[ORAL ARGUMENT NOT YET SCHEDULED]
No. 21-5304

In the United States Court of Appeals for the District of Columbia Circuit

UNITED THERAPEUTICS CORP., *Plaintiff-Appellee*,

v.

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

On Appeal from the United States District Court
for the District of Columbia, No. 1:21-cv-01686-DLF (Hon. Dabney L. Friedrich)

BRIEF OF *AMICUS CURIAE* JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC. IN SUPPORT OF UNITED THERAPEUTICS CORP. AND AFFIRMANCE

GABRIELA ILLA
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
Telephone: (312) 853-7000

WILLIAM A. SARRAILLE
Counsel of Record
CHRISTOPHER S. ROSS
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

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Counsel for Amicus Curiae

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), amicus curiae Johnson & Johnson Health Care Systems, Inc. certifies the following information regarding the parties, rulings and related cases in this appeal.

Parties and Amici. All parties and amici appearing before the district court are as stated in the Opening Brief of the Federal Defendants.

In this Court, all parties are as stated in the Opening Brief of the Federal Defendants. The amici curiae in this Court thus far are as identified in the brief filed by Plaintiff-Appellee United Therapeutics Corporation. JJHCS files this brief as amicus curiae in support of United Therapeutics.

Ruling Under Review. References to the ruling at issue appears in the Opening Brief of the Federal Defendants.

Related Cases. The Federal Defendants and Plaintiff United Therapeutics Corporation identify the related cases.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1(a), Johnson & Johnson Health Care Systems, Inc. ("JJHCS") states that JJHCS is wholly owned by Johnson & Johnson, a publicly traded corporation.

Pursuant to D.C. Circuit Rule 26.1(b), JJHCS states that it provides contracting, supply chain, and business support services to other Johnson & Johnson companies and has developed and implemented a policy that is similar to United Therapeutics Corporation's policy at issue in this case.

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GLOSSARY

340B program/ 340B statute	Section 340B of the Public Health Services Act (42 U.S.C. § 256b)
GAO	Government Accountability Office
HHS	Defendants-Appellant United States Department of Health and Human Services
HRSA	Defendants-Appellant Health Resources & Services Administration
JJHCS	Amicus Curiae Johnson & Johnson Health Care Systems Inc.
MDRP	Medicaid Drug Rebate Program
OIG	Office of Inspector General
UT	Plaintiff-Appellee United Therapeutics Corp.

INTEREST OF AMICUS CURIAE AND SUMMARY OF ARGUMENT[1]

Johnson & Johnson Health Care Systems, Inc. ("JJHCS") provides contracting, supply chain, and business support to Johnson & Johnson, the world's most comprehensive manufacturer of health care products for the pharmaceutical, biotechnology, and medical device markets. As a pharmaceutical manufacturer, JJHCS is committed to the 340B program, and is proud to participate in it. JJHCS seeks only to have it operate in a manner that protects against duplicate discounting and diversion, as promised by the 340B statute.

Given the billions of dollars JJHCS provides to 340B covered entities and contract pharmacies each year, JJHCS has been deeply disappointed (1) so little of those funds are actually used to reduce patient co-

[1] No party's counsel authored this brief in whole or in part, and no party, its counsel, or any other person—other than JJHCS or its counsel—contributed money intended to fund preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). The Federal Defendants and United Therapeutics Corporation have consented to the filing of this amicus brief. Johnson & Johnson is a member of the Pharmaceutical Research and Manufacturers of America, which, JJHCS understands, is also filing an amicus brief in this case. JJHCS did not participate in the filing of that separate brief.

payments at the pharmacy counter,[2] (2) how many of those dollars are paid to large for-profit, commercial pharmacies,[3] and (3) by covered entities' and the government's systematic failure to address widespread duplicate discounts and diversion.[4] After years of trying (unsuccessfully) to reduce duplicate discounts and diversion in other ways, JJHCS has now implemented a policy that generally requires all customers—whether 340B covered entities or not—to receive the product they order at a location that is part of that ordering entity.

Notwithstanding that policy, JJHCS permits covered entities to benefit from a series of broad exceptions to its policy that expansively

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[2] *See* Gov't Accountability Office ["GAO"], *Drug Discount Program; Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 31, (June 2018), https://www.gao.gov/assets/700/692697.pdf; OIG, HHS, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[3] *See, e.g.*, Ltr. from Adam J. Fein, Drug Channels Inst., to Hon. Lamar Alexander & Hon. Greg Walden, at 1–2 (Oct. 30, 2020), http://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf (noting that "there is … zero transparency around the profits earned by billion-dollar public companies that dominate 340B pharmacy networks…and that occur at the expense of needy and uninsured patients").

[4] *See infra* at 9–14.

support contract pharmacy deliveries.[5] For instance, all covered entities that receive a grant from HRSA may use an unlimited number of contract pharmacies for an unlimited number of transactions. For hospitals that are covered entities, another exception permits those covered entities to use an unlimited number of contract pharmacies for an unlimited number of transactions, if they choose to provide limited claims data that can be used to identify and reduce duplicate discounts and diversion.

As the government has repeatedly acknowledged, contract pharmacies result in diversion and duplicate discounting. For over a decade, JJHCS and other manufacturers have tried repeatedly to address these rampant problems. But these efforts have not resulted in meaningful changes, because covered entities often refuse to cooperate or make repayments, even when they admit to statutory violations;[6] HRSA tolerates this, leaving manufacturers without the protections promised by the statute.[7]

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[5] *See infra* 14–16.

[6] *See infra* 13.

[7] *See infra* 11.

JJHCS submits this amicus brief in support of affirming the district court's judgment. JJHCS' policy is similar in a number of respects to the UT policy at issue here. Because the Court's decision could affect JJHCS' policy, JJHCS offers additional background on the 340B statute and its history, and it writes to correct several misstatements in the government's and Amici's briefs.

Although the government contends—without offering any factual support—that the 340B program was intended to be "broad," the history of the 340B program demonstrates that it had a modest, narrow purpose. In trying to argue for its ahistorical vision of the scope of the 340B program, the government asserts—repeatedly—that contract pharmacies have been used "since the inception" of the 340B program. *E.g.*, Gov't Br. at 25.

The government is incorrect about the origins and history of the program.[8] In enacting the 340B program, Congress intended only to restore drug discounts to a select group of providers of direct care to the nation's poor that had received voluntary discounts from JJHCS and

[8] *See infra* 6–9.

other manufacturers until Congress passed the Medicaid Drug Rebate Program ("MDRP") in 1990. Unfortunately, because Congress did not shield these discounts from setting punishingly high Medicaid rebates, the MDRP prevented manufacturers from continuing to offer these discounts. The 340B statute restored those discounts, which had only been offered to safety-net providers with their own in-house pharmacies.

Contract pharmacies were not used by covered entities at the beginning of the 340B program. Despite the government's unsupported suggestion to the contrary, it was only **after** the 340B statute had been passed and was already implemented that a few covered entities and HRSA developed the concept of contract pharmacies in a concerted effort to expand the 340B program beyond its original, narrow purpose.[9] HRSA and covered entities then, over a period of 20 years, broadly expanded even that concept—all without any statutory basis.

Particularly given the broken nature of HRSA's program oversight, the District Court was correct to hold that the statute does not prohibit manufacturers from imposing reasonable non-price conditions on their

[9] *See infra* 18–23.

340B price offers. Conditions, like limited claims data requirements, further the statutory purposes of controlling duplicate discounts and diversion, while providing covered entities with an opportunity to engage an unlimited number of contract pharmacies. Further, the government's and its Amici's arguments of covered entity and patient harm are belied by the broad access offered under a claims data policy. Finally, despite the government's contentions to the contrary, the data requested is readily available, and data is required widely in the 340B program and throughout the entire health care system.

BACKGROUND

I. 340B PROGRAM HISTORY

Congress enacted the 340B program in 1992 to address an "unintended consequence" resulting from the enactment of the MDRP in 1990. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision*, 22 J. Health Care L. & Pol'y 25, 30 (2019). Before the MDRP, manufacturers "regularly offered discounts to … hospitals and other safety-net providers" on a voluntary basis. *Id.* at 29. These historic discounts did not involve "contract pharmacies," and there is no evidence in the administrative record that they did. *Id.* (referencing "discounts **to**…hospitals and other safety-net providers") (emphasis added).

Because the MDRP included a new requirement for manufacturers to report their "Best Price" to calculate Medicaid drug rebates, without excluding these voluntary discounts, *see id.* at 30, those discounts resulted almost overnight in significantly higher rebates. This so penalized manufacturers, they could no longer offer the discount. *See id.* at 29.

In response, Congress sought to remedy this specific pricing problem through the 340B program. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967. When enacted, the 340B program restored the discounts that manufacturers had previously extended directly to Federally-funded clinics and public hospitals that "serve large numbers of low-income and uninsured patients." H.R. Rep. No. 102-384, pt. 2 ("House Report"), at 10–12 (1992). The covered entities that received outpatient drugs at discounted prices were the same entities that previously received voluntary discounts. *See id.* When Congress created the 340B program, it amended the MDRP to exclude those substantial discounts from the "Best Price." 106 Stat. at 4962 (excluding "prices charged … **to** a … covered entity") (emphasis added) (codified at 42 U.S.C. § 1396r-8(c)(1)(C)).

Because there was concern that the substantial 340B discounts would inevitably lead to diversion, the statute specifically limited access to the restored discounts to enumerated "covered entities" and declared that any "transfer" of discounted product by a covered entity to anyone, other than a patient of the covered entity, was prohibited. *See* 42 U.S.C. § 256b(a)(5)(B). The statute's legislative history reinforces that Congress only intended to safeguard the availability of discounts to Federally-funded clinics and public hospitals "that provide ***direct clinical care*** to large numbers of uninsured Americans." *See* House Report at 12 (emphasis added).[10] In other words, Congress wanted to ensure that the entities providing "direct clinical care" and their patients would have access to the discounts—but no one else.

[10] As the Committee report explained, "[t]he Committee expect[ed] that this exemption [from the Best Price calculation] will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts ***to these*** clinics, programs, and hospitals." *See* House Report at 12 (emphasis added). "Indirect" care provided using contract pharmacies was not included anywhere in the text or the legislative history of the bill that passed.

II. THE 340B PROGRAM'S ENDEMIC PROBLEMS

Even the government concedes that the 340B program lacks adequate controls. Indeed, the government itself recognizes that the unchecked growth in contract pharmacies has increased the risk of duplicate discounts and diversion. *See, e.g.*, GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 28, GAO-11-836 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Similarly, a 2018 GAO report concluded that "[t]he **identified noncompliance** at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices." *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, *supra*, at 44 (emphasis added). GAO found that approximately two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." *Id.*

The Department of Health and Human Services' ("HHS") Office of Inspector General ("OIG") has also documented the "challenges" that "aris[e] from the widespread use of contract pharmacy arrangements."

Examining Oversight Reports on the 340B Drug Pricing Program: Testimony Before the S. Comm. on Health, Educ., Labor, & Pensions, 115th Cong. 5 (May 15, 2018) (statement of Ann Maxwell, Assistant Inspector Gen., HHS), https://oig.hhs.gov/testimony/docs/2018/maxwell-testimony05152018.pdf. OIG also reported that contract pharmacies create compliance "complications" because covered entities "did not report a method to avoid duplicate discounts." *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, *supra* n.2, at 1–2, 16.[11]

Despite a history of audits documenting covered entity and contract pharmacy violations, HRSA has largely turned a blind eye to these systemic problems. It says it cannot monitor contract pharmacies for duplicate discounts and diversion. *See* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 1,

[11] The government and Amici wave their hands at these concerns, contending that they are merely "risks," not actual problems. *E.g.*, States Amicus Br. at 12; AHA Amicus Br. at 16–19. But that is belied by the record. GAO has documented "[t]he **identified noncompliance** at contract pharmacies," and, as UT points out, over 80 percent of the audits HRSA has completed have found violations. *See* GAO, Federal Oversight of Compliance, *supra*, at 44; UT Br. at 18. J&J's own experience, further underscores the seriousness of the problem. *See infra* 12–14.

15–16 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.[12] As a consequence, HRSA found contract pharmacy violations in audits but, nevertheless, "did not issue findings for a failure to comply with guidance related to contract pharmacies." *Id.*

The enormity of the problem posed by duplicate discounts and diversion is shown by the challenges JJHCS faces. Although the 340B program was designed to restore discounts to a small number of providers, JJHCS' 340B program now is 88 percent *larger* than its MDRP program. *See* Janssen Pharms., Inc., *2021 Janssen U.S. Transparency Report* (2022).[13] Since 2016, JJHCS' 340B program has grown at a rate that is 80 percent *higher* than the increase in its Medicaid program. *See id.* at 6. For JJHCS, the 340B program is now the second-largest discount program in the country. *See id.* at 1. The challenge of trying to monitor the duplicate discount and diversion risks posed by contract pharmacies,

[12] HRSA simultaneously states that a covered entity's violation of the contract pharmacy guidance *is not* a clear statutory violation, but that a manufacturer's providing 340B pricing to an unlimited number of contract pharmacies, where some are asked only to provide limited claims data, *is* a statutory violation. There is no coherence to HRSA's position.

[13] https://transparencyreport.janssen.com/_document/the-2021-janssen-u-s-transparency-report?id=00000180-0108-dccf-a981-a52ec8300000.

without claims data, is only underscored by the fact that JJHCS, in just a recent one-year period, was asked to provide 340B discounts for more than 21,000[14] contract pharmacy locations.

An example of a large hospital covered entity with a web of contract pharmacies illustrates the breadth of the oversight challenge JJHCS faces. The covered entity, located in Florida, has listed 499 contract pharmacies, including locations in California and Arizona, almost 3,000 miles away. *See* HRSA, HHS, *Office of Pharmacy Affairs*, https://340bopais.hrsa.gov/cedetails/20962 (last visited June 14, 2022). The covered entity also listed contract pharmacies in Delaware, Indiana, and Michigan. *Id.* "Mega-networks" like these are not isolated occurrences, particularly among hospital covered entities.

JJHCS has long tried to address these problems, without success. The failure of covered entities to cooperate in responding to "good faith" inquiries and the willingness of HRSA to permit that lack of cooperation

[14] This number undercounts the contract pharmacy locations, as this analysis was undertaken without the benefit of claims data.

renders such inquiries almost useless.[15] JJHCS has also considered undertaking audits or initiating alternative dispute resolution proceedings. But, for the reasons acknowledged by the GAO, HRSA's audit requirements are hopelessly burdensome, rendering them useless as a means to address statutory violations. *See* GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212, at 26 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf. This is particularly true where JJHCS is subject to 21,000 contract pharmacy arrangements. Because the ADR process requires an audit as a prerequisite and does not even apply to claims below a stated dollar amount, it is equally unavailing. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.21(b). The futility of

[15] Some examples from JJHCS' own experiences illustrate the point:

- covered entity refused to return duplicate discounts involving four different drugs for discounts claimed from 2017 to 2020;
- contract pharmacy diversion involving transactions from 2014 to 2019 and review of 436 different invoice lines, which took 1,986 days to resolve;
- following adverse HRSA audit, covered entity asserted that duplicate discounts were the responsibility of the state Medicaid program; after 22 communications involving JJHCS, the covered entity, the state, and others, the covered entities paid an amount below the JJHCS calculated overpayment amount.

audits and ADR processes is clear because HRSA has already declared that it will not take action against contract pharmacy violations. *See HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, *supra*, at 15–16.

III. JJHCS' POLICY IS REASONABLE AND BALANCED

Given the agency's lack of oversight and JJHCS' inability to otherwise address duplicate discounts and diversion, JJHCS revised its policies for customers that place orders that are billed to the customer, but shipped to a party that is not part of the customer. These type of orders are called "Bill To/Ship To" orders. Under JJHCS' policy,[16] which is similar to UT's and applicable to all JJHCS customers—340B and non-340B alike—JJHCS will no longer ship a specified list of its products to Ship To locations that are not part of the Bill To entity, subject to certain broad exceptions benefiting covered entities.

[16] *See* Johnson & Johnson Health Care Sys., Inc., *Notice to 340B and Non-340B End Customers Regarding Bill To/Ship To Orders* (Mar. 21, 2022), https://www.340besp.com/resources.

For instance, under the applicable exceptions, grantee covered entities[17] may use an unlimited number of contract pharmacies, without providing limited claims data. Non-grantee covered entities[18] may also use an unlimited number of contract pharmacies, if they elect to provide certain limited claims data. Non-grantee covered entities that lack an in-house pharmacy and choose not to provide limited claims data may instead designate one contract pharmacy site. Further, covered entities may place Bill To/Ship To orders for wholly owned not-for-profit contract pharmacies located within the same site as their Bill To location.

In addition, several of JJHCS' pulmonary arterial hypertension drugs are distributed through specialty pharmacies under a pre-existing limited distribution program that HRSA has approved.[19] Grantee covered entities may order such drugs through a specialty pharmacy at any

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[17] Grantee Covered Entities include entities eligible to participate in the 340B Program under 42 U.S.C. § 256b(a)(4)(A)–(K).

[18] Non-grantee Covered Entities include entities eligible to participate in the 340B Program under 42 U.S.C. § 256b(a)(4)(L)–(O).

[19] *See* Actelion, *Limited Distribution Notice for Opsumit, Tracleer, Uptravi, Veletri, Ventavis, and Zavesca* (June 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-notice-actelion.pdf. HRSA reviews manufacturer's program notices. When it posts notices online, it has concluded that the program is per-

location that is part of our pre-existing limited distribution program, without providing claims data. Non-grantee covered entities may place orders for such drugs through a specialty pharmacy at any location that is part of that limited distribution system, if they provide the requested limited claims data. Non-grantee covered entities that elect not to provide the requested limited claims data for these drugs may designate a single specialty pharmacy location that is part of JJHCS' limited distribution system. These specialty pharmacies are generally able to dispense to patients located anywhere in the country.

JJHCS contracts with a platform known as 340B ESP, the same one used by UT, to collect the requested claims data. That platform only collects patient deidentified information.[20] Covered entities are asked

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mitted under applicable law and guidance. *See* HRSA, HHS, *Clarification of Non-Discrimination Policy*, Release No. 2011-11 (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf. HRSA's prior approval of J&J's limited distribution system demonstrates that HRSA itself agrees that manufacturers may impose reasonable *non-price* conditions on 340B discount offers.

[20] The government asserts, without basis, that the privacy protections reflected in claims data systems are "unknown," Gov't Brief at 35, asserting a ground HRSA never relied upon in issuing its "violation" letters. The robust privacy notifications in place are a matter of public record.

for limited claims data such as (1) the "Rx number" identifying the prescription, (2) the date of service, (3) the National Drug Code identifying the product dispensed to the patient, and (4) the Prescriber ID of the physician. As UT notes, providing claims data is not an onerous task. UT Br. at 21; *see infra* at 30–31. Indeed, it is a common practice in the healthcare industry. *See infra* at 30–31. These data allow JJHCS to detect whether a contract pharmacy is engaging in duplicate discounts or diversion, while simultaneously providing broad access to 340B discounted product.

ARGUMENT

I. THE GOVERNMENT MISSTATES THE ORIGINS OF THE 340B PROGRAM AND CONTRACT PHARMACIES.

As UT explains, the plain text, structure, and purpose of the 340B statute offer no support for HRSA's claim that manufacturers cannot assert reasonable non-price conditions on their 340B offers. UT Br. at 28–37. Manufacturers must offer their covered outpatient drugs at or below a ceiling price to an enumerated list of covered entities—which does not include contract pharmacies. *See* 42 U.S.C. § 256b(a)(4). As evidenced

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See 340B ESP, *Covered Entity Portal Terms of Use*, https://www.340besp.com/terms-of-use (last updated Apr. 6, 2022).

by HRSA's absence of gap-filling authority, Gov't Br. at 38, the statute leaves the other conditions of sale to the reasonable negotiations of private parties.

The 340B statute's origins and HRSA's subsequent, unauthorized efforts to thereafter substantially broaden the program confirm this conclusion. The statute was meant to be a narrow corrective measure after the MDRP penalized manufacturers for extending discounts to a limited number of providers. There is no evidence in the administrative record—or elsewhere—that manufacturers allowed "direct care" providers to transfer or resell these discounted products to third-party pharmacies. *See supra* at 8 & n.10. On the contrary, despite the government's and Amici's unsupported assertions to the contrary, contract pharmacies were not a part of the 340B program "at its inception."

The ahistorical claim that contract pharmacies were part of the 340B program "at its inception" is offered by the government and the States, Gov't Br. at 1, 6; States Amicus Br. at 9–10, in an unsuccessful effort to defeat the necessary conclusion that contract pharmacy transactions are not required by the statute. The plain language of the statute (1) limits the enumerated covered entities, but does not include contract

pharmacies as a covered entity,[21] (2) references multiple agents of program participants, but never acknowledges that contract pharmacies are agents of covered entities,[22] and (3) *prohibits* any "transfer"[23] of discounted product by a covered entity, except to a patient of that covered entity.[24] The fact that the government's statutory interpretation rests on

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[21] 42 U.S.C. § 256b(a)(4).

[22] *See, e.g.*, *id.* § 256b(d)(3)(B)(vi) (separately referring to "covered entities" and their agents, "associations or organizations" representing their interests in ADR proceedings); *id.* § 256b(d)(1)(B)(v) (referring to "wholesalers" contracted with manufacturers); *id.* § 256b(d)(2)(B)(iv) (referencing "distributors").

[23] 42 U.S.C. § 256b(a)(5)(B). There cannot be, in our view, any real debate about whether a prohibited "transfer" from a covered entity to a contract pharmacy occurs as a matter of regular course. In the dominant replenishment model, HRSA has conceded this point, using the euphemism that 340B discounted product goes into the contract pharmacy's "neutral inventory." *See* Mot. for Summary Judgment, Ex. 1, Decl. of Krista M. Pedley ¶¶ 9, 11, *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686-DLF (D.D.C. Aug. 10, 2021), ECF No. 17-1 ("Pedley Decl."). There is no question that contract pharmacies then, as UT says, dispense that discounted product to whomever walks into the pharmacy. UT Br. at 13.

[24] Amici admit that "Congress assigned the 340B Program's savings and revenue benefits solely to covered entities." States Amicus Br. at 4. Amici then argue that transfers of discounted product to contract pharmacies are not diversion, because, supposedly, "[a]ny profits, or revenue, from the sale of manufacturers' drugs cannot in practice enrich contract pharmacies." *Id.* at 14. Although Amici call this "a critical point," the public record is clear that large, for-profit pharmacies receive significant benefits from their contract pharmacy activities. As UT emphasizes, two

a false historical premise underscores the weakness of its position. The public record demonstrates that covered entities only asked HRSA to permit contract pharmacy arrangements **after** the 340B program began.

Congress designed the 340B program as a specific, targeted response to a specific, defined pricing issue Congress had inadvertently created. *See supra* at 6–8. That pricing issue, which had nothing to do with the non-price terms that applied, including data requirements, was limited to a small set of "direct care" providers; the discounts were not extended to third parties, contract pharmacies or otherwise. Indeed, when enacting the 340B Program, Congress estimated that only approximately 90 hospitals would be eligible to participate, *see* House Report at 13[25]; the

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national chain pharmacies have publicly declared that their 340B revenue is "material" to their financial performance. UT Br. at 17.

[25] Congress likewise estimated that just 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS-assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers would qualify, compared to the 30,000 contract pharmacies in the country today. *Compare* House Report at 13, *with* Adam Fein, Drug Channels Inst., *340B Continues Its Unbridled Takeover of Pharmacies and PBMs* (June 15, 2021), https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html.

extremely limited scope of the expected reach of the statute is inconsistent with any suggestion that the historical discounts were leveraged by contract pharmacies.

Contract pharmacies are not "direct care" providers. They are merely an indirect mechanism to provide care. There is no mention in the statute or the legislative history of the bill that was enacted discussing discounts where "indirect" care might be provided by "contract pharmacies." As the Committee report explained, "[t]he Committee expect[ed]" that the Best Price exemption would restore "discounts ***to these*** clinics, programs, and hospitals" that had been the specific source of concern. *Id.* (emphasis added). Contract pharmacies were therefore not a part of the program that Congress envisioned or created.

Indeed, contrary to the government's unsupported contention that contract pharmacies were used "from the inception of the 340B program," Gov't Br. at 31, the government and others have repeatedly acknowledged the exact opposite. A public HRSA Pharmacy Services Support Center presentation concluded openly that "Contract Pharmacy" was "not part of [the] original [340B] legislation" in 1992. *See* Presentation of

Lisa Scholz, *340B Contract Pharmacy*, 14th Annual 340B Coalition Conference (July 20, 2010) (on file with JJHCS). The presentation directly stated that "[e]ntities expressed [a] need to contract with a separate pharmacy" **after** the program's implementation, resulting in a "Contract Pharmacy Federal Register Notice"—*i.e.*, the 1996 Guidance[26]—being "finalized to provide guidance." *Id.* Unsurprisingly, HRSA said as much when, without citing any regulatory authority, it sought to permit 340B covered entities to expand beyond the clear limits of the statute by allowing transfer of discounted product to "contract pharmacies." *See* 61 Fed. Reg. at 43,550 (referencing talks between a few covered entities and HRSA to "develop[]" a mechanism "to use outside pharmacies" "[a]s early as 1993," after the 340B law was passed).

Program advocates have similarly admitted that contract pharmacy arrangements were not part of Congress's design. A founder of 340B Health, a trade association that filed an amicus brief in this case,[27] wrote that "[w]hen Congress enacted section 340B, *Congress did not consider that some covered entities*—especially FQHCs, city and county

[26] 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

[27] *See* Amicus Br. of Am. Hospital Ass'n ("AHA") *et al.*, Doc. # 1946862.

health departments, and other small facilities—*would not be able to participate due to the lack of an in-house pharmacy capable of purchasing and dispensing the discounted drugs*." William H. von Oehsen III, Pub. Health Inst., Pharm. & Indigent Care Program, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, at 14 (May 2001) (emphasis added).[28] Thus, it was only after the statute was enacted that "[t]hese facilities began complaining to [HRSA's Office of Pharmacy Affairs ("OPA")] about their inability to participate" in the 340B program. *Id.* And it was only then that "OPA responded to these complaints by developing guidelines that allow covered entities to use contract pharmacies to dispense 340B-discounted drugs." *Id.*

This Court should reject the ahistorical assertions made by the government and Amici.

[28] Mr. von Oehsen's biography states that he "helped establish and serves as outside counsel to 340B Health, formerly Safety Net Hospitals for Pharmaceutical Access, an advocacy organization of more than 1,200 public and private nonprofit hospitals participating in the 340B program." *See* https://www.powerslaw.com/professional/william-h-von-oehsen-iii/. It further states that "[h]e played a key role in helping to enact the 340B program in 1992." *Id.*

II. THE GOVERNMENT'S ARGUMENT THAT THE 340B STATUTE IS A "DEAD LETTER" WITHOUT CONTRACT PHARMACIES IS BASELESS.

The government and Amici also argue that, without contract pharmacies, the 340B program would be a "dead letter." Gov't Br. at 28; *see also* States Amicus Br. at 9; Amicus Br. of Nat'l Ass'n of Cmty. Health Ctrs. at 21 This is wrong for multiple reasons.

First, there is no dispute that the 340B program, when enacted, did, in fact, provide the "direct care" entities that had previously lost access to discounts with lower pricing. That result alone shows that the statute is not a "dead letter." HRSA and its Amici fall into a classic trap of statutory interpretation. Their proposed "[a]pplication of [the] 'broad purposes'" of the 340B statute "at the expense of specific provisions" ignores the statute's origins in narrowly restoring discounted prices to entities providing direct care to safety-net patients. *Bd. of Governors of the Fed. Reserve Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 373–74 (1986).

Second, beyond that, the suggestion that only a small fraction of covered entities can access 340B pricing without resort to using contract pharmacies is demonstrably incorrect. The government fails to recognize

how 340B covered entities have developed in-house pharmacies to capitalize on the statute. The OPAIS website maintained by HRSA shows thousands and thousands of covered entities with on-site pharmacies. *See* HRSA, HHS, *Office of Pharm. Affairs, 340B OPAIS*, https://340bopais.hrsa.gov/ (last visited June 14, 2022). Indeed, for just a recent one year period, JJHCS alone sold 340B discounted drugs to 14,138 in-house pharmacies. That, quite clearly, is no "dead letter."

Finally, the district court rightly noted that UT's claims-based policy has given covered entities "far more opportunities to purchase drugs at 340B prices than they did when HRSA limited covered entities to one contract pharmacy." *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021); *see also* 61 Fed. Reg. at 43,550. This is also true of JJHCS' policy, which permits covered entities to employ as many contract pharmacy arrangements as they would like, if the covered entity submits the limited requested claims data.

III. MANUFACTURERS' USE OF CLAIMS DATA CONDITIONS IS PERMISSIBLE, BASED ON ROUTINE EXISTING PRACTICES, AND NOT BURDENSOME.

Nothing in the 340B statute suggests that manufacturers may not place appropriate conditions on their offers to covered entities. So long

as they make bona fide offers for their covered outpatient drugs at or below the ceiling price, they abide by the statute.[29] Incorporating other non-price terms into the private bargain between manufacturers and covered entities is not new within the 340B program. HRSA has long permitted manufacturers to condition their 340B sales on the provision of certain information. And, here, claims data will unquestionably further the 340B statute's purposes, is easily satisfied with readily available data, and is entirely consistent with routine, existing practice.

A. HRSA Has Previously Approved Manufacturers' Use of Conditions.

The government takes the position that the 340B statute "necessarily precludes manufacturers from imposing their own conditions." Gov't Br. at 27. Not so. Neither the 340B statute nor HRSA's longstanding guidance supports this position. *Novartis*, 2021 WL 5161783, at *9. Indeed, the use of conditions, including data conditions, has long been permitted by HRSA within the 340B program.

[29] The government, in a sign of the weakness of its position, posits a manufacturer policy that nowhere exists: where the manufacturer only offers a 340B price if covered entities do not buy any competitor's product. Gov't Br. at 30. Such an entirely speculative offer would not be bona fide—and this hypothetical is easily set aside on that basis.

HRSA guidance specifically permits manufacturers to condition a 340B offer on a covered entity's provision of "standard information" to confirm eligibility for 340B pricing. *See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. 25,110, 25,112 & 25,114 (May 13, 1994). HRSA's guidance also reflects that manufacturers may require that covered entities agree to "the manufacturer's normal business policies" when the covered entities accept a manufacturer's offer and purchase 340B products. *Id.* at 25,112 & 25,113–25,114.

In addition, HRSA's guidance has consistently permitted and approved manufacturer-imposed procedures for allocating drug sales where pricing may lead to excessive orders of 340B product, the drug requires special use or handling, or where supply is constrained. These are recognized conditions on discount offers that are much more significant than a request for limited claims data. Indeed, HRSA has expressly stated that "[t]his policy is consistent with section 340B(a)(1) of the Public Health Service Act," which is the "must offer" clause. *See* HRSA, HHS, *340B Drug Pricing Program Notice, Release No. 2011-1.1* (May 23, 2012) (citing 59 Fed. Reg. 25,110 (May 13, 1994)). As noted above, *see supra* at

15, J&J has imposed such a program for some of its rare-disease products that require special handling and use. HRSA approved those conditions.

B. Claims Data Policies Will Not Harm Patients or Covered Entities, and Will Ensure the 340B Program's Integrity.

Because HRSA is not providing protection against duplicate discounts and diversion at contract pharmacies, *see supra* at 11, several manufacturers, including UT and JJHCS, have added a claims-data option in their offers under the 340B statute. Under a claims-data policy, covered entities may elect to provide a limited set of claims data in order to obtain unlimited amounts of 340B-discounted products at contract pharmacies. Despite this, the government and Amici spend page after page of briefing arguing that the entire safety net will collapse if covered entities are not permitted to continue as they have—without any attempt to control duplicate discounts and diversion. But these claims of possible harm make no sense where a claims data approach is used.[30]

As stated previously, claims data approaches permit an unlimited number of contract pharmacies and an unlimited supply of discounted

[30] Indeed, under J&J's and a number of other manufacturers' policies, most covered entities—in J&J's case, **all** non-grantee covered entities—are not even asked to submit claims data.

products. As long as a covered entity and any contract pharmacy are not violating the statute, the funds they generate will be unchanged. The government's and Amici's claims about covered entity and patient harm cannot be squared with the broad access permitted by claims-based policies, which offer extensive access to 340B pricing, in exchange for data that contract pharmacies already have on hand.

The government and Amici also assert that manufacturer policies will harm patients by denying them the ability to access drugs. At one point, the government suggests that, without contract pharmacies, patients would have to travel "hundreds of miles" to receive prescriptions. Gov't Br. at 18. This is a specious argument for multiple reasons. First, in a claims data program, an unlimited number of contract pharmacies can be accessed. Second, regardless of the manufacturer program, because a patient who goes to a contract pharmacy is invariably going to a chain or community pharmacy, those pharmacies are equally available to those patients, whether the pharmacy claims the customer is a 340B patient or not. As the government itself acknowledges, patients and contract pharmacies typically have no idea if they are entering into a 340B transaction at the time of dispense. Third, even more fundamentally,

there are over 80,000 pharmacies in the United States. IQVIA, *U.S. National Pharmacy Market Summary*, at 3 (July 2019). Finally, products, like JJHCS', are readily available nationwide through a diverse distribution system that includes retail, mail order, and specialty pharmacies. Patients' access to pharmaceutical products is simply not dependent on contract pharmacies dispensing those products.

Because they appear to understand how unreasonable their absolute opposition to providing claims data is, the government and Amici also argue that supplying that data will be unduly burdensome. S*ee* Gov't Br. at 35–36; States Amicus Br. at 2; AHA Amicus Br. at 28–30. But that contention cannot withstand scrutiny. Claims data and comparable data are already available to covered entities and contract pharmacies, and are regularly expected both within the 340B program and throughout the broader health care system.

Claims data substantially in excess of what either UT or JJHCS requests for a 340B drug are required for a contract pharmacy to secure reimbursement from any third-party payor, like a state Medicaid program. *See, e.g.,* Or. Health Auth., *Pharmacy Billing Instructions*, at 17,

20–21 (June 2017), https://www.oregon.gov/oha/HSD/OHP/Tools/Pharmacy%20Billing%20Instructions.pdf (showing more than 50 data elements used by Oregon's Medicaid program for a pharmacy claim submission, including elements requested by UT and JJHCS, such as Rx number and prescriber identification). Contract pharmacies, which routinely submit claims for reimbursement to the third party payors moments after they dispense medications to patients, readily have this data available. *See, e.g.,* N.H. Dep't of Health and Human Servs., *Average Pharmacy Claims Processing Time,* https://medicaidquality.nh.gov/reports/average-pharmacy-claim-processing-time (last visited June 14, 2022) (average claim processing time is "less than or equal to three (3) seconds").[31] Indeed, the third party administrators retained by covered entities to pur-

[31] Inexplicably, even while the Amici states require ***more*** data to pay a pharmacy claim than UT or J&J request, the states baselessly assert that manufacturer policies are "intrusive audits." States Amicus Br. at 2. It cannot be that manufacturers act unreasonably when they request *less* data than the states and other payors, like the federal government in the Medicare, Tricare, and Veterans' Affairs programs.

portedly "match" contract pharmacy dispenses to 340B covered entity patients already regularly receive prescription data from contract pharmacies.[32]

Further, HRSA also has long permitted manufacturers to require data to support both 340B chargebacks and 340B rebates. HRSA, *Notice Regarding Rebate Option*, 63 Fed. Reg. 35,239, 35,241 (June 29, 1998) (permitting "[s]tandard business practices" for "*claim data* reporting" to secure 340B rebates) (emphasis added); Model N*, Best Practices for Managing PHS 340B Chargebacks*, at 6 (2013), http://pages.modeln.com/rs/modeln/images/WP_340B.pdf (showing data elements required "for chargeback processing").

Significantly, 340B ESP has publicly reported that over 30,000 pharmacy locations are eligible for 340B pricing. *See* 340B Report, *The New Rules of 340B Contract Pharmacy—A Recap of 340B Report's First-Ever Webinar*, (May 24, 2022), https://340breport.com/the-new-rules-of-340b-contract-pharmacy-a-recap-of-340b-reports-first-ever-webinar/ (sub req.). This is no surprise because data expectations as a condition

[32] *See* Pedley Decl., *supra,* n.22.

to substantive requests for other discounts and rebates are routine parts of the wider healthcare system. Data is required to substantiate Medicare Part D rebate claims; it is required for commercial discounts to commercial health plans and pharmacy benefit managers; it is necessary when Medicaid states, like Amici, request manufacturer rebates under that program; and it is required for commercial discounts provided to non-340B hospitals and other providers.[33] But that is not the limit of such data requirements, as data is also required in connection with a broad array of discounts on non-drug health care items, such as medical devices, equipment, and supplies.[34]

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[33] *See, e.g.*, Nat'l Council for Prescription Drug Plans, *Manufacturer Rebate Utilization, Plan, Formulary, Market Basket, and Reconciliation Flat File Standard; Implementation Guide, Version 07.02*, at 15, 20–22 (Jan. 2019); CMS, *MDRP Electronic State Invoice Form CMS-R-144; Data Definitions* (2020), https://www.medicaid.gov/medicaid/prescription-drugs/downloads/cms-r-144-state-invoice-data-definitions-jul-2021.pdf.

[34] The government argues, without pointing to anything in the administrative record, that a purported "web" of manufacturer policies will burden covered entities. Gov't Br. at 36. This, of course, was no part of the rationale for the "violation" letters at issue here. In any event, every claims data-based policy to date functions similarly. But, beyond that, every Medicare Part D plan and every state Medicaid plan has its own coverage and billing rules with which it expects pharmacies to comply. The federal government and the States do not consider this "web" to be burdensome to pharmacies.

Manufacturer policies, like UT's and JJHCS', which, among other options, provide covered contract pharmacies access when claims data is submitted, reflect the balanced approach taken by the text, structure, and purpose of the 340B statute. They provide broad access to 340B pricing, while giving manufacturers at least some opportunity to protect against duplicate discounts and diversion. HRSA's recent, absolutist prohibition on manufacturer conditions ignores the balance that lies at the heart of the statute and the program.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Date: June 15, 2022

Respectfully submitted,

/s/ William A. Sarraille

GABRIELA ILLA
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
Telephone: (312) 853-7000

WILLIAM A. SARRAILLE
Counsel of Record
CHRISTOPHER S. ROSS
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000

Counsel for Johnson & Johnson

CERTIFICATE OF COUNSEL

Pursuant to D.C. Circuit Rule 29(d), I certify that JJHCS's separate amicus brief is necessary because of the company's unique perspective from implementing a policy similar to the one implemented by Plaintiff-Appellee United Therapeutics Corp. at issue in this case.

Date: June 15, 2022

/s/ William A. Sarraille
WILLIAM A. SARRAILLE

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 6,492 words (as determined by the Microsoft Word 2016 word-processing system used to prepare the brief), excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a)(5)–(6). The brief was prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

Date: June 15, 2022

/s/ William A. Sarraille
WILLIAM A. SARRAILLE

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2022, a true and correct copy of the foregoing was timely filed with the Clerk of the Court using the appellate CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

/s/ William A. Sarraille
WILLIAM A. SARRAILLE