Nos. 21-3167 & 21-3168

United States Court of Appeals for the Third Circuit

SANOFI AVENTIS U.S., LLC,

Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Appellees.

NOVO NORDISK INC. and NOVO NORDISK PHARMA INC.,

Appellants,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Appellees.

Appeals from the United States District Court for the District of New Jersey
Nos. 21-cv-634 & 21-cv-806, Hon. Freda L. Wolfson, Chief District Judge

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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third 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.

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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 *amicus* brief to detail how the 340B Program operates and to explain how the explosion of contract pharmacy arrangements has distorted the 340B Program. The drastic increase in those arrangements has artificially expanded the 340B Program without adequate

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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 that was intended to fund the preparation or submission of this brief. 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 Sanofi-Aventis U.S., LLC and Novo Nordisk Inc. are members of PhRMA but did not directly contribute financially to the preparation or submission of this brief.

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 the preparation or submission of this brief.

safeguards against 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 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 thus created the 340B Program in 1992 in response to this unintended consequence and restored these discounts. But today's 340B Program bears little resemblance to the one Congress designed. Flawed guidance and weak oversight have rendered the 340B Program unrecognizable and turned it into a Program that too often serves to enrich large hospitals, large pharmacy chains, and other intermediaries without benefiting the vulnerable patient populations that Congress intended to help. The 340B statute does not contemplate contract pharmacies participating in the Program—much less the creation of an economic windfall for those for-profit contract pharmacies or the associated diversion of funds intended to support healthcare for indigent patients. Indeed, 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. Hospitals and their pharmacy partners retain their increasingly sizable profits instead of passing those savings on to patients.

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 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. The Government Accountability Office (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 (2011 GAO Rep.). And when GAO reviewed the 340B Program in 2018, GAO again 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.). But nothing has changed. HRSA is well aware that contract pharmacies impair the Program's integrity, yet it continues to maintain the status quo rather than address the fundamental problems with contract pharmacies.

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 worst contract pharmacy-related abuses of the 340B Program. The district court's decision, which largely upheld HRSA's violation letters issued to appellants because of their policies, rests on a fundamental misunderstanding of the 340B Program and how appellants' policies operate. Appellants' policies fully accord with the statutory requirements—and they do not prevent covered entities from ordering 340B drugs or block access to those drugs by patients.

BACKGROUND

A. The 340B Program

Congress established the 340B Program in 1992 to improve access to essential medications for specified hospitals and federal grantees that serve certain poor, uninsured, and otherwise vulnerable patient groups. *See* H. Rep. No. 102-384 (II),

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). Under the 340B 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 statutory "ceiling price" on certain outpatient prescription drugs purchased by those entities for the entities' patients. 42 U.S.C. § 256b(a)(1), (4). The 340B statute operates in part through a contractual opt-in mechanism—it directs the Department of Health and Human Services (HHS) to "enter into an agreement" with pharmaceutical manufacturers under which the amount a "covered entity" is "required" to pay for certain of the manufacturer's prescription drugs "does not exceed" a maximum ceiling price calculated under a statutory formula. *Id.* § 256b(a)(1). The ceiling price is calculated based on a manufacturer's reported drug pricing data and rebate amounts determined under the Medicaid Drug Rebate Program. *See id.*[2]

HRSA, the federal agency within HHS that oversees the 340B Program, has explained that the 340B Program is meant to benefit uninsured and underserved

[2] Participation in the 340B Program is effectively mandatory for manufacturers because "if drug manufacturers wish to receive reimbursements for their drugs under Medicare Part B and Medicaid programs, [they] must permit covered entities to buy those drugs at the 340B Program's discounted rates." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 50 (D. Del. 2021); 42 U.S.C. § 1396r-8(a)(1), (5).

populations. The 340B Program was designed so that covered entities would "pass all or a significant part of the discount to their patients." HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996). That means uninsured or underinsured patients would directly benefit from the 340B Program by receiving discounted drugs or charity care.

Congress wrote several safeguards into the statute to ensure the integrity of the Program and that the Program's steep discounts would serve indigent and uninsured patients of the covered entities. Among other things, 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. § 256(a)(4). The statute also prohibits 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." *Id.* § 256b(a)(5)(B). And 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). Covered entities that dispense 340B drugs to Medicaid beneficiaries (potentially triggering a manufacturer rebate obligation to Medicaid) are expected to take certain steps to guard against duplicate discounts. 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 all designed to ensure that only patients and covered entities 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 340B 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* HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1540 (Jan. 12, 2007) ("a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity").

While HRSA sought to facilitate participation by covered entities without an in-house pharmacy, HRSA 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 (explaining that 1996 guidance and its 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 the 340B drugs until they were sold to a patient because the covered entity "retain[ed] responsibility" for ensuring that the drugs were not sold "to an individual who is not a patient of the covered entity." *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; *see also id.* at 43,556.

In 2010, without any intervening change in the 340B statute, HRSA shifted course and issued guidance that fundamentally changed its policy. *See* HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 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 2010 guidance but stated that the guidance "impose[d] [no] additional burdens upon

manufacturers." *Id.* at 10,273. And HRSA still emphasized that a covered entity "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). Hospital covered entities used an average of 22 contract pharmacies by 2020. Vandervelde at 7.[3] And the distance between hospital covered entities and their contract pharmacies also changed dramatically: Instead of an average of 34 miles in 2010, they were separated from their contract pharmacies by 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).

[3] Many covered entities also have an in-house pharmacy. *See, e.g.*, 2018 GAO Rep. at 30 n.46.

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 the beneficiaries of the Program's discounts—from patients to large commercial pharmacies, third-party administrators (some of which are affiliated with a large commercial pharmacy), and certain types of hospitals.

A. The Explosive Growth In Contract Pharmacy Use Has Been Driven By The Prospect Of Higher Profits

Over the last two decades, the 340B Program's size and character has shifted dramatically. Broadly speaking, the statute contemplates two types of covered entities eligible to participate in the Program. The first type are clinics and other entities that receive a federal grant from HHS to support care for vulnerable patients. *See* 42 U.S.C. § 256b(a)(4). These grantees, including Community Health Care Centers, Ryan White clinics, and hemophilia treatment centers, provide care to our country's most vulnerable patients who often lack other sources of care. The second type are certain nonprofit hospitals, which includes hospitals serving a qualifying number of low-income Medicare and Medicaid patients in their in-patient facilities—known as the disproportionate share hospital ("DSH") metric. *See id.* DSH was intended as a proxy for safety-net hospitals treating a significant number

of uninsured patients, but as Medicaid has expanded, more hospitals have qualified for the 340B Program even as charity care and the number of uninsured patients have declined. *See* HHS, Off. of Health Pol'y, *Issue Brief: Trends in the U.S. Uninsured Population, 2010-2020* (Feb. 11, 2021), https://bit.ly/3ITrCB9; MedPac, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015), https://bit.ly/3tDWiA9.

In the last twenty years, the balance between grantees and hospitals has shifted dramatically. In 2004, grantees accounted for roughly 51% of 340B sales volume and hospitals accounted for roughly 49%. *See* Christopher Hatwig, Apexus Update—340B Health Summer Conference (July 2016); *see also* PhRMA, *Chart Pack: Medicines in 340B* at 3 (Jan. 5, 2022), https://onphr.ma/35Bf7vx (340B Medicines). But by 2016, grantees' share of 340B sales volume had plummeted to 13% while hospitals' share skyrocketed to 87%. *Id.* That radical shift was driven by DSH hospitals, which made up 81% of hospitals' share. *Id.* And as hospitals' participation in the Program has increased, they have sought to maximize their profits through increased contract pharmacy utilization:

340B Medicines at 15.

This dramatic growth in contract pharmacies 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.* As an example, more than 80% of all Walgreens locations and more than 66% of all CVS locations are now 340B contract pharmacies. *See generally* Fein. The 340B-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] Indeed,

[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.

national pharmacy chains have publicly disclosed that 340B profits were 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 23 (Oct. 15, 2020), https://bit.ly/3ISDfIA; *see also* Letter from Senator Charles Grassley to Gregory Wasson, President and CEO, Walgreens (July 31, 2013), https://bit.ly/35ycpa8 (explaining that the 340B Program "is not intended to subsidize pharmacies that team up with covered entities to turn a profit").

Contract pharmacies now 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 that actually costs a fraction of that price. *See* Vandervelde at 4. For example, a recent analysis found that the median markup for 340B drugs is "3.8 times their 340B acquisition costs," with the lowest median being 2.4 times acquisition cost and the highest median being 11 times acquisition cost. Aharon Gal, *Examining Hospital Price Transparency, Drug Profits, & the 340B 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 requirement that they be disclosed.

B. Through Creative Accounting, Contract Pharmacies Have Expanded Their Access To 340B Discounts

Given the profit incentives involved, the specific arrangements between contract pharmacies and covered entities have evolved to maximize the dispensing of 340B discounted drugs. Under HRSA's pre-2010 guidance, contract pharmacies were used almost exclusively by covered entities that lacked an in-house pharmacy for dispensing 340B-purchased drugs and served the limited role of dispensing only to the covered entities' patients. *See* 61 Fed. Reg. at 43,552; *see also id.* at 43,550. But under HRSA's 2010 guidance, contract pharmacies play a far more extensive role. And they 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 the access of covered entities, pharmacies, and third-parties to 340B discounts.

In most cases, as described by regulators and watchdog agencies, the replenishment model works like this: An individual (who is unlikely to know whether his or her provider is a 340B covered entity, let alone whether he or she qualifies as a patient of such entity) submits a prescription for dispensing at a contract pharmacy. Typically, that prescription also does not indicate whether the individual is a patient of a 340B covered entity. 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* Decl. of Krista M. Pedley ¶¶ 9, 12, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 (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 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.) (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 full price, not the discounted 340B price—do contract pharmacies attempt to sort out whether the prescription was *actually* an eligible 340B prescription. *See* HHS Office of Inspector General, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 9 (Feb. 4, 2014) (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 (where "administrators . . . determine eligibility after drugs are *dispensed*, . . . 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 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 serves to dispense or transfer 340B drugs to persons who are *not* patients of the covered entity: The contract pharmacy replenishes its general inventory using 340B drugs, taking title to the drugs (which the covered entity relinquishes); and the contract pharmacy then dispenses the drugs to any patient that walks through the door, without regard to whether he or she 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 at contract pharmacies remains largely hidden—from both manufacturers (who are nonetheless being told they must provide 340B discounts) and the government. Indeed, HRSA appears to lack detailed knowledge of how the replenishment model works in many contexts. Nothing in HRSA's administrative records in these cases provides this information, but what is clear is that, after a drug is dispensed (maybe to a 340B patient, or maybe not), contract pharmacies or a "third-party administrator" (*i.e.*, commercial companies that facilitate the data exchange between contract pharmacies and covered entities—for a fee) will generally use some kind of black-box software "algorithm" to conclude whether that patient was eligible to be dispensed 340B-purchased drugs (although the patient likely did not benefit from the 340B discount). *See AstraZeneca*, 543 F. Supp. 3d at 61 n.19; *see also* Pedley Decl. ¶ 6 (acknowledging that "[v]arious 340B-tailored software programs exist" to perform this function); *see also* 2018 GAO Rep. at 2 (explaining how some "covered entities hire and pay a private company, referred to as a third-party administrator ('TPA'), 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 that "certain configurations are associated with *greater risk of noncompliance.*"[5]

HRSA does not appear to know how these algorithms work in general, or how the specific algorithm works for individual manufacturers' drugs. Indeed, conspicuously absent from the administrative record is an actual contract purporting to govern a contract pharmacy relationship. It is unclear if HRSA has ever read one.

Taken together, these changes have dramatically refashioned the 340B Program. Put simply, the Program today bears little resemblance to the one Congress enacted—and contract pharmacies have been one of the primary drivers of that radical transformation. Contract pharmacies are not even mentioned in the 340B statute, and today they have ballooned into a massive participant that often facilitates profit-taking rather than patient care.

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[5] Apexus, 340B Split-Billing Software Key Attributes (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-keyattributes.docx. This acknowledgement is notable, as Apexus is the 340B "prime vendor" operating under a contract with HRSA.

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

As explained below, 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.

A. Contract Pharmacy Arrangements Have Little Or No Benefit For Patients

As the use of contract pharmacies has grown, patients have not reaped the benefits. Large commercial pharmacies, third-party administrators, and most DSH hospitals are not sharing benefits with patients either directly through discounted drugs or indirectly through charity care.

Notwithstanding the significant profit that hospitals, contract pharmacies, and related third parties are making on 340B drugs, they rarely 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"); *see also id.* at 15 ("to the extent 340B [hospitals] fulfill their mission of providing lower cost care, we are not seeing it reflected in their drug prices."). Indeed, as the GAO has found, 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. While covered entities that are grantees must typically meet federal requirements of reinvesting their revenue into care for uninsured or vulnerable patients as part of their grant requirements, the 340B Program lacks similar rules for participating hospitals. Hospitals are thus left free to use 340B-discount-derived profits in any way they see fit. And 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 uninsured or vulnerable patients. *See* Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* at 10 (Oct. 2021), https://bit.ly/3vYZEjM (observing that while DSH hospitals rapidly gained 340B market share since 2012, "charity care provided by all US hospitals declined over the same period"); 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 DSH hospitals provided charity care at a rate below the national average for all hospitals).[6]

[6] And despite their booming profits, DSH hospitals do not appear to be expanding their reach into medically underserved areas either. Sayeh Nikpay et al., *Association of 340B Contract Pharmacy Growth With County-Level Characteristics*, 28 Am. J. Manag. Care at 133 (Mar. 2022), https://bit.ly/3JfAh15 (finding that although "[g]rowth of contracts with 340B [grantees] was *more likely* in areas with higher poverty rates and in metropolitan areas," "[g]rowth of contracts

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); *see also* AIR 340B at 9-10 (observing that 65% of DSH hospitals had charity-care rates *below* the 2.9% national average for all hospitals, including for-profit hospitals). And Medicare data shows that only 29% of DSH hospitals are providing 80% of the charity care provided by *all* DSH hospitals—meaning that most DSH hospitals are simply retaining their 340B profits without passing those savings on to patients. *See* AIR 340B at 10.

It appears that, rather than improving patient care, the increase in DSH hospitals and the use of contract pharmacies has a *negative* effect for patients and communities. For example, there is evidence that the promise of increased profits has prompted 340B hospitals to acquire independent physician practices to have those practices qualify for 340B discounts:

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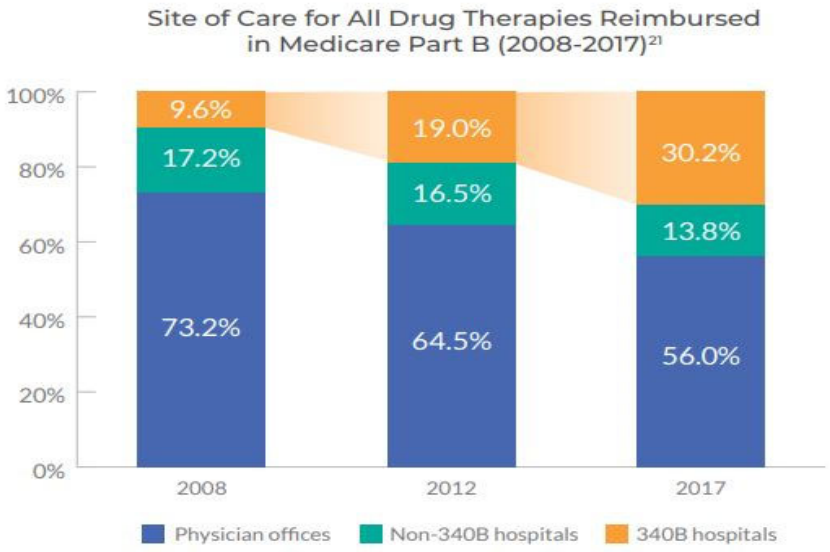
with 340B hospitals was *less likely* in areas with higher uninsured rates and in medically underserved areas" (emphasis added)).



Eleanor Blalock, BRG, *Site-of-Care Shift for Physician-Administered Drug Therapies* at 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 resulting in higher spending on outpatient drugs at 340B hospitals. *See* M. McCaughan, *The 340B Drug Discount Program*, Health Affairs Pol'y Br. (Sept. 14, 2017), https://bit.ly/3I6YOny ("Arguably, 340B pricing encourages providers to choose a higher-cost agent, even when a lower-cost therapy is available, because the spread will be larger and the profit margin therefore higher."). At 340B hospitals, the average annual spend per patient is $457, while it is $159 at non-340B hospitals—an almost *three fold* difference. Michael Hunter & Jason Gomberg,

Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Participating Hospitals at 2 (Mar. 2018), https://bit.ly/3MSSyU5.

As one study aptly put it, the 340B Program has evolved "from [a program] that serves vulnerable communities to one that enriches hospitals." R. Conti & P. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 Health Affairs 1786, 1786 (Oct. 2014), https://bit.ly/37q6R21. And the explosion in contract pharmacies has facilitated that unfortunate evolution—and enriched large for-profit pharmacy chains too.

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

The rampant abuses under the 340B Program—and HRSA's inadequate supervision—are well documented. Over a decade ago, the GAO flagged that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion"—dispensing a drug purchased at the 340B price to someone who is *not* a patient of a covered entity—"compared to in house pharmacies." 2011 GAO Rep. at 28. And since then, HRSA itself has identified hundreds of instances of diversion. *See* 2018 GAO Rep. at 37; *see also id.* at 44 (diversion involving contract pharmacies).

With respect to duplication of Medicaid rebates, the Centers for Medicare & Medicaid Services (CMS) "conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts[]" and "does not have the information needed

to effectively ensure that states exclude 340B drugs from Medicaid rebate requests." 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://www.gao.gov/assets/gao-20-212.pdf. And on the 340B side, HRSA "audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply" with the duplicate discount prohibition. *Id.*[7] Contract pharmacies make this situation significantly worse. *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.").

HRSA has consistently refused to rein in these abuses under the 340B Program. The agency has explained that it does not issue audit findings against covered entities "for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use." GAO, GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure*

[7] Matters are even worse with respect to Medicaid managed care (rather than fee-for-service) because "HRSA does not require covered entities to address [duplicate discounts] or work with manufacturers to repay them" in that context. *Id.* at Highlights. "As a result, manufacturers may be subject to duplicate discounts for drugs provided under managed care." *Id.*

Compliance With 340B Requirements at 15-16 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf; *see also* 2018 GAO Rep. at 37 ("Weaknesses in HRSA's audit process impede its oversight of 340B program compliance at contract pharmacies."). And even when HRSA discovers a violation through its audits, HRSA does "not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit." *Opportunities to Improve the 340B Drug Pricing Program*, *Hearing Before the H. Subcomm. on Health*, 115th Cong. at 54 (July 11, 2018) (testimony of Rep. H. Morgan Griffith); *see also id.* at 55 (GAO witness testifying that HRSA should require "more rigorous information . . . from the covered entities as to what they've done"). 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 Cong. at 63, 79 (testimony of Krista M. Pedley, former Director of HRSA's Office of Pharmacy Affairs) (July 18, 2017) (2017 H. Subcomm. Hr'g) 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)).

III. MANUFACTURERS' CONTRACT PHARMACY POLICIES LIKE THOSE INVOLVED HERE ARE CONSISTENT WITH AND SERVE THE 340B PROGRAM'S DESIGN

The explosive growth in the use of contract pharmacies and the parallel use of the replenishment model—benefiting large hospitals, for-profit pharmacies, and third-party administrators at the expense of patients—as well as the resulting blatant statutory violations led to the policies at issue in this case. HRSA knows that 340B discounts are being siphoned to for-profit entities that Congress never intended. Yet HRSA has consistently refused to address these problems.[8] *See* 2017 H. Subcomm. Hr'g (former Director Pedley testifying that contract pharmacy arrangements are "a business matter between the parties and their contract" and conceding that HRSA does not prohibit contract pharmacies from sharing the 340B revenue).

Spurred by contract pharmacy abuses and HRSA's deliberate refusal to ensure compliance with the 340B statute's requirements, pharmaceutical manufacturers have started to implement reasonable contract pharmacy policies to ensure Program integrity and facilitate their participation in the 340B Program. The exact contours of these policies differ from manufacturer to manufacturer, but—consistent with the

[8] Indeed, PhRMA, has repeatedly tried to engage with HRSA to improve the administration of the 340B Program. *See, e.g.*, PhRMA, *Petition for Rulemaking ADR Process* (Nov. 24, 2020), https://onphr.ma/3KLtexg; PhRMA, *Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA)* (Oct. 27, 2015), https://bit.ly/3MKZClH. But PhRMA has repeatedly been rebuffed by the agency.

340B statute—each permits every covered entity to purchase an unlimited number of 340B drugs at the 340B-discounted price for delivery directly to the covered entity. Many of the manufacturers' policies add reasonable limitations on deliveries to contract pharmacies to mitigate unlawful diversion and duplicate discounts. For example, appellant Sanofi's policy requires covered entities to submit de-identified claims data in order for 340B-priced drugs to be dispensed by an unlimited number of contract pharmacies. Sanofi also lets covered entities without an in-house pharmacy designate a single contract pharmacy for 340B-priced orders even if the covered entity does not provide claims data. And Sanofi's policy is aimed at the types of covered entities that Sanofi has observed account for significant contract pharmacy abuse—and exempts all others. Appellants Novo Nordisk Inc.'s and Novo Nordisk Pharma, Inc.'s (collectively, Novo) policy similarly requires covered entities without an in-house pharmacy to designate a single contract pharmacy for 340B-priced orders. And Novo allows covered entities to place orders for an unrestricted number of contract pharmacies that are wholly owned by the covered entity.

These policies and others like them are fully consistent with the 340B statute, which requires that manufacturers "offer" their drugs to covered entities for "purchase" at discounted prices. 42 U.S.C. § 256b(a)(1). Nothing in the 340B statute "prohibit[s] manufacturers from placing any conditions on covered entities"

before fulfilling 340B orders. *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021). And none of these policies prevents a covered entity from purchasing as many 340B drugs from the manufacturers as it wants, nor keep patients from accessing drugs that are 340B eligible. Rather, claims-data policies like Sanofi's "enable [manufacturers] to better utilize the anti-fraud audit and [administrative dispute resolution] procedures that Congress established for manufacturers in Section 340B." *Id.* at *8; *see* 42 U.S.C. § 256b(a)(5)(C), (d)(3).

Moreover, these types of policies are consistent with HRSA's own historic views. HRSA explained in 1994 that manufacturers were allowed to "request standard information" from covered entities. HRSA, *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). And the agency's 1996 guidance—which was in effect for 14 years—contemplated that covered entities would contract with a single pharmacy, which HRSA considered to be consistent with the 340B statute. *See* 61 Fed. Reg. at 43,549; *see also id.* at 43,556 (recommending that covered entities instruct contract pharmacies to dispense only *"*[u]pon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or a similar telephone prescription).

What's more, in its 2010 guidance—where the agency switched positions and endorsed multiple contract pharmacies—HRSA said that these arrangements were conditional on covered entities' compliance with 340B Program integrity measures: "Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. at 10,273.[9] The types of manufacturer policies at issue here serve the same purpose of protecting the 340B Program's integrity. And they do not contravene any source of law.

[9] HRSA has acknowledged that its broad "patient" definition—which it has not updated since 1996—is likely causing Program abuses. *See* HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient,"* 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) (observing that covered entities "may have interpreted the definition too broadly"). But HRSA has twice declined to finalize proposed updated definitions, which underscores its unwillingness to control the Program's unlawful growth and abuses. *See, e.g.*, *id.*

CONCLUSION

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

Dated: March 15, 2022

Respectfully submitted,

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COMBINED CERTIFICATIONS

1. CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Local Rule 28.3(d), I, Andrew D. Prins, certify that at least one of the attorneys whose names appear on this brief is a member in good standing of the bar of this Court.

2. CERTIFICATE OF WORD COUNT

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 6,386 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 with 14-point Times New Roman font.

3. CERTIFICATE OF IDENTICAL BRIEFS AND VIRUS CHECK

Pursuant to Local Rule 31.1(c), I certify that the text of the electronic version of this brief is identical to the text in the paper copies. I also certify that the electronic brief was scanned using virus-detection software—namely with McAfee Endpoint Security version 11.5—and that no virus was detected.

4. CERTIFICATE OF SERVICE

I certify that on March 15, 2022, I caused a copy of this Brief for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America (PhRMA) in Support of Appellants to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

Dated: March 15, 2022

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