No. 22-1676

In the United States Court of Appeals for the Third Circuit

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff-Appellee,

v.

SECRETARY, UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Delaware, No. 1:21-cv-00027 (Hon. Leonard P. Stark)

BRIEF OF *AMICUS CURIAE* JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Third Circuit Rule 26.1.1, Johnson & Johnson Health Care Systems Inc. states that it is wholly owned by Johnson & Johnson, a publicly traded corporation.

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INTEREST OF AMICUS CURIAE AND SUMMARY OF ARGUMENT[1]

Amicus Curiae Johnson & Johnson Health Care Systems Inc. ("JJHCS") provides contracting and supply chain support to Johnson & Johnson, the world's most comprehensive manufacturer of health care products, including pharmaceuticals. JJHCS is proud to participate in the 340B program. JJHCS seeks only to be protected from duplicate discounting and diversion, as promised by the 340B statute.

Given the billions of dollars JJHCS provides to 340B covered entities and contract pharmacies, JJHCS has been deeply disappointed (1) little of those funds are actually used to reduce patient co-payments,[2]

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[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). Counsel for AstraZeneca and the appellants consented to this filing.

[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.

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

Nevertheless, JJHCS permits covered entities to benefit from broad exceptions that expansively support contract pharmacy deliveries. For instance, all covered entities that receive a grant from HRSA may use an unlimited number of contract pharmacies. Hospitals that are covered entities may also have an unlimited number of contract pharmacies, if they choose to provide limited claims data used to identify duplicate discounts and diversion.

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[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 ("there is … zero transparency around the profits earned by billion-dollar public companies that dominate 340B pharmacy networks").

The government has repeatedly acknowledged that contract pharmacies result in diversion and duplicate discounts, and JJHCS and other manufacturers have tried to address these rampant problems. But these efforts have not been successful, because covered entities often refuse to cooperate or make repayments; HRSA tolerates this, leaving manufacturers without the protections promised by the statute.

Because this Court's decision could affect JJHCS' policy, JJHCS offers additional background on the 340B statute and its history. It also writes to correct several misstatements in the government's and its amici's briefs.

Although the government contends that the 340B program was intended to be "broad," the history of the 340B program demonstrates that it actually had a modest, narrow purpose. In arguing for its ahistorical vision of the 340B program, the government asserts that contract pharmacies have been used "since the inception" of the program. *E.g.*, Gov't Br. at 30.[4]

[4] JJHCS files this brief in support of AstraZeneca in Case No. 22-1676. Citations to the Government's Brief are to the Defendants' Principal Brief filed in *Sanofi Aventis U.S., LLC v. U.S. Department of Health and Human Services* and *Novo Nordisk Inc. v. U.S. Department of Health and*

The government is incorrect about the program's origins and history. In enacting the 340B program, Congress intended only to restore discounts to a select group of providers of direct care to the poor that had been provided voluntarily by manufacturers until Congress passed the Medicaid Drug Rebate Program ("MDRP") in 1990. Because Congress did not shield these discounts from setting 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 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 suggestion to the contrary, it was only **after** the 340B statute was passed that a few covered entities and HRSA developed the concept of contract pharmacies, seeking to expand the 340B program beyond its original, narrow purpose. HRSA's Pharmacy Services Support Center confirmed this publicly, noting that contract pharmacies were "not part of [the] original [340B] legislation," but were added at covered entities' behest after the program's

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Human Services, Nos. 21-3167, 21-3379, 21-3168, 21-3380 (3d Cir. May 9, 2022).

implementation.[5] HRSA then, over the next 20 years, broadly expanded even that concept—without statutory basis. The District Court correctly held that the government's "flawed statutory interpretation" and violation letter "cannot stand." *AstraZeneca Pharms. LP v. Becerra*, No. 21-27-LPS, 2022 WL 484587, at * 6 (D. Del. Feb. 16, 2022)

HRSA contends that manufacturers cannot condition 340B sales in any way. But conditions, like JJHCS' claims-data requirements, are permitted. Significantly, they further the statutory purposes of controlling duplicate discounts and diversion, while allowing covered entities to have an unlimited number of contract pharmacies. JJHCS' policy demonstrates, even in its first month of implementation, that it reasonably reflects the text, purpose, and structure of the statute. In one month, the policy facilitated more than $400 million in 340B discounts, provided 340B pricing to more than 8,800 contract pharmacies, and found a high percentage of duplicate discounts.

[5] *See* Presentation of Lisa Scholz, *340B Contract Pharmacy*, 14th Annual 340B Coalition Conference (July 20, 2010) (on file with JJHCS).

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 this, manufacturers "regularly offered discounts to … hospitals and other safety-net providers" voluntarily. *Id.* at 29. These historic discounts did not involve "contract pharmacies," and there is no evidence in the record that they did. *Id.* (referencing "discounts **to**…hospitals and other safety-net providers") (emphasis added). Because the MDRP did not exclude these voluntary discounts in calculating Medicaid rebates, *see id.* at 30, those discounts resulted almost overnight in higher rebates. This so penalized manufacturers, they stopped offering discounts. *See id.* at 29.

Congress quickly sought to remedy this narrow pricing problem by creating 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 did just that, restoring discounts extended directly to safety-net

providers that "serve large numbers of low-income and uninsured patients." H.R. Rep. No. 102-384, pt. 2 ("House Report"), at 10–12 (1992).[6]

Because large 340B discounts inevitably invited diversion, the statute specifically limited access to the discounts to enumerated "covered entities"; any "transfer" of discounted product by a covered entity to anyone, other than its patient, 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 select providers "that provide ***direct clinical care*** to large numbers of uninsured Americans." *See* House Report at 12 (emphasis added).[7] Congress wanted to ensure that the entities providing "direct clinical care" and their patients received discounts—but no one else.

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[6] Simultaneously, Congress also amended the MDRP to exclude those discounts from "Best Price." 42 U.S.C. § 1396r-8(c)(1)(C) (excluding "prices charged … **to** a … covered entity") (emphasis added).

[7] 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 by contract pharmacies was not included anywhere in the statute or the legislative history of the bill that passed.

II. THE PROGRAM'S ENDEMIC PROBLEMS

The government concedes that the 340B program lacks adequate controls. The government itself recognizes that the unchecked growth in contract pharmacies has increased 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. A 2018 GAO report concluded that "[t]he **identified noncompliance** at contract pharmacies raises questions about the effectiveness of covered entities' current oversight." *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, *supra*, at 44 (emphasis added). GAO found that most 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).[8] OIG also found that covered entities lacked "a method to avoid duplicate discounts." *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, *supra* n.2, at 1–2, 16.[9]

Despite all this, HRSA has turned a blind eye to these systemic problems, because it says it cannot address contract pharmacy duplicate discounts and diversion. *See* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 1, 15–16 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.[10] HRSA has

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[8] https://oig.hhs.gov/testimony/docs/2018/maxwell-testimony05152018.pdf.

[9] Amici wave their hands at these concerns, contending that they are merely "risks," not actual problems. *E.g.*, Amicus Br. of Connecticut et al. ("States"), at 12, *Sanofi* & *Novo* Nos. 21-3167 et al. (3d Cir. May 16, 2022); Amicus Br. of Am. Hospital Ass'n, et al., Doc. 25, at 13. But GAO has documented "[t]he **identified noncompliance** at contract pharmacies," and over 80% of the audits HRSA has completed have found violations. *See* GAO, Federal Oversight of Compliance, *supra*, at 44.

[10] HRSA 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, but asking for limited claims data, *is* a statutory violation. HRSA's position is inconsistent.

found contract pharmacy violations but, nevertheless, "did not issue findings for [the] failure to comply." *Id.*

The problem of duplicate discounts and diversion is enormous. Although the 340B program was designed to restore discounts to a small number of providers, JJHCS' 340B program now is 88% *larger* than its Medicaid Drug Rebate Program. *See* Janssen Pharms., Inc., *2021 Janssen U.S. Transparency Report* (2022).[11] The challenge of trying to identify contract pharmacy duplicate discount and diversion violations, without claims data, is shown by the fact that JJHCS provides 340B discounts to thousands of contract pharmacies annually.

An actual example illustrates the oversight challenge. A single covered entity in Florida has 499 contract pharmacies, including in California and Arizona, 3,000 miles away. *See* HRSA, HHS, *Office of Pharmacy Affairs*, https://340bopais.hrsa.gov/cedetails/20962 (last visited June 14, 2022). These "mega-networks" are not isolated occurrences.

JJHCS previously tried to address these problems, without success. Covered entities' failure to cooperate and HRSA's willingess to permit

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

that lack of cooperation has undermined these efforts.[12] JJHCS has considered audits or initiating alternative dispute resolution proceedings, but HRSA's audit requirements are hopelessly burdensome. *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. Because the alternative dispute resolution process first requires an audit, it is equally unavailing. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.21(b). The futility of audits and administrative dispute resolution is clear because HRSA has already declared that it will not act on 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 address these issues, JJHCS revised its policies for orders that are billed to a

[12] Some JJHCS examples illustrate the point:

- covered entity refused to return duplicate discounts involving multiple drugs purchased from 2017 to 2020;
- following an adverse HRSA audit, covered entity refused to take responsibility; after 22 communications with multiple parties, the covered entity only made a partial refund.

given customer, but shipped to a different party. These type of orders are called "Bill To/Ship To" orders. Under the policy,[13] which is applicable to all customers—340B and non-340B—JJHCS no longer ships its products to Ship To locations that are not part of the Bill To entity. But broad exceptions benefit covered entities.

For instance, grantee covered entities[14] may have unlimited contract pharmacy arrangements, without providing limited claims data. Non-grantee covered entities[15] may also have an unlimited number of contract pharmacies, if they elect to provide claims data. Non-grantee covered entities that lack an in-house pharmacy and choose not to provide limited claims data may designate a contract pharmacy site. Further, covered entities may place Bill To/Ship To orders for specified wholly owned not-for-profit contract pharmacies.

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[13] *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.

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

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

In addition, for JJHCS' pulmonary arterial hypertension drugs distributed through specialty pharmacies under a previously approved HRSA limited distribution program,[16] grantees may order through a specialty pharmacy at any location of the limited distribution program, without providing data. Non-grantees may place orders for such drugs through a specialty pharmacy at any location of the limited distribution system, if they provide data. Non-grantees that elect not to provide the requested data may designate a specialty pharmacy location that is part of system. These specialty pharmacies dispense to patients nationally.

[16] *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 permitted under applicable law. *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 approval of JJHCS' limited distribution system demonstrates that HRSA agrees that manufacturers may impose conditions.

JJHCS contracts with the 340B ESP platform, the same one used by other manufacturers, to collect claims data. That platform only collects patient deidentified information.[17] Covered entities are asked for limited claims data such as (1) the "Rx number" identifying the prescription, (2) the date of service, and (3) the National Drug Code identifying the patient-dispensed drug. Providing claims data is not burdensome, *see infra* at 31–32, and is a common healthcare practice. *See id.* Duplicate discounts and diversion are identified with this data.

JJHCS' policy, which just became effective on May 1, 2022, has already demonstrated the need for the program and shows the balanced nature of JJHCS' efforts. In just the policy's first month, JJHCS identified more than 11,000 duplicate discounts. These duplicate discounts were 26% of all submitted claims.

However, despite this high level of identified duplicate discounts, *none* of these duplicate discounts will result in 340B covered entities not

[17] The government asserts that privacy protections for the claims data are "unknown," Gov't Brief at 35, asserting a ground never raised in the "violation" letters. The robust privacy notifications in place are a matter of record. *See* 340B ESP, *Covered Entity Portal Terms of Use*, https://www.340besp.com/terms-of-use (last updated Apr. 6, 2022).

receiving a 340B discount. JJHCS will be seeking a return of the duplicate discounts from the *non*-340B covered entities that received the duplicate discount, *not* from covered entities.

Even though implementation of any policy takes some time, the implementation of JJHCS' policy has been rapid and positive. In just the first month, JJHCS supplied more than **$400 million** in 340B discounts, involving more than **8,800** contract pharmacies.

ARGUMENT

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

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. AZ Br. 25–37. 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 by HRSA's absence of gap-filling authority, Gov't Br. 47–48, 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 broaden the program confirm this. The statute was a narrow

measure designed to correct the MDRP-created pricing problem for 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 voluntarily discounted products to third-party "contract" pharmacies. *See supra* at 6 & n.7. On the contrary, despite the government's and its amici's unsupported assertions, 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 amici, Gov't Br. 1, 6; States Amicus Br. 10, in an unsuccessful effort to defeat the plain language of the statute, which does not require contract pharmacy transactions. The text of the statute (1) limits the enumerated covered entities, but does not include contract pharmacies as a covered entity,[18] (2) references multiple agents of program participants, but never acknowledges that contract pharmacies are agents of covered entities,[19]

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[18] 42 U.S.C. § 256b(a)(4).

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

and (3) *prohibits* any "transfer"[20] of discounted product by a covered entity, except to its patient.

In fact, the government's amici admit that "Congress assigned the 340B Program's savings and revenue benefits solely to covered entities." States Amicus Br. 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

[20] 42 U.S.C. § 256b(a)(5)(B). There cannot be, in our view, any 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 dispense that discounted product to whomever walks into the pharmacy.

receive significant benefits from their contract pharmacy activities. National chain pharmacies have publicly declared that 340B revenue is material to their financial performance.[21]

In the face of this evidence that contract pharmacies are not required by statute, the government tries to support its statutory position by relying on a false historical premise—that contract pharmacies were used "at the inception" of the program. But, as noted, 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 6–7. That pricing issue, which had nothing to do with the non-price terms of sales, 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

[21]*See* CVS Health Corp., *Annual Report (Form 10-K)*, at 22–23 (Feb. 9, 2022), https://www.sec.gov/ix?doc=/Archives/edgar/data/64803/000006480322000008/cvs-20211231.htm.

the 340B program, Congress estimated that only approximately 90 hospitals would be eligible to participate, *see* House Report at 13[22]; the 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.

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[22] Congress likewise estimated that just 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS-assistance programs, 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.

Indeed, contrary to the government's unsupported contention that contract pharmacies were used "[f]rom the inception of the 340B Program," Gov't Br. 38, 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* Scholz Presentation, *supra* note 5. 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[23]—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).

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

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,[24] wrote that "[w]hen Congress enacted section 340B, *Congress did not consider that some covered entities*—especially FQHCs, city and county 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).[25] 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.

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[24] *See* Am. Hospital Ass'n Amicus Br.

[25] 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.*

Id.[26] 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.*

Amicus National Association of Community Health Centers ("NACHC") points to two short statements from non-legislator witnesses in a July 31, 1992 hearing discussing three bills, none of which passed, arguing that they show that Congress "explicitly discussed" contract pharmacies. Amicus Br. of NACHC, Doc. 16, at 14–15. This is simply incorrect. Significantly, "contract pharmacies" are never mentioned in either statement, and neither ever say that safety-net providers are sending discounted drugs to commercial, retail pharmacies.

In fact, they say the opposite. Although the first statement begins by saying that a majority of surveyed health centers had in-house pharmacies, which belies the government's "dead letter" argument, it also says, more to the point here, that use of commercial pharmacies by patients of the centers without in-house pharmacies do **not** result in lower

[26] JJHCS' policy permits a covered entity that lacks an in-house pharmacy to designate a contract pharmacy to distribute 340B product.

prices. This is an admission that there were no "contract pharmacy" relationships in place involving the sharing of discounts. *Bills to Amend the Public Health Service Act and the Social Security Act to Establish Limits on Certain Drug Prices*, 102d Cong. 77-82 (July 31, 1992) (statement of Jose Camacho).

The second, a statement by a person representing commercial pharmacies, refers to "special contracts," but clearly states that those contracts are with "non-profits." *Id.* at 285. The speaker is arguing that commercial pharmacies should get "access" to those prices, precisely because those commercial pharmacies were not benefiting from or otherwise involved in those "special contracts." *Id.*[27]

Finally, even if these few lines from these statements were not so fundamentally mischaracterized, statements made by non-legislators during a hearing related to bills that were never ultimately passed hold

[27] The second statement also references the not-for-profits getting "special contract[]" product through the "private drug distribution system," but that was just stating that the not-for-profits were buying their drugs from "wholesaler[s]," which are explicitly referenced in the next paragraph. *Id.* This is not a reference to contract pharmacies, which, again, are never mentioned in the statement.

no sway. *See Kelly v. Robinson*, 479 U.S. 36, 51 n.13 (1986) (declining "to afford any significance" to "a few comments" in a bill's hearing).

This Court should reject the ahistorical assertions made by the government and its amici. Contract pharmacies were not an original part of the 340B program, a fact that reinforces that the statute's plain language, purpose, and structure do not require contract pharmacies.[28]

[28] AHA suggests that manufacturers should resort to Congress to address the problems with contract pharmacies, citing *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). *See* AHA Amicus Br. at 2–3. This citation is puzzling. *Becerra* addressed whether, under the Medicare Act, reimbursement from the government to hospital pharmacies could vary by type of hospital in the absence of a survey of hospital costs, as required by the plain text of that Act. *See* 142 S. Ct., slip op. at 2–3. The case did not address or interpret the 340B statute in any way. *Becerra* does mention the 340B program and covered entity positions on the program when discussing covered entity amicus "claims" about why they believe these should not be differential Medicare payment. But the case never addresses, or even mentions, contract pharmacies. Nor does the case refer in any way to the government's interpretation of the 340B statute as barring any manufacturer conditions—the relevant question here. Indeed, *Becerra*'s reference to HHS's seeking a policy change from Congress was specifically limited to the question of the government's desire to change Medicare reimbursement. *See id.*, slip op. at 10. It did not relate to contract pharmacies, HRSA's new policy here, or other issues before this Court.

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

The government and its amici also argue that, without contract pharmacies, the 340B program would be a "dead letter." Gov't Br. 28; *see also* States Amicus Br. 9; NACHC Amicus Br. 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. A 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."[29]

III. MANUFACTURERS' USE OF CLAIMS DATA CONDITIONS IS PERMISSIBLE, REFLECTS ROUTINE EXISTING PRACTICES, AND IS 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

[29] Finally, as another district court has noted, a claims-based policy offers 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 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. Even the earliest implementation of the JJHCS policy shows it is no "dead letter." In just the first month of implementation, more than 8,800 contract pharmacies received pricing, and 340B discounts provided exceeded $400 million.

below the ceiling price, they abide by the statute. 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. Claims data will unquestionably further the 340B statute's purposes, is readily available, 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. 35. 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.

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.

HRSA's guidance has also consistently permitted and approved manufacturer-imposed procedures for instituting limited distribution systems where (i) pricing may lead to excessive orders of 340B product, (ii) the drug requires special use or handling, or (iii) 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 13, JJHCS 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 Help To Ensure 340B Program Integrity.

Because HRSA is not providing protection against duplicate discounts and diversion at contract pharmacies, *see supra* at 9, several manufacturers, including JJHCS, have added a claims-data option in their 340B offers. 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, especially where a claims data approach is used, permitting covered entities to use contract pharmacy arrangements even where the 340B statute does not require them to do so. The government's and its 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.[30]

The government and its 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 "over a hundred miles" to receive prescriptions. Gov't Br. 17. This argument fails for multiple reasons. First, 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. Second, 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

[30] Again, in just the first month of implementation, JJHCS has provided more than $400 million in 340B discounts, with pricing provided to more than 8,800 contract pharmacies, while 340B ESP reports that 30,000 contract pharmacies have registered to provide claims data.

available nationwide through a diverse distribution system that includes mail order and specialty pharmacies—many of which offer nationwide services. Patients' access to pharmaceutical products is simply not dependent on contract pharmacies dispensing those products.

Because it appears to understand how unreasonable its opposition to providing claims data is, the government argues in the consolidated cases that supplying that data will be unduly burdensome. S*ee* Gov't Br. 41–42; States Amicus Br. 2. 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 JJHCS requests for a 340B drug is 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 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 the 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-1 (last visited July 25, 2022) (average claim processing time is "less than or equal to three (3) seconds"); *see also* OIG, HHS, *Point-of-Service Claims Management Systems for Medicaid*, OEI-01-91-00820, at i (May 1992), https://oig.hhs.gov/oei/reports/oei-01-91-00820.pdf.[31] Indeed, the third party administrators retained by covered entities to purportedly "match" contract pharmacy dispenses to 340B covered entity patients already regularly receive prescription data from contract pharmacies.[32]

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[31] Inexplicably, even while the amici states require ***more*** data to pay a pharmacy claim than UT or JJHCS request, the states baselessly assert that manufacturer policies are "intrusive audits." States Amicus Br. 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.

[32] *See* Pedley Decl., *supra,* n.20.

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, as noted above, 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 to substantive requests for other discounts and rebates are routine parts of the healthcare system. Data is required to substantiate Medicare Part D rebate claims; it is required for commercial discounts to health plans and pharmacy benefit managers; it is necessary when Med-

icaid 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] And data is also required in connection with discounts for many non-drug health care items, like medical devices, equipment, and supplies.[34]

Manufacturer policies, like JJHCS' and others', which provide covered contract pharmacies access when claims data is submitted, represent a particularly balanced approach that respects the text, structure, and purpose of the 340B statute. They provide broad access to 340B pric-

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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. 36. This, of course, was not 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.

ing, while giving manufacturers an opportunity to protect against duplicate discounts and diversion. HRSA's recent prohibition on manufacturer conditions such as this policy ignores the balance that lies at the heart of the statute and the program.

CONCLUSION

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

Date: July 28, 2022

Respectfully submitted,

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CERTIFICATE OF COUNSEL

Pursuant to Third Circuit Local Circuit Rule 28.3(d), I hereby certify that I am a member of the Bar of this Court

Date: July 28, 2022

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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 6,493 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.

Pursuant to Local Rule 31.1(c), the undersigned also certified that the text of the electronic brief is identical to the text in the paper copies.

Date: July 28, 2022

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I hereby certify, pursuant to Local Rule 31.1(c), that virus scan detection programs have been run on the file of the electronic version of this brief and that no virus was detected. The virus detection programs are: Cisco Threat Grid: v. 3.5.27; Crowdstrike: v. 6.25.15316.0.

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I hereby certify that on July 28, 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.

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