NOS. 21-5299, 21-5304

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

NOVARTIS PHARMACUETICALS CORPORATION,
Plaintiff-Appellee,

v.

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

UNITED THERAPEUTICS CORPORATION,
Plaintiff-Appellee,

v.

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

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

BRIEF OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND CHILDREN'S HOSPITAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rules 26.1 and 28(a) of this Court and Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure: *Amici Curiae* American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and National Association of Children's Hospitals d/b/a Children's Hospital Association are not-for-profit organizations. None of the *Amici* has a parent company, and no publicly held company holds more than a ten percent interest in any of the *Amici*.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersign counsel certifies as follows:

A. Parties and Amici

All parties, intervenors, and *amici* appearing before the district court and in this court are listed in the Brief for Appellants.

B. Rulings Under Review

References to the rulings at issue appear in the Brief for Appellants.

C. Related Cases

These cases have not previously been before this Court or any other court. Appeals involving similar enforcement actions have been docketed in the Third and Seventh Circuits. *See Sanofi-Aventis U.S., LLC v. HHS*, No. 21-3167 (3d Cir.); *AstraZeneca Pharmaceuticals LP v. Secretary United States Department of Health and Human Services*, No. 22-1676 (3d Cir.); *Eli Lilly and Co. v. Becerra*, No. 21-3128 (7th Cir.). Challenges to similar agency actions have been filed in the District Court for the District of Columbia and the District Court of Maryland. *Boehringer Ingelheim Pharmaceuticals, Inc. v. Becerra*, No. 21-2826 (D.D.C.); *Kalderos, Inc. v. United States*, No. 21-cv-02608 (D.D.C.); *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-02906 (D.D.C.); *National Association of Community Health Centers v. Azar*, No. 20-cv-03032 (D.D.C.); *Pharmaceutical Research & Manufacturers of America v. Cochran*, No. 8:21-cv-198 (D. Md.).

D. Statues and Regulations

All applicable statutes, etc., are contained in the Brief for Appellants.

/s/ Casey Trombley-Shapiro Jonas
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GLOSSARY

AMP: average manufacturer price

GAO: U.S. Government Accountability Office

HHS: Department of Health and Human Services

HRSA: Health Resources and Services Administration

NDC: national drug code

PBM: Pharmacy Benefit Manager

TPA: third-party administrator

INTEREST OF *AMICI CURIAE*[1]

Amici are five hospital/health system associations whose members use 340B discounts for drugs dispensed through contract pharmacies to support health care programs and services. The discounts, for example, allow these members to (1) provide more patient care services; (2) provide more uncompensated and unreimbursed care; (3) provide more services in underserved areas; (4) develop targeted programs to serve vulnerable patients; and (5) keep their doors open.

INTRODUCTION

The continued viability of the 340B drug discount program is at stake in these cases. Congress created the 340B program to provide discounts to nonprofit hospitals and community health centers so that they could offer additional, more affordable health care services to the underserved. In Congress's words, it was designed to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *American Hospital Ass'n v. Azar*, 385 F.Supp.3d 1, 5 n.7 (D.D.C. 2019). The 340B program has easily met Congress's goals. The discounts at issue cost the profitable

[1] Appellees and Appellants do not object to the filing of this brief. Undersigned counsel for *amici curiae* certify that this brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for the brief; and no one other than *amici* and their counsel has contributed money for this brief.

drug companies a drop in the bucket, but provide an indispensable lifeline for 340B hospitals.

That program is under attack by the highly profitable pharmaceutical industry. But neither the statute nor the drug companies' mischaracterizations provide a basis to decimate the program as these companies are doing. *Amici* urge this Court to hold that the drug companies must go back to providing 340B discounted drugs to covered entities, regardless of whether these vital medicines are being dispensed in-house or through outside pharmacies.

BACKGROUND

A. History of the 340B Program

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve low-income patients (340B providers or covered entities). 340B providers play a critical role in the safety net,[2] which is accompanied by substantially lower operating margins than those of non-340B

[2] *See, e.g.*, Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 3 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

providers—and in fact, often *negative* operating margins.[3] 340B providers provide a disproportionate amount of uncompensated care,[4] and community health and other specialized services at a proportionally higher rate than non-340B hospitals.[5] Accordingly, unreimbursed and uncompensated care costs are 27.4 percent higher, on average, for 340B hospitals than for non-340B hospitals.[6]

The purpose of the 340B program is to stretch the funding 340B providers have available to meet the needs of their most vulnerable patients.[7] A 2011 report from the U.S. Government Accountability Office (GAO) found that the 340B program has had this exact effect.[8]

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[3] *See id.* at 3–4 (July 10, 2020); Am. Hosp. Ass'n, *Setting the Record Straight on 340B: Fact vs. Fiction* 2 (Mar. 2021), https://www.aha.org/system/files/2018-02/340BFactvsFiction.pdf.

[4] L & M Policy Research, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018), https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf.

[5] Dobson et al., *supra* note 4, at 3–4.

[6] L & M Policy Research, *supra* note 6, at 1.

[7] H.R. Rep. No. 102-384(II), at 12 (1992.

[8] *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, Report to Congressional Committees 17–18 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf; *see also* 340B Health, *2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on Hospitals*, https://www.340bhealth.org/files/340B_Health_Survey_Report_2021_FINAL.pdf; Ryan P. Knox et al., *Risks to the 340B Drug Pricing Program Related to Manufacturer Restrictions on Drug Availability*, JAMA (Apr. 15, 2022), https://jamanetwork.com/journals/jama/article-abstract/2791334.

Drug manufacturers may charge 340B providers no more than the statutorily defined "ceiling price" for 340B covered drugs, which is calculated by subtracting the unit rebate amount from the "average manufacturer price" (AMP).[9] Congress provided for a larger rebate when drug companies increase drug prices faster than the inflation rate.[10] This inflation-based penalty could have resulted in *negative* ceiling price calculations for 340B covered drugs, but HRSA's position is that when the calculated 340B ceiling price for a drug is zero or less, drug companies shall charge one penny for the drug.[11]

Since the beginning of the 340B program, Appellees and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 they have sold drugs at 340B prices to covered entities that used multiple contract pharmacies. A quarter of the 340B hospitals' 340B benefit comes from 340B drugs dispensed through these contract pharmacy arrangements. Critical access hospitals (small hospitals in rural areas) report that an average of 52 percent of their benefit

[9] *See* 42 U.S.C. § 256b(a); 42 C.F.R. § 10.10.

[10] 42 U.S.C. § 1396r-8(c)(2)(A).

[11] 82 Fed Reg. 1210, 1215 (Jan 5, 2017).

comes from drugs distributed through contract pharmacies.[12] 340B providers use their 340B benefit to provide services to underserved populations in their communities.[13]

B. Appellees' Unlawful 340B Contract Pharmacy Policies

For decades, drug manufacturers have provided 340B discounts no matter how the drugs were dispensed, but starting in 2020, in the midst of a devastating pandemic, Appellees and fourteen other major drug companies substantially cut the 340B benefit to certain public and not-for-profit hospitals.[14] The Novartis policy limits hospital covered entities to use contract pharmacies that are located within a 40-mile radius of the main hospital facility. Novartis says that it will consider exemptions,[15] and although at least two exemptions were sought, *Amici* are not aware of any that have been granted. The United Therapeutics (UT) policy offers

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[12] 340B Health, *Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients* (340B Health Survey) 4, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf.

[13] *See, e.g.*, Ryan P. Knox et al., *Risks to the 340B Drug Pricing Program Related to Manufacturer Restrictions on Drug Availability*, JAMA (Apr. 15, 2022), https://jamanetwork.com/journals/jama/article-abstract/2791334 ("Since its enactment, the 340B program has been extremely successful for 340B centers, which have used revenue from 340B drugs to fund uncompensated care, expand service offerings, and offer free or low-cost drugs to patients.")

[14] *See, e.g.*, Maya Goldman, *Hospital groups worry as more drugmakers limit 340B discounts*, Modern Healthcare (Mar. 25, 2022), https://www.modernhealthcare.com/safety-net-hospitals/hospitals-worry-more-drugmakers-limit-340b-discounts.

[15] JA343.

discounts only on purchases to be shipped to contract pharmacies that the covered entity used to make a valid 340B purchase during the first three quarters of calendar year 2020. Covered entities that have neither a contract pharmacy which fits that condition, nor an in-house pharmacy are permitted to designate a single contract pharmacy. All covered entities using contract pharmacies must provide claims data to UT in order to receive 340B discounts.[16]

The contract pharmacy arrangements Appellees and others are refusing to honor have existed since the beginning of the program. When a 340B provider uses a contract pharmacy outside its premises, it orders and pays for the drugs, which are shipped directly to the contract pharmacy to be dispensed or to replenish drugs that have been dispensed. The pharmacy receives a fee for this service.[17]

Some providers use a "separate inventory" model, but most use a "replenishment inventory" model. For the separate inventory model, 340B drugs are kept in stock, separate from non-340B drugs. For the replenishment model, when filling prescriptions for the provider's patients, the pharmacy uses its own stock, and the provider purchases replacement drugs at the discounted 340B price to replenish

[16] JA803.

[17] The fee generally ranges between $6 and $15 per prescription, though it can be as low as $0, and can occasionally be higher for more expensive drugs. *See Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, Report to Congressional Requesters 26 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf.

the pharmacy's stock. The pharmacy then remits to the 340B provider the payments the pharmacy received less a dispensing fee, thus ensuring that the provider receives the benefit of the 340B discount.

These arrangements are typically done using a computerized tracking system following rules designed to ensure that only eligible patients of 340B providers are receiving drugs for which the provider receives the 340B discount.[18] Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the contract pharmacy. Appellees have ceased or placed restrictions on 340B discounts to certain 340B covered entities for drugs distributed under either model.

On May 17, 2021, the Department of Health and Human Service (HHS) sent letters to Appellees and four others (the Violation Letters) finding that the companies' refusals to provide 340B discounts for drugs dispensed through contract pharmacies is unlawful.[19] Appellees challenged the Violation Letters.

SUMMARY OF ARUMENT

The district court did not rule that Novartis' and UT's policies are permitted by the 340B statute, as the manufacturers requested. Instead, it granted what it characterized as "narrow relief" and "set aside" the Violation Letters on the ground

[18] *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx.

[19] JA 596–97.

that the letters incorrectly stated that the 340B statute does not permit manufacturers to impose additional requirements on the purchase of 340B drugs.[20]

The district court's decision should be reversed. The Violation Letters correctly concluded that Novartis' and UT's contract pharmacy policies are unlawful. The "purchased by" language in the statute requires drug manufacturers to provide discounts on 340B drugs purchased by covered entities and dispensed by contract pharmacies without imposing conditions restrictions.

ARGUMENT

A. The 340B Statute Requires Drug Manufacturers to Provide Discounts on 340B Drugs Purchased by Covered Entities and Dispensed by Contract Pharmacies, Without Imposing Conditions.

Amici agree with HHS's arguments regarding 340B statute's meaning, the agency's authority to enforce it, and the propriety of the Violation Letters, and elaborate on certain issues on which *Amici* can provide additional insights.

1. *The District Court Ignored Critical Statutory Text that Requires Drug Manufacturers to Charge Covered Entities No More Than the Ceiling Price for 340B Drugs Regardless of Where the Drugs Are Dispensed.*

The district court concluded that the statute's silence on permissible distribution systems means that the statute does not compel any particular outcome with respect to the use of contract pharmacies.[21] But the 340B statute's silence with

[20] JA410.

[21] JA403.

respect to contract pharmacies does not resolve this case. Indeed, the 340B statute is silent regarding essentially all questions of how covered entities are entitled to operate under the program. The statute does not dictate how covered entities must order drugs, how they must dispense the drugs, or what they must do with the benefit obtained from the 340B discount.

Contrary to the district court's position that the Health Resources and Services Administration's (HRSA's) policy on contract pharmacies constituted gap filling,[22] there is no "gap" in the statute that HRSA needed to fill to require drug companies to provide 340B discounts to covered entities that use contract pharmacies. Rather, the statute speaks directly to what drug manufacturers are required to do and what they are prohibited from doing. That drug manufacturers cannot deny 340B discounts to covered entities that use contract pharmacies, nor unilaterally impose conditions on the provision of 340B discounts, derives from the statute's stated requirements and prohibitions, not its silence regarding contract pharmacies.

The district court focused on the requirement in the 340B statute that drug manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price"[23] But the court wrongly concluded that UT and Novartis can

[22] *See* JA409.

[23] *See* JA403.

meet this obligation by sometimes offering covered entities the discounted price, and in the case of UT, doing so only if covered entities provide claims data that the statute does not require.[24] This position, however, ignores the statutory text that provides that "the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by a covered entity* . . . does not exceed" the ceiling price.[25] Thus, as the government argues,[26] whenever a covered entity purchases a covered outpatient drug, it is entitled to the 340B discount without restriction.

"[O]ne of the most basic interpretive canons" is that "a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant,"[27] and the district court's disregard of the 340B statute's "purchased by" provision is striking. The "purchased by" language appears *twice* in the 340B statute,[28] and in its title: "Limitation on prices of drugs *purchased by covered entities*."[29]

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[24] JA404.

[25] 42 U.S.C. § 256b(a)(1) (emphasis added).

[26] HHS Br. 25.

[27] *Corley v. United States*, 556 U.S. 303, 314 (alteration omitted) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)).

[28] 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 256b(a)(3) ("Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.").

[29] 42 U.S.C. § 256b (emphasis added).

The importance of the "purchased by" provision is further underscored by the fact that the "shall offer" provision upon which the district court relied was not added until 2010. When Congress added the "shall offer" language, it did not displace drug manufacturers' obligation to charge no more than the ceiling price for 340B drugs purchased by 340B providers. To the contrary, the provision "mostly reiterates that manufacturers cannot prioritize full-priced commercial purchases over § 340B sales."[30]

Moreover, the statute does not say "purchased *and dispensed* by" a covered entity, and the fundamental rule of statutory construction is that the unambiguous plain language of the statute controls.[31]

The 340B statute's legislative history directly supports this conclusion. Congress rejected a version of the bill that would have allowed Appellees to prevail in this case: 340B discounts would have been required *only* for on-site pharmacy services (either operated by the 340B provider or under a contractual arrangement),

[30] *See* 82 Fed. Reg. at 1225 ("Section 340B(a)(1) . . . provides that a manufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.").

[31] *DirectTV v. Pepe*, 431 F.3d 162, 168 (3d Cir. 2005); *see also United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989).

since the drugs would have had to have been "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services*."[32]

It is important that Congress eliminated both the "under a contract entered into for on-site pharmacy services" *and* the "dispensed by" language, which changed the provision to render where the 340B drug is dispensed legally irrelevant—all that matters is that the drug be "purchased by a covered entity."[33] Had Congress intended for the 340B program to be as limited as Appellees suggested in district court, it would have said so explicitly and would not have *rejected* language in 1992 doing just that. It is not surprising that Congress decided to permit dispensing by contract pharmacies since, at the time the bill was passed, less than five percent of 340B providers had on-site dispensing services.[34]

That drug manufacturers may not charge more than the ceiling price for 340B drugs purchased by covered entities is the core requirement of the statute and program, and the central question in this case is whether the drugs subject to Appellees' policies are "purchased by" covered entities. They are.

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[32] S. Rep. No. 102-259, at 2 (1992 (emphasis added).

[33] 42 U.S.C. § 256b(a)(1).

[34] *See* 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

2. *Appellees' Policies Result in 340B Providers Being Charged More than the Ceiling Price for Covered Drugs, in Violation of the 340B Statute.*

Regardless of the distribution model employed—"replenishment" or "separate inventory"—contract pharmacies never purchase 340B drugs. Rather, covered entities purchase the drugs and directs them to be *shipped* to the contract pharmacy. Thus, Appellees' policies unlawfully result in drug companies charging more than the 340B ceiling price for drugs purchased by certain 340B providers.

HHS's Violation Letters appropriately reached the conclusion—after examining an extensive record, including thousands of pages of complaints from covered entities[35]—that Novartis's and UT's policies have resulted in (and are continuing to result in) covered entities being charged more than the ceiling price for 340B drugs the covered entities purchased from the drug manufacturers, in violation of the 340B statute.

B. The Restrictions and Conditions Set Forth in Novartis' and UT's Contract Pharmacy Policies Violate the 340B Statute.

Drug manufacturers may not add their own requirements to the 340B statute. Novartis' policy prohibits 340B hospitals from using contract pharmacies that are more than 40 miles away. UT's policy limits all covered entities to either contract pharmacies that had been in use for its products during the first three quarters of

[35] *See* HHS Br. 19.

calendar year 2020 or, if none, to one contract pharmacy—but in either case requires covered entities using contract pharmacies to provide claims data to obtain discounts. These types of restrictions and conditions are absent from the statute and undermine the operation of the 340B program and Congress's intent.

1. *The 340B Statute Does Not Allow Drug Companies to Unilaterally Impose Restrictions or Conditions on Their "Offer" of 340B Discounts.*

The Novartis and UT policies ignore the statute's central requirement that drug manufacturers charge no more than the 340B ceiling price when covered entities purchase 340B drugs, including when they are dispensed from a contract pharmacy, no matter its distance from the entity or whether it has been used before and even if the 340B covered entity refuses to provide sensitive data to which a drug company is not entitled. There is no authority for Appellees' position that they may unilaterally impose whatever additional restrictions or conditions they chose.

Consistent with HRSA's longstanding position, drug manufacturers may require the 340B covered entity to comply with certain standard business practices that are required of all other drug purchasers.[36] From the very beginning of the program, however, HRSA distinguished manufacturer requirements that facilitate

[36] 59 Fed. Reg. 25,110, 25,114 (May 13, 1994).

access from those that restrict access.[37] Thus, manufacturers can "require the covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account) if this is the usual business practice of the manufacturer,"[38] but "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" or "place limitations on the transactions . . . which would have the effect of discouraging entities from participating in the discount program."[39] Nothing in the 340B statute permits Novartis and UT to impose the restrictions and conditions they have adopted.

Since 2010 and until recently, manufacturers had not restricted covered entities' use of contract pharmacies.[40] And covered entities were not required to provide the highly sensitive information for drug claims that UT now seeks.[41] The

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[37] *See e.g.*, Defs.' Combined Mem. Pts. & Auths. Opp'n Pl.'s Mot. Summ. J. & Supp. Defs.' Mot. Summ. J., ECF No. 16-1, at 28–29, *United Therapeutics Corp. v. Espinosa*, Case No. 1:21-cv-01686-DLF (D.D.C. Aug. 10. 2021).

[38] 59 Fed. Reg. at 25,112.

[39] *Id.* at 25,113.

[40] That HRSA issued guidance in 1996 that stated that covered entities may use just one contract pharmacy is irrelevant. *See* 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996). In that guidance, HRSA likely acted outside of its delegated authority, as nothing in the 340B statute limits how covered entities may dispense 340B drugs. *See also* HHS Br. 38 ("Nor has Congress authorized HHS to restrict covered entities' contract-pharmacy arrangements.").

[41] *See* JA803–04.

Novartis and UT restrictions undermine the purpose of the 340B program by limiting its application. Likewise, UT's conditions undermine the purpose of the program because, as discussed in subsection C below, they impose a significant burden on 340B providers not permitted by Congress, and they discourage participation in the program.

2. *The Program Integrity Concerns that Novartis and UT Argue Support Their Unlawful Polices are Unfounded and Do Not Render Their Policies Lawful.*

As further described in subsection C(2) below, the limit on the number of contract pharmacies by both Novartis and UT and the UT claims data requirement are nothing more than attempts to maximize the drug manufacturers' profits at the expense of 340B providers and their patients. Neither company has offered a single reason why these restrictions, or in the case of UT its claims data requirements, are necessary to make their participation in the 340B program possible, and indeed, they are not, as both companies participated in the 340B program for decades without restrictions or conditions. Rather, both assert that their new policies grow out of program integrity concerns.

Appellees claim that their new policies are intended to prevent the diversion of drugs and duplicative discounts that the 340B statute itself prohibits.[42] But

[42] JA222, JA808–09.

Congress specified how diversion and duplicate discounts should be addressed in the 340B statute.

Moreover, a recent GAO report indicated that between 2012 and 2019, *only 23* of the 429 duplicate discount audit findings related to contract pharmacies.[43] And state and federal laws effectively limit the use of 340B for Medicaid for most 340B hospitals.[44] In fact, 82 percent of 340B hospitals with contract pharmacies report that they do not use contract pharmacies to dispense 340B drugs to Medicaid managed care patients, and only 80 of the 31,000 contract pharmacies used by covered entities involve the use of 340B drugs for Medicaid fee-for-service patients.[45] Also, contrary to manufacturers' assertions, hospitals' use of contract pharmacy is not accompanied by widespread diversion in the 340B program. In fiscal years 2019, 2020, and 2021 HRSA has conducted nearly 500 audits of 340B hospitals, and 95% of those audits did not identify any instances of diversion related to a contract pharmacy.[46] These

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[43] *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, Report to Congressional Committees 14 (Table 1) (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

[44] *See, e.g.*, Kathleen Gifford et al., *How State Medicaid Programs are Managing Prescription Drug Costs: Results from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, Kaiser Family Found. (Apr. 29, 2020), https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-state-strategies-to-manage-340b-programs/.

[45] 340B Health Survey, *supra* note 14, at 8.

[46] https://www.hrsa.gov/opa/program-integrity/index.html; https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results;

result hardly support manufacturer arguments that pervasive diversion of 340B drugs necessitates their placing restrictions on contract pharmacy arrangements.

Even if Appellees had legitimate program integrity concerns, Congress gave them statutory tools to address such concerns, providing authority for manufacturers to audit covered entities.[47] If after an audit and a hearing, the HHS Secretary (not the manufacturer) finds that the covered entity has violated the prohibition on diversion or duplicate discounts, the covered entity must refund the manufacturer.[48] Congress therefore recognized that duplicate discounts in the 340B program could be a problem and specifically addressed the issue; to protect 340B providers from the potentially onerous burdens that giving unlimited audit authority to manufacturers would have permitted (which is precisely what UT seeks with its contract pharmacy policy), Congress required that audits be done in accordance with guidance from

https://www.hrsa.gov/opa/program-integrity/audit-results/fy-20-results; https://www.hrsa.gov/opa/program-integrity/audit-results/fy-21-results.

[47] 42 U.S.C. § 256b(a)(5)(C); *see also id.* 42 U.S.C. § 256b(d)(2). The statute also provides for an administrative process for the resolution of claims by manufacturers, after the conduct of such audits, of violations of the prohibition on diversion and duplicate discounts. Thus, the regulatory scheme that Congress created involves audits and dispute resolution – not unilateral self-help by drug manufacturers. Courts are required to interpret the statute to create a symmetrical and coherent regulatory scheme. *Gustafason v. Alloyd Co.*, 513 U.S. 561. 569 (1995).

[48] 42 U.S.C. § 256b(a)(5)(D); *see also* Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406 (Dec. 12, 1996).

HHS. To the extent Appellants believe Congress's regulatory structure is insufficient, they must address the issue with Congress.

C. Novartis' and UT's Policies Undercut the Purpose of the 340B Program.

The district court found that the parties had "not adequately argued their respective positions on Section 340B's structure" and on that basis declined to decide whether 340B permits or prohibits any of the specific conditions at issue here.[49] The court noted that the answer "likely turn[s], for example, on the mechanics of how audits work and the degree to which the manufacturer conditions at issue here undermine the operation of the 340B program."[50] The district court was wrong in failing to find that the restrictions and conditions being imposed by Novartis and UT are unlawful under the terms of the 340B statute. Moreover, the drug companies' restrictions and conditions clearly undermine the operation of the 340B program.

1. *Contract Pharmacy Arrangements Greatly Benefit 340B Providers and Patients.*

The use of contract pharmacies benefits covered entities and their patients. While the increased use of contract pharmacies has not expanded the number of patients eligible for discounted drugs, it has expanded 340B providers' patients'

[49] JA408.

[50] JA408 n.6.

access to those drugs. Such patients, who may live very far from the provider,[51] benefit when their usual, local pharmacy can dispense their 340B drugs; for example, the patients are more likely to fill their prescriptions and pharmacists can more easily manage drug interactions.

Even though contract pharmacies generally recoup a modest fee for dispensing drugs to covered entities' patients,[52] the *covered entity* is the one *purchasing* the 340B drug from the drug manufacturer and is thus still receiving the 340B benefit by receiving a discount from the manufacturer and reimbursement from the patient or third-party payer, which the contract pharmacy passes through to the covered entity. The covered entity in turn can use the benefit to increase services and programming for underserved populations, as Congress intended.

It is this added benefit that permits 340B hospitals to provide substantial community benefits. Indeed "[h]ospitals provided nearly $42 billion in uncompensated care in 2019, of which 340B hospitals roughly made up 68% of that number."[53] In 2017, 340B hospitals participating in 340B provided $64.3 billion in

[51] *See, e.g.*, HHS Br. 18 (citing examples).

[52] *See supra* note 30.

[53] Am. Hosp. Ass'n, *supra* note 5, at 2.

total benefits to their communities, including uncompensated care.[54] Total community benefit provisions by 340B hospitals increased to $68 billion in 2018, accounting for almost 14 percent of the hospitals' total expenses.[55]

Finally, more than half of 340B hospitals report they do not operate in-house retail pharmacies, and only one in five have their own specialty pharmacy,[56] which many payers require the use of for dispensing specialty drugs.[57] This is one more way that contract pharmacies are a necessary and beneficial component of the 340B program.

2. *The Novartis and UT Policies are Designed to Maximize Profits at the Expense of 340B Providers and Patients.*

Appellees are among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits.[58] These companies agree to participate in 340B only because they *must* do so to participate in Medicaid and

[54] Am. Hosp. Ass'n, *340B Hospital Community Benefit Analysis* 2 (Sept. 2020), https://www.aha.org/system/files/media/file/2020/09/340b-community-benefits-analysis-report.pdf.

[55] Am. Hosp. Ass'n, *340B Hospital Community Benefit Analysis* 2 (Sept. 2021), https://www.aha.org/system/files/media/file/2021/09/340b-community-benefits-analysis-0921.pdf.

[56] 340B Health Survey, *supra* note 14, at 4.

[57] *See infra* note 66.

[58] Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared with Other Large Public Companies*, 323(9) J. Am. Med. Ass'n 834–43 (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308.

Medicare Part B. The larger the 340B program—*i.e.*, the more discounts the drug companies must provide to covered entities—the lower their profits. Having been unable to convince Congress to limit a program they do not like, the drug companies began taking unilateral action to curb the 340B program. Two specific data points further demonstrate the profit motive driving Appellees' policies.

(a) *Drug Manufacturers Are Using Unlawful Contract Pharmacy Policies to Skirt Congress's Inflationary Penalty.*

Drug manufacturers, including Appellees, are using their contract pharmacy policies to avoid having to pay congressionally imposed penalties they otherwise would (and should) face. As explained above, Congress sought to minimize skyrocketing drug prices by creating a scheme in which drug companies pay a penalty when they increase prices on drugs covered by 340B and/or Medicaid above the rate of inflation. Research has demonstrated that this inflationary penalty against price increases slows price increases for drugs sold to all purchasers, not just 340B providers.[59]

[59] Sean Dickson, *Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases*, JAMA (Sept. 11, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540#:~:text=Conclusions%20and%20Relevance%20In%20this,and%20decrease%20overall%20drug%20spending; *see also* Sean Dickson & Ian Reynolds, *Estimated Changes in Manufacturer and Health Care Organization Revenue Following List Price Reductions for Hepatitis C Treatments*, JAMA (July 2019), https://pubmed.ncbi.nlm.nih.gov/31276176/.

Appellees and other drug manufacturers should not be permitted to avoid this inflationary penalty by developing policies that allow them to deny 340B discounts to covered entities altogether. Yet the companies' contract pharmacy policies do just that.[60] For Novartis, 22 percent of the 340B discounts for hospitals come from nominally-priced drugs.[61] Reducing the share of these drugs subject to the inflationary penalties greatly reduces the effectiveness of Congress's scheme by undermining the 340B statute's use of the inflationary penalty to exert pressure on drug companies to limit drug price increases.[62]

(b) *Drug Manufacturers Are Using Unlawful Contract Pharmacy Policies to Avoid Providing Discounts on Specialty Drugs.*

Appellees are also using their contract pharmacy policies to avoid having to provide 340B discounts on expensive "specialty" drugs. 340B providers' increased use of contract pharmacies reflects, in part, a major shift in the market toward high-priced specialty drugs[63] for which many payers require the use of specific specialty

[60] Data based on 340B Health analysis of the difference in cost for hospitals under 340B accounts and non-340B accounts (*i.e.*, hospital group purchasing accounts) based on 2020 340B sales volume for restricted drugs. The volume estimates include drugs dispensed at contract pharmacy and non-contract pharmacy hospital settings. *See also* 340B Health Survey, *supra* note 11, at 3.

[61] *Id.*

[62] *See* 82 Fed. Reg. at 1229.

[63] *See* IQVIA, *The Use of Medicines in the U.S., Spending and Usage Trends and Outlook to 2025* (May 27, 2021), https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us.

pharmacies.[64] Specialty drugs are typically used to treat chronic, serious, or life-threatening conditions, and are generally priced much higher than traditional drugs.[65] Patients cannot obtain most specialty drugs at retail pharmacies. Specialty pharmacies are generally mail-order [66]and are widely dispersed across the country.[67] Nearly *three-quarters* of the total 340B discount associated with the drugs of the 16 manufacturers with policies came from drugs that appear on at least one list of specialty drugs across the four largest specialty pharmacy companies.[68] For Novartis, 88% of the 340B discount associated with Novartis drugs comes from drugs that are on the specialty list for at least one specialty pharmacy and for UT it is 100%.[69] Eighty-six percent of 340B hospitals recently surveyed reported that most

[64] Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html..

[65] Specialty Drug Coverage and Reimbursement in Medicaid, HHS OIG, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[66] GoodRX, Specialty Pharmacy and Specialty Medications: What You Should Know https://www.goodrx.com/healthcare-access/pharmacies/specialty-pharmacy-and-specialty-medications-what-you-should-know.

[67] HRSA Office of Pharmacy Affairs, OPAIS. https://340bopais.hrsa.gov/.

[68] 340B Health Survey, *supra* note 21, at 6.

[69] *Id.* at 7.

of their specialty pharmacy arrangements are outside of a 40-mile radius (the restriction that Novartis is imposing).[70]

The vast majority of 340B hospitals do not operate their own specialty pharmacies capable of dispensing these drugs, and even when they do, those pharmacies are not able to serve all patients, as Pharmacy Benefit Managers (PBMs) and payers have placed restrictions on how specialty drugs may be purchased, often requiring patients to obtain specialty medicines through their own specialty pharmacy networks that frequently exclude hospital specialty pharmacies.[71] In order to have access to specialty drugs at the 340B price for patients restricted to different PBM/Payer specialty pharmacy networks, 340B hospitals must have a contract with each of them.[72] Additionally, almost 85 percent of drug manufacturers manage some or all of their products through a limited-distribution network where they tightly control which specialty pharmacies can dispense certain drugs. These networks also

[70] *Id.*

[71] For example, one benefit guide states, "For specialty medicines . . . you must use Accredo, the Express Scripts specialty pharmacy." Your Pharmacy Benefits Handbook, Express Scripts, 5, https://www.express-scripts.com/art/open_enrollment/FCPS_MemberHandbook.pdf; *see also* Adam J. Fein, *supra* note 89. 340B Health Survey, *supra* note 11, at 7.

[72] Your Pharmacy Benefits Handbook, Express Scripts, 5, https://www.express-scripts.com/art/open_enrollment/FCPS_MemberHandbook.pdf.

often exclude 340B hospitals.[73] Thus, to have access to specialty drugs at 340B prices for specific patients, 340B hospitals *must* contract with one or more specialty contract pharmacies, and by limiting 340B providers' ability to use such specialty contract pharmacies, Appellees' policies undermine the 340B program.

(c) *Policies Conditioning 340B Discounts on the Indefinite Provision of Extensive, Sensitive Claims Data Are Also Unlawful.*

Contract pharmacy policies like UT's further undermine the 340B program by requiring certain 340B providers to limit the use of contract pharmacies or expend limited resources submitting sensitive claims data as a condition to receiving the 340B discounts to which they are entitled. Neither the 340B statute nor any other federal law authorizes manufacturers to coerce 340B providers to assist them in enforcing their voluntary agreements with commercial payors or PBMs or when manufacturers owe commercial rebates.

3. *The Novartis and UT Policies Undermine the Operation of the 340B Program.*

340B providers are increasingly feeling the harmful impact of drug manufacturers' policies.[74] Between December 2021 and March 2022, during which

[73]2019 State of Specialty Pharmacy Report, CSI Specialty Group, 6, https://academynet.com/sites/default/files/csi2019spreport.pdf.

[74] *E.g.*, Knox et al., *supra* note 22 ("A survey of 510 340B centers conducted in late 2021 found that disproportionate share hospitals, rural referral centers, and sole community hospitals had lost on average 23% of their contract pharmacy revenue because of manufacturers' restrictions, while critical access hospitals had lost on

time the number of manufacturers imposing restrictions increased from eight to 14, the financial impact on 340B hospitals using contract pharmacies more than doubled.[75] The median annualized impact on Disproportionate Share Hospitals, Rural Referral Centers, and Sole Community Hospitals went from $1.0 million to $2.2 million, and 10 percent of those hospitals expect annual losses of $21 million or more.[76]

More than three quarters of 340B hospitals analyzed in a recent survey reported that they will need to make cuts or adjustments to programs if the drug manufacturers' restrictions become permanent. A third of critical access hospitals report that the loss of revenue due to these restrictions puts their hospitals at risk of closure.[77]

UT's policy of requiring 340B hospitals to submit sensitive data imposes additional onerous burdens on 340B providers. On top of imposing logistical

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average 39%."); Gina Shaw, *Manufacturers' 340B Restrictions On Contract Pharmacies Draw Ire*, Pharmacy Practice News (May 10, 2021), https://www.pharmacypracticenews.com/Article/PrintArticle?articleID=63395 (contract-pharmacy policies are "having unintended consequences, including compromised patient care" and "[m]any individuals with diabetes, for example, are having to pay steep price increases for their insulin or switch to less expensive—and potentially less effective—products").

[75] 340B Health Survey, *supra* note 21, at 3.

[76] *Id.*

[77] *Id.* at 5.

burdens, complying with UT's policy does not necessarily result in receiving 340B discounts.

UT's policy requires that 340B hospitals submit data on 340B contract pharmacy claims to Second Sight Solution's 340B ESP data platform for UT's drugs.[78] The platform, however, has more than 800 national drug codes (NDCs) listed as being subject to manufacturer restrictions requiring submission of data.[79] UT is just one of at least 10 companies conditioning the provision of 340B discounts on claims data submission. The specific claim elements that 340B ESP requires include the prescription number, the prescribed date, the fill date, the NDC, the quantity, the pharmacy ID, and 340B covered entity ID.[80]

To submit these data, hospitals must obtain the data elements relating to all their contract pharmacy claims that include these 800 NDCs. Prior to launching a contract pharmacy arrangement, the hospital contracts with a third-party administrator (TPA) to assist with managing the contract pharmacy arrangement. To get the data it needs, the hospital must go to the portal for each TPA and download claims information for all of the contract pharmacies covered by each TPA. TPAs

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[78] *E.g.*, JA803–810.

[79] 340B ESP, *What NDCs do we look for?*, https://help.340besp.com/en/articles/4455011-what-ndcs-do-we-look-for.

[80] *See* 340B ESP, *Submitting your 340B claims through 340B ESP*, https://help.340besp.com/en/articles/4323537-submitting-your-340b-claims-through-340b-esp.

all have different systems, and all generate reports with vastly more information than is needed for 340B ESP. Hospitals download the information into a spreadsheet, then manually review it to remove information related to nonrestricted NDCs and data elements that 340B ESP does not request. This can involve manually reviewing and editing information related to thousands of claims.

This process needs to be completed biweekly, but it can take days to obtain the data from the TPA(s) and to edit and submit the data to 340B ESP. As a result, hospitals using the replenishment model do not always receive the 340B price on those drugs, even when they attempt to report the requested data.[81] Thus, not only are 340B hospitals not receiving the 340B discount to which they are entitled, they are paying *more* than the higher drug price because of the administrative costs associated with complying with UT's policy and the fees owed to the contract pharmacies to dispense the drugs. 340B hospitals spend a significant amount of time identifying why purchases were not processed at the 340B price and seeking refunds via the credit/rebill process. Even then, the refunds are not always granted, and many hospitals have reported having to hire additional staff just to handle issues associated

[81] *See* Letter from Maureen Testoni, President & CEO, 340B Health, to Xavier Becerra, Secretary of Health and Human Services, HHS, & Carole Johnson, Administrator, HRSA (May 10, 2022), https://www.340bhealth.org/files/340B-Health-Letter-to-HHS-on-Burdens-of-Manufacturer-Claims-Data-Conditions-5.10.22.pdf.

with collecting and submitting data, as well as correcting improperly withheld discounts.

The burden of complying with these increasingly numerous policies demonstrates why *Congress's* solution for addressing concerns of fraud in the 340B program—allowing manufacturers to audit covered entities "in accordance with procedures established by [HHS]"[82]—is the proper one.

As a final note, that UT's policy allows 340B providers to use "a single, designated contract pharmacy, if the covered entity has no in-house pharmacy,"[83] still imposes an impermissible burden on 340B hospitals that undermines the purpose of the 340B program. Ninety percent of hospitals with specialty contract pharmacies reported in a recent survey that such restrictions are limiting their ability to purchase specialty drugs at the 340B price.[84]

CONCLUSION

For the foregoing reasons, and for those outlined in HHS's brief, the district court's order should be reversed, and the case should be remanded with instructions to grant summary judgment in favor of HHS.

[82] 42 U.S.C. § 256b(a)(5)(C); *see also id.* § 256b(d)(2).

[83] JA809.

[84] 340B Survey, *supra* note 11, at 7.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) and the rules of this Court, because it contains 6,498 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 with 14-point Times New Roman font.

/s/ William B. Schultz
William B. Schultz

CERTIFICATE OF SERVICE

I certify that on May 16, 2022, I caused a copy of this Brief of American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and Children's Hospital Association as *Amici Curiae* in Support of Appellants to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

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