No. 24-2180

In the United States Court of Appeals
For the Ninth Circuit

UNITED STATES OF AMERICA ex rel. ADVENTIST HEALTH SYSTEM/WEST,

Plaintiff-Appellant,

v.

ABBVIE INC., *et al.,*

Defendants-Appellees.

On Appeal from the United States District Court for the Central District of California (No. 2:21-cv-04249-DSF-SK)
Hon. Dale S. Fischer, District Judge

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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Ninth 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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STATEMENT OF INTEREST OF *AMICUS CURIAE*

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 Drug Pricing Program, PhRMA's members provide billions of dollars in discounts on outpatient drugs to many entities that provide healthcare to underserved and indigent patients. PhRMA's unique industry perspective warrants its filing of this separate brief.

PhRMA and its member companies support the 340B program and wish to see the program chart a sustainable path so that it can continue to support our nation's most vulnerable patients, as Congress intended. PhRMA submits this *amicus* brief to detail how the 340B program operates in conjunction with other government healthcare programs and explain how *qui tam* suits like this one would distort the 340B program and undermine the Department of Health and Human Services' ability to administer the program as sole arbiter.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress created the 340B program to enable certain healthcare facilities serving large populations of low-income or otherwise vulnerable patients to purchase certain prescription drugs at lower costs. It does so by imposing price ceilings on drugs sold

[1] All parties have consented to the filing of this brief; no party or party's counsel has contributed money intended to fund this brief's preparation or submission; and no person other than PhRMA contributed money intended to fund this brief's preparation or submission.

to "covered entities" by pharmaceutical manufacturers that wish to have their "covered outpatient drugs" federally reimbursed under the Medicare Part B and Medicaid programs.

But the 340B program—which is administered by the Health Resources and Services Administration (HRSA), a component of the Department of Health and Human Services (HHS)—does not operate in a vacuum. It works in conjunction with other government safety-net programs. Thus, the 340B program is tied to the earlier-enacted Medicaid Drug Rebate Program (MDRP), likewise administered by HHS. The price ceilings established by Section 340B derive from MDRP's rebate calculations and use pricing data submitted to the Centers for Medicare & Medicaid Services (CMS). And the statute prohibits covered entities from receiving Section 340B pricing on a drug that is also subject to a Medicaid rebate. "[T]he interdependent nature of the two programs' requirements means that an adjudication of rights under one program must proceed with an eye towards any implications for the other"—and that HHS must be empowered to "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra USA, Inc.* v. *Santa Clara Cnty.*, 563 U.S. 110, 120 (2011).

Today's 340B program, however, bears little resemblance to the one Congress created, which centralized oversight of the program in the federal government. To begin with, the overwhelming majority of covered entities in the 340B program are nongovernmental hospitals that benefit by receiving market-rate reimbursements for 340B drugs far exceeding the marked-down cost of those drugs. And, increasingly,

those beneficiaries are large hospital conglomerates serving high-income populations. At the same time, the program has been coopted by "contract pharmacies" that acquire large volumes of 340B-discounted drugs, dispense them at a profit, and divvy up the proceeds with their hospital partners.

The explosion of covered entity hospitals and contract pharmacies has resulted in a massive increase in spending on 340B drugs. It has also unleashed a wave of abuses in the form of diversion of 340B drugs to individuals who are ineligible to receive them, and the prohibited receipt by covered entities of duplicate discounts on 340B drugs that are also subject to a Medicaid rebate. Yet while covered entities and contract pharmacies are incentivized to milk ever-larger profits from the 340B program, they are increasingly using those profits to subsidize their own expansive growth—rather than the provision of care to low-income and otherwise vulnerable patients. See *infra* Part II(D).

Those and other abuses of the 340B program underscore the importance of uniform oversight by a single federal government arbiter. The 340B landscape is more complex than ever. HHS can provide the clarity and consistency needed to fairly administer the program; False Claims Act relators dispersed across the country cannot. To the contrary, the centralized 340B pricing system—in which HRSA verifies official ceiling prices based on data that it obtains from CMS and manufacturers—would only be destabilized by covered-entity *qui tam* challenges to those prices. Nor can the 340B program be extricated from other healthcare programs administered by HHS. Section

340B drug ceiling prices are based on the Medicaid rebate formula, and a covered entity's 340B drug costs can, in turn, affect the costs incurred by both Medicare and Medicaid. HHS has the authority and expertise necessary to balance those competing factors, and to vindicate Congress's "unitary administrative and enforcement scheme." *Astra*, 563 U.S. at 120. *Qui tam* relators scattered across jurisdictions— motivated by their own provincial (and pecuniary) interests—do not.

ARGUMENT

I. SECTION 340B's PRICE CEILINGS ARE INTENDED TO BOLSTER CARE FOR INDIGENT AND VULNERABLE PATIENTS AND SUPPLEMENT RELATED PROGRAMS ADMINISTERED BY HHS

Congress created the 340B Drug Pricing Program in 1992 to enable healthcare providers that serve low-income patients to purchase drugs at lower costs. See Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967 (codified at 42 U.S.C. § 256b). To that end, Section 340B imposes price ceilings on certain drugs sold to "covered entities" by pharmaceutical manufacturers that also wish to have their "covered outpatient drugs" federally reimbursed under the Medicare Part B and Medicaid programs.[2] *Astra USA, Inc.* v. *Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Covered entities fall, broadly, into two groups: (1) certain community health providers that receive federal grants to support care, such as Ryan White HIV/AIDS Program grantees and Black Lung Clinics; and (2) hospitals that meet statutorily defined criteria,

[2] A manufacturer's agreement to be bound is memorialized in a form Pharmaceutical Pricing Agreement with HHS. See 42 U.S.C. § 256b(a)(1).

the vast majority of which are private, nonprofit hospitals that have contracts with local or state governments and serve a "disproportionate share" of low-income patients. See 42 U.S.C. § 256b.[3] The price cap is calculated quarterly using a complex formula driven generally by a manufacturer's "best price" and "average manufacturer price" to select customers for a given drug, see *Astra*, 563 U.S. at 114-15, and also accounts for price increases that exceed inflation—often resulting in 340B ceiling prices that fall well below the drug's market price. See *Novartis Pharms. Corp.* v. *Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024). Covered entities "benefit through insurance reimbursements that exceed the marked-down cost of the drugs." *Id.* at 455.

Section 340B was intended to rectify an unintended consequence of the Medicaid Drug Rebate Program (MDRP) passed two years earlier. The problem with MDRP was that its pricing formula punished drug manufacturers' benevolence: The formula uses manufacturer pricing data to set a rebate amount that drug manufacturers must remit to states for their Medicaid drug purchases. *Astra*, 563 U.S. at 114-15. Before MDRP, manufacturers often voluntarily offered discounts to healthcare providers that served large low-income and vulnerable communities and provided high levels of charity care. With MDRP, though, came a system of mandatory manufacturer rebates to states, pegged in part to the manufacturers' "best price"—creating a strong disincentive to give

[3] Other participating hospitals include governmental hospitals and hospitals granted state or local powers; as discussed below in Part II(A), disproportionate share hospitals comprise the overwhelming majority of spending by hospital covered entities.

discounts, lest those discounts set the MDRP floor and yield massive MDRP rebates. See Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 30 (2019).

Congress enacted Section 340B as a corrective. Capping prices charged to "covered entities" serving the poor would, Congress thought, effectively restore the discounts that existed pre-MDRP. Fisher, *supra*, at 30. Section 340B "draws on the larger [MDRP] scheme's pricing methodology"—a "complex enterprise requiring recourse to detailed information about the company's sales and pricing." *Astra*, 563 U.S. at 115. Accordingly, "Congress made [the Department of Health and Human Services (HHS)] administrator of both the Medicaid Drug Rebate Program and the 340B Program"—a sensible allocation of authority given the "interdependent nature of the two programs' requirements." *Id.* at 120.

In short: Section 340B was passed because of MDRP; is meant to supplement MDRP payments when MDRP would not apply; and uses MDRP's pricing formula and data submitted to the Centers for Medicare & Medicaid Services (CMS) under MDRP.[4] And, given the interconnection between the programs, "an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Astra*, 563 U.S. at 120. Thus, to operate as Congress intended, both programs must be administered "harmoniously and on a uniform, nationwide basis." *Ibid.* HHS—which

[4] See *infra* Part III(B) (describing 340B pricing process).

delegated administration of the Section 340B program to its subunit, the Health Resources and Services Administration (HRSA)—is the forum Congress chose to manage and adjudicate those rights "harmoniously."

While Section 340B does not require covered entities to pass their savings directly to patients, Congress imposed two key limitations to maintain program integrity and ensure that the program is limited to 340B patients. The first is tied to the existing MDRP. Specifically, "the statute prohibits covered entities from receiving the section 340B discount on drugs also subject to a Medicaid rebate." *Novartis*, 102 F.4th at 456. Covered entities are thus (in theory) prohibited from causing a double discount on drugs. The second limitation "prohibits 'diversion,' which occurs when covered entities 'resell or otherwise transfer the drug to a person who is not a patient of the entity.'" *Ibid.* (quoting 42 U.S.C. § 256b(a)(5)(B)). That prohibition aims to target the benefit of 340B pricing to the low-income and vulnerable patient populations for which it was intended.

At first, HRSA had limited enforcement mechanisms against covered entities and drug manufacturers that skirted Section 340B's requirements. Toothless enforcement led to widespread complaints that "HRSA's oversight of the 340B program [was] inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements." U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program*

Offer Benefits, But Federal Oversight Needs Improvement at intro. (Sept. 2011) ("2011 GAO Rep."), https://perma.cc/RL3G-G5ZB; see Appellees' Br. 6.

In response, Congress amended Section 340B in the 2010 Affordable Care Act by directing HHS to formulate specified procedures to police covered entity and manufacturer compliance. 42 U.S.C. § 256b(d); see *Astra*, 563 U.S. at 121-22 ("Congress thus opted to strengthen and formalize HRSA's enforcement authority"); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7101–02, 124 Stat. 119, 821-827 (2010). HRSA, in turn, created a formal dispute procedure, including a penalty system for complaints by and against covered entities and manufacturers. See 42 C.F.R. § 10.21. The Affordable Care Act also granted HRSA new authority to (among other things) develop and enforce "precisely defined standards and methodology for the calculation of ceiling prices." 42 U.S.C. § 256b(d)(1)(B)(i); see Appellees' Br. 8. The consequences of noncompliance, such as through overcharging, can be severe. For example, HRSA may terminate a manufacturer's Pharmaceutical Pricing Agreement, rendering the manufacturer ineligible for Medicaid and Medicare Part B reimbursement. 42 U.S.C. § 1396r-8(a)(1), (b)(4)(B)(i), (b)(4)(B)(v).

II. LARGE HOSPITALS AND CHAIN PHARMACIES EXPLOIT SECTION 340B TO BOOST PROGRAM PROFITS INSTEAD OF CARING FOR UNDERSERVED PATIENTS

Today's Section 340B looks very different from the program that Congress created. Cost savings meant to increase access to medicines for low-income and otherwise vulnerable patients have, instead, become a profit stream for hospital

conglomerates (which make up a vastly increased proportion of covered entities, as compared to federal grantees) and large chain pharmacies. As profit-driven arrangements between those entities have proliferated, so too have statutorily proscribed abuses of the Section 340B program—particularly double-discounting and diversion. And the windfalls that hospitals reap along the way are not being passed on to those patients most in need; instead, they are often applied to fund hospital expansion into high-earning patient communities. All of that comes at a steep cost to the healthcare system as a whole.

A. 340B Sales Have Tilted Sharply To Nongovernmental Hospitals, Driving Massive Spending As Hospitals Chase 340B Revenue

As noted, covered entities, which are enumerated in the statute, generally fall into two baskets: federal grantees, and hospitals. Those two baskets used to split 340B sales volume close to evenly. See PhRMA, *Chart Pack: Medicines in 340B*, at 4 (Sept. 2022), https://perma.cc/CTY2-QQEB (hospitals made up 49 percent of volume in 2004). No longer. Now, hospitals make up fully 87 percent of 340B sales volume. *Ibid.* And overwhelmingly—accounting for over 70% of sales volume—those hospitals are disproportionate share hospitals, which have no obligation to actually invest their program profits in expanding affordable access to low-income and underserved patients (let alone provide discounts on 340B drugs to these patients). Elizabeth Watts et al., *340B Participation and Safety Net Engagement Among Federally Qualified Health Centers*, JAMA Health Forum, at 8 (Oct. 4, 2024), https://perma.cc/A4NT-BXFT.

That shift was spurred by a series of regulatory changes—and the opportunistic response to those changes by covered entities and their partners. First, the Affordable Care Act expanded the universe of covered entities to include "certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals." 2011 GAO Rep. 4 n.11. Second, a 2010 policy change by HRSA permits hospitals to contract with as many pharmacies as they wish, thus unleashing a massive, previously untapped profit stream that made 340B participation much more lucrative. *Novartis*, 102 F.4th at 457 ("The 2010 Guidance prompted a significant expansion in the section 340B program."); see *infra* Part II(B). Finally, hospital systems are rapidly acquiring more and more smaller physician practices, converting them to satellite hospital sites that serve high-income, insured populations—all while sourcing their drugs at steeply discounted 340B prices, and pocketing the difference. Anthony M. DiGiorgio & Wayne Winegarden, *Reforming 340B to Serve the Interests of Patients, Not Institutions*, JAMA Health Forum, at 1 (July 26, 2024), https://perma.cc/5SLB-K8ND ("340B hospitals are expanding in wealthier neighborhoods by acquiring clinics (child sites), which gain the [covered entity] designation of the parent hospital," allowing hospitals to "generate greater returns by delivering drugs to a largely insured population"). In order to satisfy the "covered entity" criteria, those "hospitals exhibit strategic corporate behavior to meet, without exceeding, the minimum share of low-income patients to qualify for the 340B program." *Ibid.*

As the market share of those hospital conglomerates has ballooned, so too has spending on 340B drugs. "In calendar year 2018, 340B drug purchases totaled more than $24 billion; about $21 billion of those purchases (87 percent) were made by hospitals." U.S. Gov't Accountability Off., GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 2 (Dec. 2019), https://perma.cc/673T-RDXP. In 2009, total 340B purchases amounted to only $4 billion. *Ibid.* And by 2019, 340B drugs accounted for a staggering seven-to-eight percent of the total U.S. pharmaceutical market. Adam. J. Fein, *340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019), https://perma.cc/KP57-SSKX. That trajectory has continued—in 2024, 340B spending hit a record $66.3 billion (nearly 40% more than Medicaid drug spending). Adam. J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://perma.cc/APC8-YP7P. As discussed below, that seismic shift has failed to deliver improved care to low-income and vulnerable patients, even as it distorts the market and encourages abuse.

B. The Rise Of Contract Pharmacies Has Compounded The Problem

Hospitals' efforts to milk Section 340B to boost their general revenue are abetted by a willing partner: contract pharmacies. Before 2010, "HRSA stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Novartis*, 102 F.4th at 457. And that made sense;

some covered entities don't have an in-house pharmacy, so they must engage a contract pharmacy to provide reduced-cost drugs to patients as Congress intended. See *ibid.*

In 2010, however, "HRSA swerved" sharply from the one-pharmacy limitation, "opin[ing] that covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Novartis*, 102 F.4th at 457. The result? The number of participating contract pharmacies exploded over the next decade "from about 1,300 to 23,000," with "the country's largest chain pharmacies—such as Walgreens and CVS—account[ing] for most of this market." *Ibid.*

Unsurprisingly, those mega-chains did not flood the market out of a desire to provide charity care or cheaper drugs to patients in need. They were instead attracted by the huge profits to be reaped by divvying up 340B revenue with covered entities. To see why, one must first understand the "now-prevalent 'replenishment model,'" which has radically expanded the role of contract pharmacies under the 340B program and, in the process, moved the program even further afield from Congress's design. *AstraZeneca Pharms. LP* v. *Becerra*, 543 F. Supp. 3d 47, 61 n.19 (D. Del. 2021), aff'd *sub nom. Sanofi Aventis U.S. LLC* v. *U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023); see *Novartis*, 102 F.4th at 457.

Under the replenishment model, covered entities order 340B drugs from manufacturers at bargain-bin prices. Then, notwithstanding the statute's prohibition on diverting 340B drugs to patients other than those of a covered entity, the drugs are

transferred to the general stores of contract pharmacies, where they are not earmarked or segregated for use by covered-entity patients. *Novartis*, 102 F.4th at 457 ("While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs."). The contract pharmacies often sell the 340B drugs to all comers—eligible patient or not—charging uninsured patients prices higher than the 340B ceiling price (or imposing cost sharing based on higher prices). Only then, *after* the drugs are dispensed (at a steep markup), do the pharmacies attempt to determine how many covered-entity patients received a given drug so that the pharmacy can order more, in that amount, to "replenish" its inventory. *Ibid.* Often, that task is farmed out to third-party administrators with a profit motive to "estimate" that more, rather than less, of the pharmacy's stock was sold to 340B-eligible patients. *Ibid.* ("Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount."). All the while (and notwithstanding the requirement that covered entities "must retain title to the drugs," *ibid.*), "[t]he covered entities never physically possess the drugs." *AstraZeneca Pharms. LP*, 543 F. Supp. 3d at 61 n.19. And, at the end of the day, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the

discounted price and the higher insurance reimbursement rate." *Novartis*, 102 F.4th at 457.[5]

C. The Nongovernmental Hospital And Contract Pharmacy Expansion Has Exacerbated Abuses Of The 340B Program

The explosion of covered entities (particularly private hospitals) and contract pharmacies has unleashed a wave of program abuse in the form of diversion, duplicate discounts, and participation by ineligible entities.

1. *Diversion.* In 2011, the Government Accountability Office (GAO) sounded the alarm that "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program." 2011 GAO Rep. 28. That concern was well founded.

Even aside from intentional acts of diversion, contract pharmacies, unlike in-house pharmacies, do not have access to a patient's medical record—and so questions of patient eligibility are inherently likelier to arise and may be shaded by profit motive. See *Novartis*, 102 F.4th at 458 ("the concern is that pharmacies rely on manipulable

[5] See also U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 30 (June 2018) ("2018 GAO Rep."), https://perma.cc/4WHG-TU9V (finding that only 30 of 55 covered entities[that were surveyed] provided low-income, uninsured patients with discounts on 340B drugs dispensed at some or all of their contract pharmacies); H. Comm. on Energy & Com., *Review of the 340B Drug Pricing Program*, 115th Cong., at 32-34 (Jan. 10, 2018) (discussing contract-pharmacy sharing in 340B profits).

algorithms to code whether prescriptions warrant the discount") (citing U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program* 9-15 (2014) ("2014 OIG Rep."), https://perma.cc/R346-LETK). That was why, before 2010, covered entities without in-house pharmacies were limited to one contract pharmacy; that limitation provided "a workable mechanism to use outside pharmacies under arrangements which would decrease the drug diversion potential." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). Without that one-pharmacy limitation, however, almost half of audited covered entities between 2012 and 2016 were found to have unlawfully sold or transferred 340B drugs to nonpatients, in derogation of congressional design. See 2018 House Rep. at 38.

2. *Duplicate discounts.* Duplicate discounts are a prohibited form of double-dipping in which a covered entity receives a Section 340B discount on drugs that are also subject to a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A); see *Novartis*, 102 F.4th at 456. The risk of such improper billing has only multiplied, however, as "some contract pharmacies do not track and exclude 340B-eligible prescriptions from Medicaid rebate claims, leading to impermissible duplication." *Novartis*, 102 F.4th at 458 (citing 2014 OIG Rep.). Indeed, the HHS Office of Inspector General has found that "contract pharmacy arrangements create complications in preventing duplicate discounts." 2014 OIG Rep. at 2. In practice, not all contract pharmacies even attempt to comply with

the Program's requirements, as "some covered entities that *do* dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts." *Ibid.*

At the same time, HRSA audits alone cannot prevent duplicate discounts. For example, the agency does "not assess the potential for duplicate discounts in Medicaid managed care," which has more Medicaid enrollees, prescriptions, and spending for drugs than the alternative, fee-for-service system. 2018 GAO Rep. But because "the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance," pharmaceutical "manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions. *Id.* at 40. State Medicaid programs' "policies may not prevent duplicate discounts," either, underscoring the need for enhanced—and unified—federal oversight. U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* 18 (Jan. 2020) ("Jan. 2020 GAO Rep."), https://perma.cc/R35A-Y7WM.

3. *Eligibility.* There is yet another, more fundamental problem with today's 340B landscape: confusion over whether many nongovernmental hospitals even qualify as covered entities in the first place. In 2011, the GAO warned that HRSA's reliance on self-policing created an untenable risk of 340B participation by ineligible entities. 2011 GAO Rep. 24-25. And the GAO has "remain[ed] concerned that HRSA lacks reasonable assurance that the audits are appropriately identifying nongovernmental

hospitals that may be participating in the 340B Program based on contracts that are inconsistent with program requirements and HRSA's guidance." U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* 21 (Dec. 2020), https://perma.cc/M5KU-CG2U. Even when a hospital *does* qualify as a covered entity, moreover, "disproportionate share" status has long since ceased being a useful proxy for low-income and charity care (if it ever was). Medicare Payment Advisory Comm'n, *Report to the Congress: Overview of the 340B Drug Pricing Program* 5 (May 2015), https://perma.cc/X49T-KE7G (concluding that the amount of Medicare disproportionate share payments that a hospital receives is "not a good proxy for the amount of uncompensated care" a hospital provides). Needless to say, participation in the 340B program by non-covered entities subverts the core purpose of the program, which is to provide low-cost medications to a carefully delineated subset of healthcare providers that serve large populations of low-income and otherwise vulnerable patients.

D. Hospitals And Contract Pharmacies Retain A Significant Proportion Of Their 340B Profits Without Passing Them On To Low-Income and Vulnerable Patients

Although Section 340B's animating purpose is to increase access to affordable prescription drugs for low-income and vulnerable patients, the evidence suggests that hospitals and contract pharmacies are in fact its main beneficiaries. And the benefits are substantial indeed. One study estimated that "covered entities' collective profits doubled from $20.2 billion in 2015 to $40.5 billion in 2019." Ryan P. Knox et al.,

Outcomes of the 340B Drug Pricing Program, JAMA Health Forum, at 5 (Nov. 22, 2023), https://perma.cc/3B4U-EMRG.[6] Yet the evidence is, at best, "conflicted as to whether the revenue is primarily directed toward charity care and low-income populations," as Congress intended. Knox, *supra*, at 5. Thus, for example, scholars have found that 340B participation is not "associated with increases in hospital-reported uncompensated care provision." Sunita M. Desai & J. Michael McWilliams, *340B Drug Pricing Program and Hospital Provision of Uncompensated Care*, 27 Am. J. of Managed Care 432, 436 (2021), https://perma.cc/4BTY-4EKE. And another recent study shows that fully two-thirds of nongovernmental 340B hospitals provide *less* free and reduced-cost treatment than the average of all hospitals—including those that do not hold themselves out as safety-net providers. Alliance for Integrity and Reform of 340B, *Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Drug Pricing Program* 9 (Feb. 2022) ("*Left Behind*"), https://perma.cc/RN3E-2V4Y. That is consistent with other empirical evidence showing that "participating hospitals devote fewer resources (1.7% of net patient revenues) toward charitable care than the average hospital (2.0%)." DiGiorgio & Winegarden, *supra*, at 1.

[6] In 2018 "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B purchased medicines in 2018, which represent[ed] over 25 percent of the total $48 billion in profits realized by all providers that dispensed or administered brand medicines." Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program* at 7 (Oct. 2020), https://perma.cc/39J8-VEFD.

Zooming out, from 2013 to 2017 the total value of uncompensated care provided by covered entities declined from $46.8 billion to $38.4 billion—even as 340B program participation has exploded. Fein, *Charity Care Flatlines*, *supra*; see Karen Mulligan, USC Schaeffer, *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments* 10 (Oct. 2021), https://perma.cc/3SUN-QR5U (noting that, despite growth of hospital 340B participation since 2012, "charity care provided by all US hospitals declined over the same period"). And the hospitals that spend 340B profits on increasing affordable access for low-income and vulnerable patients are decidedly in the minority; Medicare data show that just 29% of disproportionate share hospitals provide 80% of the charity care provided by all such hospitals. *Left Behind* at 10.

Rather than spend 340B profits on low-income and vulnerable patients, many hospitals instead use 340B profits to expand into higher income areas populated largely by insured patients. See Knox, *supra*, at 7 ("[C]overed entities—notably disproportionate share hospitals—also used 340B revenue for purposes seemingly unrelated to underserved patient care, including opening sites in higher-income neighborhoods and acquiring outpatient physician practices.")[7] It isn't hard to see why: "Covered entities" are "incentivized under the 340B program to collect the largest

[7] See also Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 24, 2022), https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html.

discount possible and keep it." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 662 (2015); see DiGiorgio & Winegarden, *supra*, at 1. Put simply, the richer and more insured a patient population is, the higher the price that covered entities can charge for heavily discounted 340B medications.

Contract pharmacies behave similarly, avoiding low-income neighborhoods and opting instead to spend their 340B profits by expanding into affluent areas that are already well served. In fact, since the 2010 regulatory change allowing covered entities to use unlimited contract pharmacies, "the percentage of 340B pharmacies in the lowest income neighborhoods declined by 5.6%"—even as "the percentage of *non*-340B pharmacies in the same neighborhoods increased by 1.3%." John K. Lin et al., *Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum, at 2 (June 17, 2022) (emphasis added), https://perma.cc/26UX-K3QV. Those pharmacies could scarcely be more removed from any charity-care or reduced-cost purpose; in fact, "45 percent of disproportionate share hospitals had at least one pharmacy that was more than 1,000 miles away compared to 11 percent or less for grantees and critical access hospitals." 2018 GAO Rep. 23.

In short, 340B profits are, at worst, a revenue stream to be tapped to fund rapid expansion that serves higher-income patients and the providers themselves. At best, the profits are used to cross-subsidize the provision of other healthcare services that

bear little, if any, relation to the program's statutory purpose. Indeed, *amicus* 340B Health seems to concede as much, touting the use of 340B profits to prop up "specialized services that typically operate at a loss." 340B Health Br. 4. Praiseworthy though such projects may be, they are not the "intended effect" (*id.* at 5) of Section 340B—a statute that was enacted to restore drug discounts for safety net providers providing direct clinical care to large populations of underserved patients that would otherwise slip through the cracks.

E. Hospitals' Exploitation Of The 340B Program Distorts The U.S. Healthcare System

The rapid expansion of large nongovernmental hospitals and contract pharmacies in the 340B program—with attendant increases in program abuses and failure to put profits to work for low-income and vulnerable patients—would be bad enough. But on top of all that, nongovernmental hospital 340B behavior warps the healthcare market and imposes costs elsewhere in the system.

Because hospitals may keep (and need not account for) their 340B profits, they have every incentive to maximize the spread between the 340B price and the market price at which they are often reimbursed. "Physicians may even shift their prescriptions to more expensive outpatient drugs to collect a [still] larger profit." Baer, *supra*, at 662. Such distorting incentives are borne out by the data, which show that the design of the 340B program imposes significant costs on the nation's healthcare system. Indeed, one study concluded that 340B hospitals' spending was almost triple that of non-

participating hospitals. Milliman, *Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Participating Hospitals* 2 (Mar. 2018), https://perma.cc/6MSC-DEMS.

Nongovernmental hospital use of the 340B program imposes substantial costs on the Medicare system, in particular. Because 340B drugs can be acquired at prices far below Medicare Part B reimbursement rates—but are reimbursed at full freight—covered entities can "generate significant profits," at Medicare's expense, "when they administer Part B drugs." Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017). Providers thus have a "financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals." U.S. Gov't Accountability Off., GAO-15-442, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals* 30 (June 2015), https://perma.cc/M7XV-XRN2. Lo and behold, that is just what the GAO found—that, "on average, Medicare beneficiaries at 340B [disproportionate share] hospitals were prescribed more drugs or prescribed more expensive drugs, or both, than beneficiaries at" other hospitals. *Id.* at 20-21. Thus, "[p]er-beneficiary Medicare Part B drug spending was higher at 340B hospitals compared with institutions not participating in the program." DiGiorgio & Winegarden, *supra*, at 1.

III. THE FAIR ADMINISTRATION OF THE 340B PROGRAM REQUIRES THE CONSISTENCY AND CERTAINTY OF A SINGLE ARBITER

A. 340B Program Abuse Demonstrates The Importance of Uniform Federal Government Oversight

Congress vested enforcement authority for the 340B program in HRSA alone—eschewing "assist[ance]" from "suits by 340B entities [that] would undermine the agency's efforts to administer both Medicaid and § 340B." *Astra*, 563 U.S. at 120. Program abuse by covered entities and contract pharmacies (among others) demonstrates the wisdom of "centraliz[ing] enforcement in the government." *Id.* at 119.

1. *The shift from grantees to large hospitals.* The expansion of the 340B program beyond congressional design—and increasing dominance of nongovernmental hospitals—calls out for a single federal arbiter of both covered entity and manufacturer compliance with Section 340B's requirements. As large hospitals and chain pharmacies drive massive growth in 340B program size, the complexity of an already highly technical program only increases.

Beyond the increasing scope of the current 340B system, the landscape is populated by middlemen—contract pharmacies, pharmacy benefit managers, and 340B administrators—all of whom take a cut of 340B profits, and many of whom are incentivized to increase those profits. That breeds even greater complexity—and a

greater need for oversight.[8] HHS, not private parties, has the requisite expertise and data to administer the 340B program. On the other side of the ledger, the 340B system has no need for yet another rent-seeking constituency in the form of plaintiffs' attorneys and covered-entity-*cum*-relators.

2. *Drug Diversion.* As explained above, the unchecked expansion of the 340B program has heightened the risk of drug diversion to non-patients. Indeed, two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Rep. 44. Contract pharmacies often rely on black-box algorithms to estimate, post-hoc, which units of a drug were likely dispensed to a covered-entity patient, and different algorithms may yield different results in the same circumstances. See 2014 OIG Rep. at 10 ("In some cases, covered entities using different data types and/or comparison methods categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements."). Reconciling those disparate approaches and policing compliance requires a neutral federal arbiter that speaks with one voice.

As private hospitals have come to dominate the 340B program, moreover, patients are ever more likely to be "patients of a covered entity." For example, a physician may practice both at a hospital and independently, or may prescribe a drug at

[8] Take, for example, the numerous and inconsistent replenishment-model algorithms described just below.

a visit to a covered entity that relates to a condition previously diagnosed by a non-covered entity. See 2014 OIG Rep. at 10, 12. In such circumstances, different covered entities have "differing interpretations of what HRSA guidance requires." *Id.* at 16. HRSA can provide the needed clarity; *qui tam* relators scattered across the country cannot.

3. *Duplicate Discounts.* The same holds true for the increasing problem of duplicate discounts. Covered entities vary widely in their approach to identifying and preventing such discounts. State Medicaid systems, too, exhibit wide variation in their contractual arrangements with covered entities and their requirements for avoiding duplicate discounts. For example, states differ on whether covered entities may "carve in" 340B prescriptions to Medicaid patients—that is, prescribe 340B drugs to Medicaid patients in the first instance—rather than barring altogether the prescription of 340B drugs to Medicaid patients. Jan. 2020 GAO Rep. 14. Of the majority of the states that permit "carve-ins," the procedure for preventing double discounts varies widely. See *id.* at 15. And "[i]n addition to varying by state," double-discounting policies can also vary within a state, depending on dispensing methods, type of pharmacy, and the Medicaid program (fee-for-service versus managed care) involved. *Ibid.* It is HHS—not private parties—that has the data, expertise, and capacity to adjudicate double-discounting disputes.

B. The 340B Program Would Be Undermined By A Multiplicity Of False Claims Act Suits

After the Affordable Care Act required HRSA verification of ceiling prices, the agency implemented a process that uses CMS and manufacturer data to calculate an official, quarterly ceiling price. See Appellees' Br. 9-10. In brief, manufacturers submit pricing data to HRSA, which HRSA then examines alongside pricing data that it obtains directly from CMS. HRSA then calculates a ceiling price, which the manufacturer may contest—and which HRSA may revise if it agrees that the manufacturer's data is more accurate. In the end, HRSA publishes an official ceiling price.

That centralized process—in which HHS, which has access to data from CMS and the expertise to adjudicate disagreements about price calculations, is the ultimate arbiter—is consistent with Congress's "unitary administrative and enforcement scheme." *Astra*, 563 U.S. at 120. And it would be wholly undermined by allowing covered-entity *qui tam* suits based on alleged 340B overcharges. For one thing, manufacturers and covered entities could never rely on the price ceiling that HRSA had determined, as profit-driven relators would be waiting in the wings to second-guess those numbers. Indeed, Plaintiff here challenges the very ceiling prices that HRSA itself had independently verified. See Appellees' Br. 46. For another, the timescales are grossly mismatched; ceiling prices are calculated quarterly (and will vary quarterly based on changes in a manufacturer's Medicaid rebate pricing data for a given drug), while *qui tam* suits often languish under seal for years. Allowing covered entities to "dress their

claims" in *qui tam* garb would turn a price that guides investment and other decision-making into little more than a first cut. *Astra*, 563 U.S. at 114.

C. The 340B Program's Intersection With Other Healthcare Programs Further Underscores The Importance Of A Single Government Arbiter

The 340B program cannot be separated from other federal healthcare programs administered by HHS. Take Medicaid. 340B drug pricing is based on the MDRP (Medicaid) rebate formula, uses CMS data, and is meant to supplement those rebates where MDRP doesn't apply. Whether a MDRP rebate is available depends (among other things) on whether a covered entity has received 340B pricing on the drug units at issue—which, in turn, depends on how a given state administers Medicaid/340B discounts with respect to covered entities. See *supra*, at 15-18, 25-26; see also Jan. 2020 GAO Rep. 15 (describing variation in state policies regarding carve-in prescriptions to Medicaid patients).

There are competing priorities in determining drug prices, too. As the government acknowledges, "[i]n certain circumstances, a covered entity's drug costs directly affect costs incurred by government payors such as Medicare and Medicaid." U.S. Br. 4. For example, the lower the underlying average manufacturer price, (for purposes of setting the 340B ceiling price), the cheaper a drug is for a covered entity—but the more expensive it is for a state Medicaid system. *Astra*, 563 U.S. at 120 n.6. As for Medicare, 340B's incentives drive up Medicare Part B costs and channel patients to more expensive care. See *Am. Hosp. Ass'n* v. *Azar*, 967 F.3d 818, 822 (D.C. Cir. 2020)

(noting "concerns about the intersection of the 340B program with Medicare Part B" and citing the "large gap between the amount a 340B hospital would spend" to acquire a drug "and the higher amount Medicare would reimburse the hospital"), rev'd on other grounds *sub nom. Am. Hosp. Ass'n* v. *Becerra*, 596 U.S. 724 (2022). In short, Section 340B exists in a dynamic equilibrium with other federal health care and safety-net programs—an equilibrium that *qui tam* relators have neither the capacity nor the incentives to preserve.[9]

"HHS," in contrast, "can use its expertise to ascertain and balance the competing interests." *Astra*, 563 U.S. at 120 n.6. That's why Congress assigned it that task. "Courts as first-line decisionmakers are not similarly equipped to deal with the whole picture." *Ibid.* The False Claims Act may "spread the enforcement burden," *id.* at 119, in other statutory contexts. But allowing relator-based challenges to 340B pricing would only "undermine the agency's efforts" to administer federal healthcare programs on a uniform, nationwide basis. *Id.* at 120. This Court should reject Appellant's attempt to do so.

[9] To further complicate matters, the Inflation Reduction Act of 2022, which establishes a mechanism for determining a "maximum fair price" for certain drugs covered under Medicare Part B and Part D, includes a provision stating, in general, that a manufacturer of such a drug is required to provide the relevant purchasing or dispensing entity access to the lesser of that "maximum fair price" or the drug's 340B ceiling price. See Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1842 (2022) ("Nonduplication with 340B Ceiling Price") (codified at Social Security Act § 1193(d), 42 U.S.C. § 1320f-2(d)).

CONCLUSION

The judgment of the district court should be affirmed.

Respectfully submitted,

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