See* Op. 43, 46. But that is not how statutory silence works in this context. Like any seller of goods, drug manufacturers have the right to condition the sale of their products on commercial terms they see fit,

[2] Appellants will also deliver to any contract pharmacy that is wholly owned by or shares a corporate parent with a covered entity, and they make additional exceptions for purchases of their insulins. Dixson Decl. ¶ 7.

unless constrained by law. As the court in *United Therapeutics* explained, the question here is whether the text of the 340B statute imposes a constraint requiring manufacturers to ship to contract pharmacies. *See* 2021 WL 5161783, at *6-8. And here, the text requires only that manufacturers "offer" drugs to "covered entities" at a specified price. The text does not impose any other limitations on the terms of the offer. Appellants' policy complies with that statutory constraint. *See id.* at *6. Indeed, it is difficult to understand how the statute could now silently bar a practice the agency itself embraced in guidance twenty years ago.

The district court's decision is unmoored from the statute and contravenes fundamental principles of statutory interpretation. This Court should reverse.

BACKGROUND

A. The 340B Program

Congress established the 340B Program in 1992 to improve access to covered outpatient drugs for specified hospitals and federal grantees that serve certain vulnerable patient groups. *See* H.R. Rep. No. 102-384, pt. 2, at 11-13 (1992); Veterans Health Care Act of 1992, Pub. L. No. 102-

585, § 602, 106 Stat. 4943, 4967-71 (Nov. 4, 1992) (codified as amended at 42 U.S.C. § 256b). Before the passage of the Medicaid Drug Rebate Program, manufacturers "regularly offered discounts to . . . hospitals and other safety net providers" on a voluntary basis. Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision*, 22 J. Health Care L. & Pol'y 25, 29 (2019). But the Medicaid Drug Rebate Program inadvertently disincentivized manufacturers from offering these discounts to safety-net providers, a group which did not include "contract pharmacies," as doing so led to higher rebates. Congress recognized that it had limited the healthcare providers' ability to directly purchase and receive drugs for their own use in passing the Medicaid Drug Rebate Program. So it sought to remedy that specific, limited problem through the 340B Program.

Under the Program, drug manufacturers—as a condition of federal funds being available for the manufacturers' drugs under Medicaid and Medicare Part B—must charge specified "covered entities" no more than a deeply discounted "ceiling price" on certain outpatient prescription drugs purchased by those entities for the entities' patients. 42 U.S.C. § 256b(a)(1), (4) (directing that HHS "enter into an agreement" with

pharmaceutical manufacturers); *see also id.* § 256b(a)(5)(B). Congress wanted to ensure that the covered entities who received outpatient drugs at discounted prices included the same entities who previously received discounts from manufacturers and entities "that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 10-13.[3]

HRSA has explained that the Program is meant to benefit underserved populations. Early on, HRSA acknowledged that covered entities should "pass all or a significant part of the discount to their patients," either through discounted drugs or charity care. 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996).

Congress wrote several safeguards into the statute to ensure the integrity of the 340B Program and that its steep discounts would serve covered entities' vulnerable patients. Congress carefully limited the entities that could participate in the Program by defining them at a fine level of granularity. *See, e.g.*, 42 U.S.C. § 256b(a)(4). And Congress prohibited covered entities from engaging in "diversion"—*i.e.*, "resell[ing]

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[3] Tellingly, neither the statute nor its legislative history mention making discounts available where "indirect" care might be provided by or through "contract pharmacies" or any other entity.

or otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Further, covered entities may not cause "duplicate discounts or rebates," which occur when a manufacturer sells a unit of a covered outpatient drug to a covered entity at the 340B discounted price yet is also invoiced for a Medicaid rebate on the same unit. *Id.* § 256b(a)(5)(A). The statute also requires covered entities to permit both HHS and manufacturers to "audit" "the records of the entity that directly pertain to the entity's compliance with the" bars on duplicate discounting and diversion. *Id.* § 256b(a)(5)(C).

These requirements are designed to ensure that only covered entities and their eligible patients receive the benefits of the 340B Program while also protecting manufacturers from unbounded obligations.

B. Contract Pharmacies

Four years after the 340B Program was created, HRSA issued guidance about covered entities' use of "contract pharmacy services"—commercial third-party pharmacies—under the Program. *See* 61 Fed. Reg. at 43,549-56. HRSA asserted that the statute "[wa]s silent as to permissible drug distribution systems," *id.* at 43,549, and concluded that

covered entities were authorized to contract with one contract pharmacy for the purpose of "facilitat[ing] program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services," *id.* at 43,551; *see also* 72 Fed. Reg. 1540 (Jan. 12, 2007).

While HRSA sought to facilitate participation by covered entities without an in-house pharmacy, the agency also recognized that the limit of one contract pharmacy was necessary to minimize unlawful duplicate discounts and drug diversion. *See* 61 Fed. Reg. at 43,550 (one-contract-pharmacy limit resulted from "[the] develop[ment] [of] a workable mechanism to use outside pharmacies under arrangements which would decrease the drug diversion potential"). And HRSA understood that even this limited use of contract pharmacies should be accompanied by safeguards. Most significantly, covered entities were advised to "retain[] title" to 340B drugs until they were sold to a patient. *Id.* at 43,553. 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.

In 2010, without any intervening change in the 340B statute, HRSA shifted course. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010). Under HRSA's new guidance, covered entities could use an unlimited number of contract pharmacies—regardless of whether the entity had an in-house pharmacy. *Id.* HRSA identified no statutory basis for its new guidance but incorrectly stated that the guidance "impose[d] [no] additional burdens upon manufacturers." *Id.* at 10,273. And HRSA still emphasized that a covered entity must "maintain title to the drug" to "[e]nsure against diversion." *Id.* at 10,277.

Contract pharmacy arrangements ballooned in the wake of the 2010 guidance. Between 2010 and 2020, the number of contract pharmacy arrangements grew by over 4,000%, with nearly 30,000 pharmacies participating and over 100,000 arrangements between contract pharmacies and covered entities. Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program* at 4 (Oct. 2020), https://bit.ly/36X0eUG (Vandervelde); *see also* Adam Fein, *Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, Drug Channels (June 15, 2021), https://bit.ly/3tZZi9U (Fein) (estimating number at over 140,000 arrangements as of June 2021). By

2020, hospital covered entities, on average, used 22 contract pharmacies each. Vandervelde at 7. And the distance between hospital covered entities and their contract pharmacies grew from an average of 34 miles in 2010 to an average of 334 miles in 2020, *id.*—suggesting that many contract pharmacies are actually dispensing 340B drugs to individuals "who [are] not . . . patient[s] of the [covered] entity," 42 U.S.C. § 256b(a)(5)(B).

In response, drug manufacturers implemented various policies to try to quell the statutory abuses from the proliferation of contract pharmacy use. Although the manufacturers' policies differ, they are generally more permissive than HRSA's policy allowing the use of one contract pharmacy, which was in effect for fourteen years before it was replaced by HRSA's current guidance. *Compare United Therapeutics*, 2021 WL 5161783, at *3-4 (explaining two manufacturers' policies), *with* 61 Fed. Reg. at 43,555 (explaining HRSA's one-contract-pharmacy-per-entity policy).

ARGUMENT

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

The explosion of contract pharmacy arrangements under the 340B Program has been accompanied by (and contributed to) a shift in who benefits from the Program—from patients to large commercial pharmacies, third-party administrators (some of which are affiliated with a large commercial pharmacy), and certain types of hospitals. In effect, the Program has been transformed by covered entities from a Program to facilitate charity care and drug savings into a private subsidization scheme for large hospitals, commercial pharmacies, and third-party administrators.

A. The 340B Program's Explosive Growth Has Been Driven By The Prospect Of Higher Profits For Contract Pharmacies

Over the last two decades, the 340B Program's size and character have shifted dramatically.

The government claims that the use of contract pharmacy arrangements has been a part of the 340B Program from its inception. *See* Fed. Defs.' Br. 6, *Novartis Pharms. v. Johnson*, No. 21-5299 (D.C. Cir.

May 9, 2022). This is not supported by the record, nor is it factually accurate.

Before the Medicaid Drug Rebate Program was passed, manufacturers offered discounted drugs for use by safety-net providers for "direct care," not for "resale" or "transfer" to for-profit entities such as chain retail pharmacies. *See* H.R. Rep. No. 102-384, pt. 2, at 9-10. The Medicaid Drug Rebate Program disincentivized offering these discounts, and the 340B Program was intended to fix that limited problem and restore the pre-Medicaid Drug Rebate Program status quo. *Id.* at 12 (noting removal of "disincentive" that MDRP had created to "discourage manufacturers from providing substantial voluntary or negotiated discounts"). It is no surprise, therefore, that the 340B Program was small when it was launched. That limited scope was the intended result of Congress's limited purpose. Congress did not intend a result where contract pharmacies radically expanded discounts beyond the historical discounts Congress was attempting to restore.

Nor was contract pharmacy use "commonplace" at the Program's inception. Government's Summ. J. Reply and Opp. Br. 18, ECF No. 125; *see also id.* at 39 n.17. And the government has acknowledged that

elsewhere. For example, in 2010, a HRSA Pharmacy Services Support Center presentation admitted that contract pharmacies were "not part of [the] original [340B] legislation" in 1992. Lisa Scholz, 340B Contract Pharmacy, 14th Annual 340B Coalition Conference (Jul. 20, 2010) (on file with PhRMA). It conceded that "[e]ntities expressed [a] need to contract with a separate pharmacy" only thereafter, resulting in a "Contract Pharmacy Federal Register Notice" being "finalized to provide guidance." *Id.* Only after the implementation of the Program did covered entities *ask* to be able to use contract pharmacies, indicating that they were not allowed to do so at the beginning of the Program. 61 Fed. Reg. at 43,550 ("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.").

With the growth of contract pharmacy arrangements, the Program now looks very different than in its early days. The dramatic growth in contract pharmacy use, *see supra* at 11-14, has primarily been among highly profitable chain pharmacies. Indeed, *75%* of contract pharmacies are chain pharmacies. 2018 GAO Rep. at 20. And just 5 chains account for almost 60% of all contract pharmacies. *Id.* More than 80% of all

Walgreens locations and more than 66% of all CVS locations are now 340B contract pharmacies. *See generally* Fein. And the profit incentive for these contract pharmacies and covered entities is clear: In 2018 alone, $13 billion in estimated gross profits was generated for covered entities and their contract pharmacies from 340B prescriptions filled at contract pharmacies. Vandervelde at 3.[4] National pharmacy chains have publicly disclosed that 340B profits are material to their business operations. *See* CVS Health Corporation, Annual Report (Form 10-K) at 22-23 (Feb. 9, 2022), https://bit.ly/3HVWvn5; Walgreens Boots Alliance, Inc., Annual Report (Form 10-K) at 22 (Oct. 14, 2021), https://bit.ly/38b2ybF.

Contract pharmacies profit in multiple ways from their arrangements with covered entities. Typically, a contract pharmacy will bill a patient's third-party insurer or a cash-paying patient directly at full price for a 340B drug for which it actually pays a fraction of that price. *See* Vandervelde at 4. A recent analysis found that the median markup for 340B drugs is "3.8 times their 340B acquisition costs." Aharon Gal, *Examining Hospital Price Transparency, Drug Profits, & the 340B*

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[4] Discounted purchases under the 340B Program reached at least $38 billion in 2020. Adam Fein, *The 340B Program Soared to $38 Billion in 2020*, Drug Channels (June 16, 2021), https://bit.ly/3CKFIT3.

Program at 7-8 (Sept. 2021), https://bit.ly/3MSpgEW (Gal). Sometimes, the contract pharmacy and covered entity enter into a percentage-based profit-sharing scheme, where the contract pharmacy receives "a fee based on a percentage of revenue generated for each 340B prescription," and other times, the contract pharmacy collects a flat fee per dispensed prescription. *See* GAO, GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* at 1 (Dec. 2019), https://bit.ly/3tCcth4 (finding that percentage-based fees can go up to 20 percent of revenue generated and that flat fees for brand drugs can be as high as $1,750 per dispense). The exact contours of these financial arrangements remain largely unknown because there is no disclosure requirement, but in all cases these funds come out of the savings intended to support vulnerable patient populations.

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

Given the profit incentives, the specific arrangements between contract pharmacies and covered entities have evolved to maximize the dispensing of 340B discounted drugs. Contract pharmacies now typically

use a convoluted inventory model for dispensing drugs known as the "replenishment model," which has radically changed the role of contract pharmacies under the 340B Program and greatly expanded their demand for pharmaceuticals at 340B discounts.

As described by regulators and watchdog agencies, the replenishment model generally works like this: An individual (who may not know whether her provider is a 340B covered entity or if she qualifies as a patient of such entity) fills a prescription at a contract pharmacy. Typically, that prescription does not indicate whether the individual is a patient of a 340B covered entity, and the contract pharmacy does not check. The contract pharmacy then, without knowing whether the individual is a patient of a 340B covered entity, dispenses the drug from its common inventory. That common inventory includes 340B discounted drugs, which by law may only be dispensed to patients of the relevant covered entity. *See* R.125-2 ¶ 11 (Pedley Decl.) (former HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient"); *see also* 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"). Only after the drug has been dispensed to and paid for by the patient—typically at a price well above the discounted 340B price—do contract pharmacies attempt to sort out, through various methods, whether the prescription was *actually* made to an eligible 340B patient. *See* 2014 HHS IG Rep. at 9 (21 out of 30 "covered entities reported that in at least one of their respective contract pharmacy arrangements, . . . [administrators] identif[y] 340B-eligible prescriptions by comparing the data to prescriptions filled at contract pharmacies"); *see also id.* at 14 (reporting that numerous covered entities "use administrators that determine 340B eligibility after drugs are *dispensed*, . . . [meaning] the contract pharmacies do not know to charge the discounted 340B price" and thus the patients "will have already paid the full non-340B price"). Once that determination is made, new drugs are ordered at the 340B price and used to "replenish" the contract pharmacy's general inventory.

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 transfer 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 drawn attention to and revealed the general framework of the replenishment model, its actual operation remains largely hidden—from both manufacturers (who are nonetheless being told that they must provide 340B discounts to such pharmacies) and the government. Indeed, the record suggests that HRSA has failed to investigate how the replenishment model works in many contexts. But it is clear that, after a drug is dispensed (maybe to a 340B patient, maybe not), contract pharmacies or specialized consultants called "third-party administrators" will generally run black-box data-mining "algorithms" to conclude whether that patient was eligible for 340B-purchased drugs (although the patient likely did not benefit from the 340B discount). *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp.

3d 47, 61 n.19 (D. Del. 2021); *see also* Pedley Decl. ¶ 6 (acknowledging that "[v]arious 340B-tailored software programs exist" to perform this function). And these specialized consultants take money from the covered entities and charge a fee for performing this service. *See* 2018 GAO Rep. at 2 (explaining how some "covered entities hire and pay a private company, referred to as a third-party administrator, to help determine patient eligibility and manage 340B inventory"). Those algorithms likely stretch the concept of who is and who is not a 340B patient beyond any legally plausible definition. *Cf.* Pedley Decl. ¶ 3 (conceding that "contract-pharmacy arrangements vary, and [HRSA] cannot speak to the exact details of every existing relationship"). Indeed, as a manual to one 340B billing software candidly admits, the "software uses logic based on configurations, *chosen by the [covered] entity*, to virtually separate 340B from non-340B transactions," and "certain configurations are associated with *greater risk of noncompliance*."[5]

These changes have dramatically reshaped the 340B Program. Put simply, the Program today bears little resemblance to the one Congress

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[5] Apexus, *340B Split-Billing Software Key Attributes* at 1 (July 3, 2019), https://bit.ly/3MJPLfl (emphasis added).

enacted. Contract pharmacies are not even mentioned in the 340B statute, yet today they are a massive participant at the cost of the Program's intended beneficiaries—patients.

C. The 340B Program Has Been Undermined By This Unprecedented Expansion

The explosive growth in the use of contract pharmacies does not benefit patients and instead detrimentally affects the 340B Program and the very patients the Program is intended to benefit. Notwithstanding the significant profit that hospitals, contract pharmacies, and related third parties are making on 340B drugs, the large majority fail to pass along those profits to patients in the form of drug savings. *See* Gal at 14 ("hospitals are charging cash-paying patients roughly the same as the median commercial prices"). Indeed, 57% of hospitals reported *not* providing discounts to low-income, uninsured patients on 340B drugs dispensed at contract pharmacies. 2018 GAO Rep. at 31. Another 18% only provided discounts at *some* contract pharmacies. *Id.*

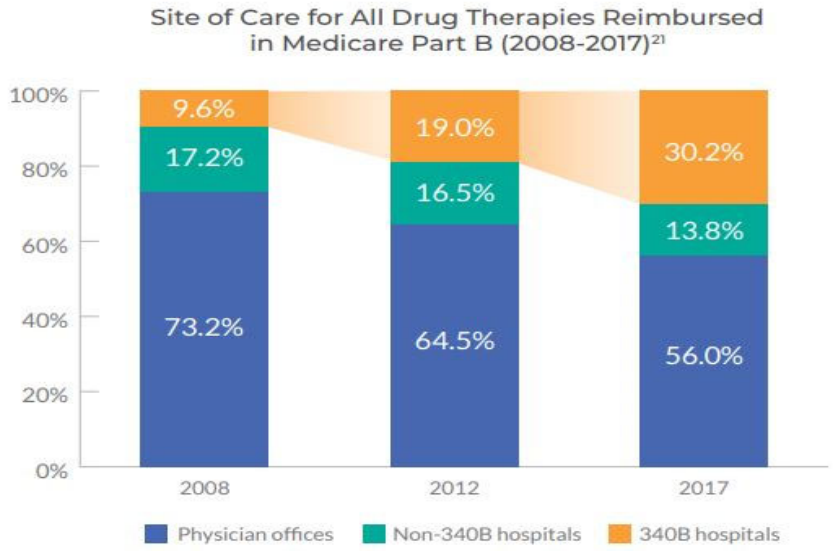
Nor are savings passed along to patients through increased levels of charity care. A majority of hospitals choose *not* to pass on any savings from their unrestrained use of contract pharmacies to patients, either as a discount on 340B drugs or as charity care to needy patients. *See*

Alliance for Integrity & Reform of 340B, *Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program* at 9-10 (Feb. 2022), https://bit.ly/3KHcWWn (AIR 340B) (reporting that in 2019, 65% of disproportionate share hospitals, which are eligible to participate in the 340B Program due to the number of low income patients they treat, provided charity care at a rate below the national average for all hospitals).

Studies have turned up "*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." S. Desai & J. Michael Williams, *Consequences of the 340B Drug Pricing Program*, 378 N. Engl. J. Med. 539, 546-47 (Feb. 8, 2018), https://bit.ly/37lDr58 (emphasis added). And Medicare data shows that only 29% of disproportionate share hospitals are providing 80% of the charity care provided by *all* such hospitals. *See* AIR 340B at 10.

It appears that, rather than improving patient care, the increase in contract pharmacies has a *negative* effect for patients and communities. For example, evidence indicates that the promise of increased profits has

prompted 340B hospitals to acquire independent physician practices to have those practices qualify for 340B discounts:



Eleanor Blalock, BRG, *Site-of-Care Shift for Physician-Administered Drug Therapies* at 2-3 (2019), https://bit.ly/3wqlMEb. 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." Stephen Parente, *Unprecedented Growth, Questionable Policy: The 340B Drug Program* at 2, https://bit.ly/3u05yP3. There are also indications that the profit incentive is causing higher spending on outpatient drugs at 340B hospitals because providers are encouraged "to choose a higher-cost agent, even when a lower-cost therapy is available" as the "spread will be

larger and the profit margin therefore higher." *See* Mike McCaughan, *The 340B Drug Discount Program*, Health Affairs Pol'y Br. (Sept. 14, 2017), https://bit.ly/3I6YOny.[6]

As it stands now, the 340B Program has been transformed by covered entities into a private subsidization scheme where the resources of drug manufacturers are used to increase the profitability of large, publicly traded pharmacy enterprises. That scheme is contrary to the statute Congress enacted.

II. THE DISTRICT COURT'S READING OF THE 340B STATUTE CONTRAVENES FUNDAMENTAL PRINCIPLES OF STATUTORY INTERPRETATION

The decision below purported to further the Program's "purposes" by prohibiting policies such as Appellants' because they are not expressly permitted by the statute. In addition to being substantively misguided, that approach is inconsistent with fundamental principles of statutory interpretation. The district court agreed with HRSA that "[t]he 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations," yet it nonetheless concluded the

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[6] *See U.S. ex rel. Liebman v. Methodist Le Bonheur Healthcare*, No. 3:17-cv-00902, ECF No. 235 (M.D. Tenn. Apr. 11, 2022) (describing a hospital's purchase of an outpatient location to receive 340B discounts).

statute also prohibits drug manufacturers from conditioning 340B sales on delivery to a particular location. Op. 41, 46-47. That was wrong.

The concept of statutory silence sometimes arises in litigation against the government when an agency claims that Congress has either explicitly or implicitly authorized the agency to speak with the force of law and the agency's efforts to fill a gap in the statute should be accorded judicial deference. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227, 229, 231-32 (2001). But that is not the issue in this case. HRSA lacks general rulemaking authority under the 340B statute, *see Pharm. Res. Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014), and HRSA has disclaimed any entitlement to deference in this case as well as in other settings, *see, e.g.*, Op. 39; Government's Br. at 38, *United Therapeutics Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 9, 2022); *see also County of Maui v. Hawaii Wildlife Fund*, 140 S. Ct. 1462, 1474 (2020) (withholding *Chevron* deference where government had not sought it).[7]

[7] It is unsurprising that Congress did not grant HRSA general rulemaking authority over the 340B Program. The 340B statute reflects a balanced and limited approach, requiring discounts to the covered entities that had previously received them, but protecting manufacturers

Far from supporting HRSA, here Congress's silence is fatal to HRSA's interpretation. HRSA's argument is premised on the "erroneous assumption that a manufacturer needs statutory authorization," *Gen. Motors Corp. v. Darling's*, 444 F.3d 98, 108-09 (1st Cir. 2006), in order to impose delivery terms on an offer to a covered entity (such as limitations on shipping to contract pharmacies), *see* A2 ("Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities."). Absent a "basis in the statute for imposing such a requirement," however, "the statute's silence means precisely the opposite of what [HRSA] says that it means"—that it is permissible. *Gen. Motors*, 444 F.3d at 109.

We start with the basic and fundamental principle that, absent constraints imposed by law, a manufacturer is generally free to sell its goods to whomever it wants on whatever terms it wants. *See, e.g.*, *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 448 (2009) ("As a general rule, businesses are free to choose the parties with whom they

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against expansion by barring the resale or transfer of discounted drugs to others.

will deal, as well as the prices, terms, and conditions of that dealing." (citation omitted)); *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984) (observing that "[a] manufacturer of course generally has a right to deal, or refuse to deal, with whomever it likes"). That includes placing limitations on where the manufacturer is willing to deliver its goods, such as conditions on the circumstances in which it is willing to deliver to someone other than the purchaser. *See Pac. Bell*, 555 U.S. at 448; *Gen. Motors*, 444 F.3d at 109 ("Absent a clear mandate from the legislature, we are disinclined to unnecessarily interfere with the bargains that have been struck between the manufacturers and their distributors."). Here, the question becomes whether, under the ordinary principles of statutory interpretation, there is a basis to conclude that the 340B statute displaces the background rule and prohibits manufacturers from refusing or limiting shipments to nonpurchasers like contract pharmacies. There is not. *United Therapeutics*, 2021 WL 5161783, at *7 (statute does not "prohibit manufacturers from placing any conditions on covered entities").

Statutory interpretation begins "as always, with the text of the statute." *Hawaii v. Office of Hawaiian Affairs*, 556 U.S. 163, 173 (2009).

The statute contains two plain and unambiguous provisions that are relevant here. First, the statute imposes a specific obligation on HRSA to "enter into an agreement" with manufacturers under which they "offer" 340B prices to particular entities: "[T]he manufacturer [shall] *offer each covered entity* covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[8] 42 U.S.C. § 256b(a)(1) (emphasis added). Second, the statute enumerates who qualifies as a "covered entity" eligible to receive an offer at the 340B price, listing 15 specific types of medical facilities that do not include contract pharmacies. *Id.* § 256b(a)(4).

The statute thus unambiguously requires manufacturers to offer 340B-priced drugs to the defined "covered entities," but not contract pharmacies. After all, "[i]t is axiomatic that the statutory definition of [a] term excludes unstated meanings of that term." *Meese v. Keene*, 481 U.S. 465, 484 (1987); *Colautti v. Franklin*, 439 U.S. 379, 392 n.10 (1979)

[8] The agreement itself—the Pharmaceutical Pricing Agreement—parrots the statutory language in relevant respects. *See* HRSA, *Pharmaceutical Pricing Agreement Example* (May 18, 2018), https://bit.ly/3PEM2BG.

(same); *AstraZeneca*, 543 F. Supp. 3d at 60 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."). And HRSA has long conceded that that the statute does not require offers for 340B-pricing to contract pharmacies themselves. *See* Email from HRSA to Lilly, ECF No. 17-4 ("Contract pharmacies . . . [are] not independent covered entities.").

The question, then, is whether the requirement to "offer" discounted drugs to "covered entities" somehow prohibits manufacturers from declining to ship 340B drugs to an entity other than the covered entity, like contract pharmacies—*i.e.*, setting the delivery term of the offer. Because the term "offer" is not defined in the statute, it bears its "ordinary meaning." *Bass v. Stolper, Koritzinsky, Brewster & Neider, S.C.*, 111 F.3d 1322, 1325 (7th Cir. 1997). And the ordinary meaning of the word "offer" does not include any delivery obligation to a non-purchaser. *See* Concise Oxford American Dictionary 614 (2006) (defining offer as "present or proffer (something) for (someone) to accept or reject as so desired"); American Heritage College Dictionary 964 (4th ed. 2004) (defining offer as "1. To present for acceptance or rejection"); *see also*

United Therapeutics, 2021 WL 5161783, at *6 ("HRSA's interpretation . . . stretches the 'Shall Offer' provision beyond its plain meaning."). A contrary reading of "offer" makes little sense because, as a matter of contract law and common commercial practice, "offers" are almost always subject to a variety of terms, limitations, or conditions. *See Comcast Corp. v. Nat'l Ass'n of Afr. American-Owned Media*, 140 S. Ct. 1009, 1016 (2020) ("[W]e generally presume that Congress legislates against the backdrop of the common law.").

Moreover, pharmaceutical manufacturers must necessarily be able to impose at least *some* terms on the sale of 340B drugs—like requiring that the purchasing entity *be* 340B eligible, that orders be submitted using the manufacturer's established ordering system, and that payment for the drugs be made within a certain amount of time.[9] Unsurprisingly, HRSA has itself long recognized that the statute allows manufacturers to impose terms and conditions on 340B sales. Since 1994, HRSA has

[9] To be sure, it is conceivable that some terms and conditions may be so onerous as to render an offer illusory. But HRSA has failed to conduct any individualized assessment of the manufacturers' policies to see whether any of them somehow result in a lack of a bona fide offer and instead takes the blanket position that *any* condition on contract pharmacies is statutorily barred.

recognized that the statute allows manufacturers to impose terms including "customary business practice[s]," to "request standard information," and to utilize "appropriate contract provisions." 59 Fed. Reg. 24,885, 25,114 (May 13, 1994). So even HRSA agrees that the "shall offer" provision does not prohibit *all* terms and conditions. But, in HRSA's view, it *does* limit manufacturers' ability to impose terms that govern delivery to contract pharmacies.

However, when Congress intended to limit the contours of an offer to a covered entity, it said so directly and expressly. And here, it dictated one of the most essential terms of an offer—the price. *See* 42 U.S.C. § 256b(a)(1) ("[T]he manufacturer [shall] offer each covered entity covered outpatient drugs for *purchase at or below the applicable ceiling price* if such drug is made available to any other purchaser at any price." (emphasis added)). Congress also declined to mandate other terms of the offer, including a delivery term. And "common sense, reflected in the canon *expressio unius est exclusio alterius*, suggests that the specification of one requirement implies the exclusion of others." *United States v. Jumaev*, 20 F.4th 518, 552 (10th Cir. 2021). Under ordinary principles of statutory construction, Congress is presumed to have imposed no other

terms. *See id.*; *Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").[10]

Another provision of the statute confirms that Congress did not intend to silently displace the background rule allowing manufacturers to set the terms (other than price) of their offers by allowing covered entities to unilaterally mandate delivery to a non-purchaser. Specifically, the statute explicitly prohibits covered entities from transferring a drug purchased at the 340B price to anyone other than

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[10] The district court's invocation of *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), to assert that the 340B statute imposes a broad rule that is not subject to qualification, is accordingly misplaced. *See, e.g.*, Op. 45-46. To be sure, *Bostock* holds that "when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." 140 S. Ct. at 1747. But you need a broad rule, supported by the text's "ordinary meaning," before that principle can apply. Here, we have a *narrow* rule: As HRSA told Congress last year, "manufacturers only have one core statutory obligation in the 340B Program - to offer the 340B ceiling price pursuant to section 340B(a)(1) of the Public Health Service Act." HHS/HRSA, *Justification of Estimates for Appropriations Committees (FY 2022)* at 418, https://bit.ly/3PGuWmQ. Because the "ordinary meaning" of the text imposes just one limitation on a manufacturer's offer (the price term), *Bostock* has no application to this case.

their patients: "With respect to any covered outpatient drug that is subject to an agreement under this subsection, 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) (emphasis added). It would be odd, to say the least, for Congress to have included such an express prohibition while simultaneously intending to silently allow covered entities to direct manufacturers to deliver 340B-discounted drugs to non-patients (such as contract pharmacies) who in turn dispense to non-patients. *See supra* at 19-22 (discussing replenishment model).

The 340B statute requires only that manufacturers offer drugs at or below a certain ceiling price to 15 enumerated covered entities. It does not require, through silence or otherwise, that manufacturers accept a covered entity's demand to ship the drugs to anyone anywhere. The district court's statutory interpretation thus cannot be squared with the 340B statute. *See United Therapeutics*, 2021 WL 5161783, at *9 (vacating violation determination as contrary to statute).

CONCLUSION

This Court should reverse in part the judgment of the district court.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitations of Seventh Circuit Rule 29 because it contains 6,936 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f). I further certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and Seventh Circuit Rule 32(b) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using 14-point Century Schoolbook font.

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