Nos. 21-3128 & 21-3405

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY and LILLY USA, LLC,

Plaintiffs-Appellants/Cross-Appellees,

v.

XAVIER BECERRA, *et al.*,

Defendants-Appellees/Cross-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana

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

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128, 21-3405

Short Caption: Eli Lilly & Co. v. Becerra

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges

National Association of Children's Hospitals d/b/a Children's Hospital Association

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

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(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

None (all represented parties are not-for-profit organizations)

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

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N/A

Attorney's Signature: /s/ William B. Schultz Date: 6/21/2022

Attorney's Printed Name: William B. Schultz

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

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N/A

Attorney's Signature: /s/ Margaret M. Dotzel Date: 6/21/2022

Attorney's Printed Name: Margaret M. Dotzel

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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N/A

Attorney's Signature: /s/ Casey Trombley-Shapiro Jonas Date: 6/21/2022

Attorney's Printed Name: Casey Trombley-Shapiro Jonas

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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INTEREST OF *AMICI CURIAE*[1]

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

INTRODUCTION

The continued viability of the 340B program—and the care it allows hospitals to provide to America's most vulnerable patients—is at stake in this case. Congress created the program to make discounts available to nonprofit hospitals and community health centers so that they could offer additional, affordable health care services to the underserved. In Congress's words, the program was designed to enable providers "to stretch scarce Federal resources as far as possible, reaching

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

more eligible patients and providing more comprehensive services."[2] The 30-year-old 340B program has been meeting Congress's goals, and until 2020 drug companies provided 340B discounts for drugs dispensed at contract pharmacies, allowing the program to provide an indispensable lifeline for 340B hospitals and their patients.

The program now is under attack by the highly profitable pharmaceutical industry. But neither the statute's text nor Eli Lilly's (Lilly's) mischaracterizations regarding how 340B hospitals use these savings provide a basis to undercut the program. Indeed, the Supreme Court's recent pronouncements on the 340B program conclusively demonstrate the weakness of Lilly's position. Just two weeks ago, the Court noted that Congress has been aware of how the 340B program is operating.[3] But the Court explained that Congress did *nothing* to change the statute to address certain alleged concerns, so the only answer would be to "ask Congress to change the law."[4]

So too here. Even if Lilly were correct in its mischaracterizations about the use of contract pharmacies in the 340B program—and it is not—Congress has done *nothing* to amend the statute in all the years covered entities have been using contract

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

[3] *See Am. Hosp. Ass'n v. Becerra*, 596 U.S. ____ (2022) (slip op., at 12–13).

[4] *Id*. at 13.

pharmacies (*i.e.*, since the beginning of the program, and even after 2010 when contract pharmacy use increased). And even if Congress did consider the issue, it "would presumably have to confront the other side of the policy story here: 340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support."[5] One thing is clear, however: absent any statutory change, Lilly may not take matters into its own hands and deny 340B discounts to 340B providers.

Amici therefore urge this Court to hold that Lilly must offer 340B discounted drugs to 340B providers, regardless of whether these vital medicines are being dispensed in-house or through outside pharmacies, as it previously did for 24 years.

BACKGROUND

A. The 340B Statute and Program

The 340B program, established by section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discounted price to certain public and not-for-profit hospitals, community health centers, and other providers that serve low-income patients (340B providers or covered entities). 340B providers play a critical role in the safety net,[6] which is

[5] *Id*.

[6] *See, e.g.*, Allen Dobson et al., *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 3 (July 10, 2020),

accompanied by substantially lower operating margins than those of non-340B providers—and in fact, often *negative* operating margins.[7] 340B hospitals provide a disproportionate amount of uncompensated care,[8] and community health and other specialized services,[9] compared with non-340B hospitals. Accordingly, unreimbursed and uncompensated care costs as a percent of total patient care costs are 27.4 percent higher, on average, for 340B hospitals than for non-340B hospitals.[10]

The purpose of the 340B program is to increase the funding 340B providers have available to meet the needs of vulnerable patients. A 2011 U.S. Government Accountability Office (GAO) report found that the 340B program has had its intended effect.[11]

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https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

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

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

[9] Dobson et al., *supra* note 6, at 3–4.

[10] L & M Policy Research, *supra* note 8, at 1, 7.

[11] *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, Report to Congressional Committees 17–18 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf; *see also* 340B Health, *2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on*

Drug manufacturers may charge 340B providers no more than the statutorily defined "ceiling price" for 340B covered drugs, which is calculated by subtracting the unit rebate amount from the "average manufacturer price."[12] Congress also provided for a larger rebate when drug companies increase drug prices faster than the inflation rate.[13] This inflation-based penalty could have resulted in *negative* prices for 340B covered drugs, but the Department of Health and Human Services (HHS) has adopted a policy that when the calculated ceiling price for a drug is zero or less, drug companies may charge one penny for the drug.[14]

Since the beginning of the program, Lilly and all other major pharmaceutical companies provided 340B discounts for drugs dispensed through both in-house and contract pharmacies to covered entities' patients, and since 2010 sold drugs at 340B prices to covered entities that used multiple contract pharmacies. As far as *Amici* can ascertain, between 1996 and 2020, there is no record that Lilly ever contested HHS's interpretation of section 340B as allowing contract pharmacies to dispense 340B drugs. Today, a quarter of 340B hospitals' 340B benefit comes from drugs dispensed

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Hospitals, https://www.340bhealth.org/files/340B_Health_Survey_Report_2021_FINAL.pdf; Ryan P. Knox et al., *Risks to the 340B Drug Pricing Program Related to Manufacturer Restrictions on Drug Availability*, JAMA (Apr. 15, 2022), https://jamanetwork.com/journals/jama/article-abstract/2791334.

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

[13] 42 U.S.C. § 1396r-8(c)(2)(A).

[14] 42 C.F.R. § 10.10(b).

through contract pharmacies. Critical access hospitals (small hospitals in rural areas) report an average of 52 percent of their benefit comes from drugs distributed through contract pharmacies.[15]

B. Lilly's and Other Manufacturers' Unlawful Contract Pharmacy Policies

For decades drug manufacturers provided 340B discounts no matter how the drugs were dispensed, but starting in 2020, in the midst of a devastating pandemic, Lilly—and subsequently sixteen other major drug companies[16]—substantially cut the 340B benefit to certain public and not-for-profit hospitals.[17]

The contract pharmacy arrangements Lilly and others now refuse to honor have existed since the beginning of the program. When a 340B provider uses a contract pharmacy, it orders and pays for the drugs, which are shipped directly to the

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[15] 340B Health, *Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients* (340B Health Survey) 4, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf.

[16] When Lilly initially filed this action in 2021, just six companies had contract pharmacy policies. As *Amici* predicted, that number keeps growing. *See* Am. Hosp. Ass'n, 340B Health, Am.'s Essential Hosps., Ass'n Am. Med. Colleges, Children's Hosp. Ass'n, & Am. Soc. Health-System Pharmacists Mem. Supp. Mot. Intervene, No. 1:21-cv-81-SEB-MJD, ECF No. 40 at 2–3.

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

pharmacy to be dispensed (or to replenish drugs that have been dispensed) to the provider's patients. The pharmacy receives a fee for this service.[18]

Some providers use a "separate inventory" model, but most use a "replenishment inventory" model. For the separate inventory model, 340B drugs are kept in stock, separate from non-340B drugs. The pharmacy dispenses the 340B drugs to the provider's patients. For the replenishment model, when filling prescriptions for the provider's patients, the pharmacy uses its own stock, and the provider purchases replacement drugs at the discounted 340B price to replenish the pharmacy's stock. The pharmacy then remits to the 340B provider the payments the pharmacy received, thus ensuring that the provider receives the benefit of the 340B discount as Congress intended. This model typically involves a computerized tracking system following rules designed to ensure that only eligible patients of 340B providers receive drugs for which the provider receives the 340B discount.[19]

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

[19] *See, e.g.*, Apexus, *340B Split-Billing Software Key Attributes* (July 3, 2019), https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-split-billing-software-key-attributes.docx. The Supreme Court and the Federal Trade Commission have endorsed accounting systems like this as an appropriate way to distinguish drugs that qualify for a discount from those that do not. *See Abbott Labs. v. Portland Retail Druggist Ass'n, Inc.*, 425 U.S. 1, 20 n.11 (1976); Federal Trade Commission, University of Michigan Advisory Opinion 1 (Apr. 9, 2010),

Under either arrangement, it is the 340B provider that purchases the 340B discounted drug—not the contract pharmacy.[20] Lilly has ceased providing 340B discounts to providers for drugs distributed under both models.

On May 17, 2021, HHS sent letters to Lilly and five other pharmaceutical companies, finding after careful deliberation that the companies' refusals to provide 340B discounts for drugs dispensed through contract pharmacies, without restrictions, is unlawful.[21] Lilly challenges its letter.[22]

The district court concluded that HHS's finding that Lilly's contract pharmacy policy was unlawful represents not only a permissible but the best reading of the

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https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

[20] In its brief, Lilly asserts without support that the contract pharmacy "or an affiliate, but not the covered entity . . . order[s] more of the drugs at the 340B price." Opening Br. & Req'd Short App'x Pls.-Appellants ("Lilly Br."), ECF No. 22 at 12–13. Despite Lilly's attempt at obfuscation, it is the covered entity that *purchases* the 340B drugs and instructs Lilly to *ship* the drugs to a contract pharmacy, as Lilly's own policy acknowledges. *See* Limited Distribution Plan Notice for Eli Lilly and Company Products, https://www.340bhealth.org/files/200901_Eli_Lilly_and_Company_Limited_Distribution_Plan_Public_Notice.pdf ("*Covered entities* will not be eligible to *purchase* Eli Lilly and Company products at the 340B ceiling price for *shipment* to a contract pharmacy.") (emphasis added).

[21] *See* Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director, Government Strategy, Lilly (May 17, 2021), A2–A3.

[22] Lilly also challenges HHS's Administrative Dispute Resolution regulation, which the district court preliminarily enjoined. No. 1:21-cv-81-SEB-MJD, ECF No. 81. A final decision on the merits remains pending. Lilly also challenges an advisory opinion HHS issued in December 2020 but later withdrew. The district court vacated the withdrawn advisory opinion. SA61.

statute.[23] Nonetheless, the court found the May letter to be arbitrary and capricious because HRSA sent mixed signals about its authority to enforce potential violations of the 340B statute.[24] On April 14, 2022, the district court entered an amended partial final judgment, including a declaratory judgment that the May 17 letter: does not violate the notice-and-comment requirement; does not exceed statutory authority; is not a taking; and is not an unconstitutional condition on the receipt of benefits but is arbitrary and capricious. The district court vacated the May 17 letter and remanded the letter to HHS.[25]

DISCUSSION

In its brief, Lilly makes clear that it developed its contract pharmacy policy to undermine the 340B program and increase its own profits at the expense of 340B providers and their patients. Lilly understates the impact of its unlawful policy on covered entities and their patients and overstates the authority it relies on to limit access to 340B discounts and to impose conditions found nowhere in the statute. In the end, the central issue for this Court to decide concerns what the 340B statute says.

[23] SA49.

[24] SA52.

[25] SA70–71.

A. The 340B Statute's Text Requires Drug Manufacturers to Provide Discounts on 340B Drugs Purchased by Covered Entities and Dispensed by Contract Pharmacies.

Amici agree with HHS's arguments regarding the 340B statute's meaning, the agency's authority to enforce it, and the propriety of HHS's Violation Letters,[26] and elaborate on certain issues.

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

Rather, the statute speaks directly to what drug manufacturers must do and may not do. That manufacturers may not deny 340B discounts to covered entities that use contract pharmacies, nor unilaterally impose conditions on the provision of 340B discounts, derives from those requirements and prohibitions.

Lilly claims that the "operative" language of the 340B statute requires only that it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at

[26] *See* Principal & Resp. Br. Fed. Defs. (HHS Br.) 29–41, 44–46. *Amici* do not address Lilly's arguments regarding the Takings Clause of the Constitution.

any price."[27] But this ignores the central statutory text, which requires that "the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by a covered entity* . . . does not exceed" the ceiling price.[28] Congress used the "purchased by" language *twice* in the 340B statute,[29] and in its title: "Limitation on prices of drugs *purchased by covered entities*."[30]

Lilly attempts to discount the importance of the "purchased by" provision by arguing that it merely "prescribes what '*the Secretary* shall' do (namely, 'enter into' [Pharmaceutical Pricing Agreements (PPAs)] setting the ceiling price of 340B drugs)," while the "shall offer" provision "simply requires manufacturers to 'offer' 340B drugs to covered entities at a certain price," which Lilly claims it is doing by "offer[ing] all of its covered outpatient drugs at the ceiling price to all covered entities" under its chosen conditions.[31] Lilly's effort fails. First, it was not until 2010 that Congress added the "shall offer" provision.[32] Lilly can hardly support an argument that Congress required *nothing* of drug manufacturers from 1992 until 2010, and Lilly offers no basis for concluding that by adding the "shall offer"

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[27] Lilly Br. 6 (quoting 42 U.S.C. § 256b(a)(1)).

[28] 42 U.S.C. § 256b(a)(1) (emphasis added).

[29] 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 256b(a)(3).

[30] 42 U.S.C. § 256b (emphasis added).

[31] Lilly Br. 29 (alteration, emphasis, and citation omitted).

[32] *See* Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010) (codified at 42 U.S.C. § 256b(a)(1)).

language Congress intended to fundamentally change or displace drug manufacturers' obligation to charge no more than the ceiling price for 340B drugs purchased by 340B providers. Rather, the "shall offer" provision "mostly reiterates that manufacturers cannot prioritize full-priced commercial purchases over § 340B sales."[33]

Second, Lilly ignores the actual language of the "purchased by" provision, which does not merely "set[] the ceiling price of 340B drugs" as Lilly asserts,[34] but requires, under the PPAs, that "the amount *required to be paid*" by covered entities "*does not exceed*" the ceiling price.[35] And, as Lilly itself points out, the PPAs "simply incorporate statutory obligations and record the manufacturers' *agreement to abide by them*."[36] Thus, the 340B statute requires that, if a covered entity

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[33] *Sanofi-Aventis v. HHS*, Nos. 21-00634 (FLW), 21-00806 (FLW), 2021 WL 5150464, at *42 (citing 82 Fed. Reg. 1210, 1225 (Jan. 5, 2017); *see also* 82 Fed. Reg. at 1225; HRSA, *Clarification of Non-Discrimination Policy* (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf. Lilly's insistence that the statute does not prohibit discrimination, *see* Lilly Br. 46–47, is belied by its own statement to the district court that "[t]he 'must offer' provision codified HRSA's 1994 'non-discrimination' guidance," Pls.' Mem. Supp. Pls.' Mot. Prelim. Inj. & Temp. Restraining Order, No. 1:21-cv-91-SEC-MJD, ECF No. 95 at 15.

[34] Lilly Br. 29.

[35] 42 U.S.C. § 256b(a)(1) (emphasis added).

[36] Lilly Br. 6 (quoting *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 118 (2011)) (emphasis added).

purchases Lilly's 340B drugs—which they do when using contract pharmacies—Lilly may not charge more than the ceiling price.

Moreover, the statute does not state that drug companies must provide 340B discounts only when drugs are "purchased *and dispensed* by" a covered entity, and the fundamental rule of statutory construction is that the unambiguous language of the statute controls.[37] Likewise, as HHS explains in its brief, the 340B statute's legislative history directly supports this conclusion.[38] Congress rejected a version of the bill that would have required 340B discounts *only* for on-site pharmacy services (either operated by the 340B provider or under a contractual arrangement), since the drugs would have had to be "purchased and dispensed by, or under a contract entered into *for on-site pharmacy services*."[39] Lilly's argument that Congress "'specifically contemplated' language permitting contract-pharmacy relationships [but] 'chose not to include pharmacy services in the version of the bill that it ultimately passed'" twists the legislative history and ignores the reality in which Congress created the 340B program.[40] For one, Congress did not merely reject the "under a contract for

[37] *See United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240–41 (1989) ("[A]s long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute.").

[38] *See* HHS Br. 7, 32–33.

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

[40] Lilly Br. 38–39 (quoting *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021)).

on-site pharmacy services" language; it also eliminated the "dispensed by" language, which changed the provision to render where the 340B drug is dispensed legally irrelevant. Had Congress intended that drug manufacturers need not provide 340B discounts unless the covered entity directly dispenses the drugs, excluding the use of even in-house contract pharmacies, it would have said so explicitly, and it would not have *rejected* language doing just that. Moreover, Congress decided to permit dispensing by contract pharmacies for a sound reason, since at the time the bill was passed *less than five percent* of 340B providers had on-site dispensing services,[41] meaning that had Congress truly "chose[n] not to include pharmacy services" in the program, as Lilly asserts,[42] it would have chosen to exclude nearly all the providers for which it created the program.

Similarly, contrary to Lilly's argument,[43] Congress did not need to include contract pharmacies in the 340B statute the way it referenced contracts in section 603 of the Veteran's Health Care Act of 1992, an unrelated statute involving contracts between commercial entities and certain federal agencies, in which the agency contracts with the commercial entity to procure covered drugs.[44] Unlike the

[41] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).

[42] Lilly Br. 38–39 (citing *AstraZeneca*, 543 F. Supp. 3d at 60).

[43] *Id.* at 30–31.

[44] *See* 38 U.S.C. §§ 8126(a)(2), (h)(3)(A)(ii).

commercial entities covered by that provision, contract pharmacies are not purchasing drugs at 340B discounts on behalf of the federal government (or 340B providers)—they are not purchasing 340B drugs at all.

Therefore, that drug manufacturers may not charge more than the ceiling price for 340B drugs purchased by covered entities is the core requirement of the statute, and the central question in this appeal is whether the drugs subject to Lilly's policy are "purchased by" covered entities. They are. Regardless of the distribution model employed—replenishment or separate inventory—contract pharmacies never purchase 340B drugs. Thus, Lilly's policy unlawfully results in charges above the 340B ceiling price for drugs purchased by 340B providers.[45]

B. Drug Manufacturers May Not Unilaterally Alter the 340B Program Simply Because They Do Not Like It.

Lilly instituted its contract pharmacy policy to combat the growing size of the 340B program and to further boost its own profits.[46] Even if Lilly were correct—it

[45] That HRSA issued guidance in 1996 that stated that covered entities may use just one contract pharmacy is irrelevant to the issues before this Court. *See* 61 Fed. Reg. at 43,549. Moreover, in that guidance, HRSA likely exceeded its delegated authority, as nothing in the 340B statute limits how covered entities may dispense 340B drugs. *See also* HHS Br. 8 ("Congress did not authorize HHS to restrict the use of contract pharmacies by covered entities.").

[46] *See* Lilly Br. 12–15. Lilly underscored its profit motive when it informed investors that it was able to offset more rebate payments made to payers in the last quarter of 2020, with fewer claims requiring 340B discounts. *See Lilly Reports Strong Fourth-Quarter and Full-Year 2020 Financial Results*, Lilly (Jan.

is not—that "changes to the 340B program would shock the Congress that created it,"[47] it would still be up to *Congress* to address (or not[48]) the scope of the 340B program, not drug manufacturers and not courts.[49] Moreover, notwithstanding Lilly's contrary assertions, contract pharmacies have greatly benefited 340B providers and their patients even while drug manufacturers have watched their profits grow at extraordinary rates.[50] On the other hand, Lilly's policy and similar restrictions and conditions being imposed by other manufacturers are having major,

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29, 2021), https://www.sec.gov/Archives/edgar/data/0000059478/000005947821000010/q420lillysalesandearningsp.htm.

[47] Lilly Br. 13.

[48] Not only has Congress not acted to limit the 340B program since it was first enacted in 1992, Congress *expanded* the program in 2010. *See* Pub. L. No. 111-148, § 7102(b), 124 Stat. 119, 827 (2010) (codified at 42 U.S.C. § 256b(a)(1)). Since then, at least 35 bills regarding 340B have been introduced in Congress, including bills intended to limit the scope of the program. Thus, "[i]t is hardly conceivable that Congress . . . was not abundantly aware of what was going on" with the 340B program, which supports that "Congress acquiesced in" HHS's interpretation that covered entities may use multiple contract pharmacies. *Bob Jones Univ. v. United States*, 461 U.S. 574, 600–01 (1983).

[49] *See Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 195 (1978) ("[I]n our constitutional system the commitment to the separation of powers is too fundamental for us to pre-empt congressional action by judicially decreeing what accords with 'common sense and the public weal.' Our Constitution vests such responsibilities in the political branches.").

[50] *See* Fred D. Ledley et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323(9) JAMA 834-43 (Mar. 2020), https://jamanetwork.com/journals/jama/fullarticle/2762308 (finding that between 2010 and 2018, "the median net income (earnings) expressed as a fraction of revenue was significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%)").

adverse impacts on 340B hospitals and their patients, undermining the 340B program and Congress's intent.

1. *Lilly's Policy Maximizes Profits at the Expense of 340B Providers and Patients.*

Lilly is among the largest companies in an industry that between 2000 and 2018 generated $8.6 trillion dollars in profits.[51] Drug companies participate in the 340B program because they *must* do so to participate in Medicaid and Medicare Part B. The larger the 340B program, the less they can profit. Simply put, having failed to convince Congress to limit the program, drug companies began acting to severely curb it. Two specific data points demonstrate the profit motive driving Lilly's policy.

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

Lilly and the other companies are using their contract pharmacy policies to avoid having to pay congressionally imposed penalties they otherwise would face. As explained above, Congress sought to combat skyrocketing drug prices by creating a scheme in which drug companies pay a penalty when they increase prices on drugs covered by 340B or Medicaid above the inflation rate.[52] This inflation-based penalty often results in drug companies having to charge one penny for a drug. For example, the price of Lilly's Humalog® insulin increased by 1,200 percent between 1999 and

[51] *Id.*

[52] *See* Background, sec. A, above; 42 U.S.C. § 1396r-8(c)(2)(A).

2019, from $21 to $275 for a one-month supply.[53] As a result, Humalog® is now penny-priced. While Lilly bemoans that 340B drugs sometimes cost covered entities "as little as one penny per dose,"[54] such drastic discounts come into play only because the drug company opted to increase its drug prices faster than the inflation rate.[55] And it is not just insulin: 18 percent of Lilly's 340B discounts that hospitals receive come from nominally-priced drugs.[56] Even the drug industry's own estimates indicate that more than half of 340B discounts are attributable to price increases in excess of inflation.[57]

Research demonstrates that this inflationary penalty slows price increases for drugs sold to all purchasers, not just 340B providers.[58] Lilly and other drug

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[53] Danielle K. Roberts, *The Deadly Costs of Insulin*, AJMC (June 10, 2019), https://www.ajmc.com/view/the-deadly-costs-of-insulin.

[54] Lilly Br. 6.

[55] *See* 42 U.S.C. § 1396r-8(c)(2)(A).

[56] Data based on 340B Health analysis of the difference in cost for hospitals under 340B accounts and non-340B accounts (*i.e.*, hospital group purchasing accounts) based on 2020 340B sales volume for restricted drugs. The volume estimates include drugs dispensed at contract pharmacy and non-contract pharmacy hospital settings. *See also* 340B Health Survey, *supra* note 15, at 3.

[57] Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

[58] Sean Dickson, *Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases*, JAMA (Sept. 11, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540; *see also* Sean Dickson & Ian Reynolds, *Estimated Changes in Manufacturer*

manufacturers should not be permitted to avoid this penalty simply by developing policies that allow them to deny 340B discounts altogether. Yet the companies' policies do just that. Reducing the share of these drugs subject to inflationary penalties not only hurts 340B providers and their patients, it also greatly reduces the effectiveness of Congress's scheme to exert pressure on drug companies to limit price increases.

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

Additionally, Lilly and the other drug companies are using their policies to avoid providing 340B discounts on particularly expensive "specialty" drugs. 340B providers' increased use of contract pharmacies reflects, in part, a shift in the market toward specialty drugs[59] for which many payers require the use of specific specialty pharmacies.[60] Specialty drugs are typically used to treat chronic, serious, or life-

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and Health Care Organization Revenue Following List Price Reductions for Hepatitis C Treatments, JAMA (July 5, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2737308.

[59] *See* IQVIA, *The Use of Medicines in the U.S., Spending and Usage Trends and Outlook to 2025* (May 27, 2021), https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us (finding that specialty medicines accounted for 53 percent of drug spending in 2020, up from 27 percent in 2010).

[60] For example, major insurers and their associated Pharmacy Benefit Managers require that many patients obtain specialty medicines through their vertically integrated specialty pharmacies. Adam J. Fein, *Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?*, Drug Channels (Dec. 12, 2019), https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html.

threatening conditions and are generally priced much higher than traditional drugs.[61] Patients cannot obtain most specialty drugs at retail pharmacies, and specialty pharmacies generally are mail-order pharmacies distributed throughout the country.[62] An analysis across the first 16 drug manufacturers with contract pharmacy policies found that nearly *three-quarters* of the total 340B discount associated with their drugs came from drugs that appear on at least one list of specialty drugs across the four largest specialty pharmacy companies.[63] Thirty-one percent of the 340B discount associated with Lilly's drugs comes from drugs that are on the specialty list for at least one specialty pharmacy.[64]

The vast majority of 340B hospitals do not operate specialty pharmacies, and even when they do, those pharmacies are not able to serve all patients because Pharmacy Benefit Managers (PBMs) and payers often require patients to use the PBM's or payer's specialty pharmacy networks, which often exclude hospital

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[61] "There is no standard definition for specialty drugs. They may be expensive; be difficult to handle, monitor or administer; or treat rare, complex or chronic conditions." *Specialty Drug Coverage and Reimbursement in Medicaid*, HHS OIG, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000255.asp.

[62] Ronilee Shye, *Specialty Pharmacy and Specialty Medications: What You Should Know* (Jan. 7, 2014), https://www.goodrx.com/healthcare-access/pharmacies/specialty-pharmacy-and-specialty-medications-what-you-should-know.

[63] 340B Health Survey, *supra* note 15, at 6.

[64] *See supra* note 56.

specialty pharmacies.[65] Additionally, nearly three-quarters of 340B providers recently surveyed reported that limited distribution networks established by manufacturers for specialty drugs prevented their hospital from using their hospital- or system-owned specialty pharmacy for all drugs.[66] To access specialty drugs at the 340B price, 340B hospitals therefore must enter into contracts with pharmacies in each of the networks. However, 90 percent of 340B hospitals with specialty contract pharmacies reported that the drug manufacturers' policies limit their ability to purchase drugs at the 340B price from outside specialty contract pharmacies even as other restrictions make it impossible to use their own specialty contract pharmacies for certain drugs and patients.[67] To have access to specialty drugs at 340B prices for certain patients, 340B hospitals *must* contract with one or more specialty contract pharmacies, but Lilly's policy restricts their ability to do so.

2. *Lilly Drastically Understates the Negative Impacts of Its Policy.*

Congress created the 340B program to benefit specifically enumerated providers and their patients, and drug companies may not recreate the 340B program

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[65] For example, one benefit guide states, "For specialty medicines . . . you must use Accredo, the Express Scripts specialty pharmacy." Express Scripts, *Your Pharmacy Benefits Handbook* 5, https://www.express-scripts.com/art/open_enrollment/FCPS_MemberHandbook.pdf; *see also* Adam J. Fein, *supra* note 60.

[66] 340B Health Survey, *supra* note 15, at 7.

[67] *Id.*

to meet their desire to maximize profits. Yet while contract pharmacies significantly benefit 340B providers and their patients, Lilly's and others' restrictive contract pharmacy policies impose significant burdens on them.

(a) *Lilly Understates the Benefit of Contract Pharmacies to 340B Providers and Patients.*

Despite Lilly's assertion otherwise, contract pharmacies greatly benefit covered entities and their patients. While the increased use of contract pharmacies has *not* expanded the number of patients eligible for discounted drugs, 340B providers' patients, who may live very far from their provider,[68] benefit when their local Walgreens or CVS can dispense their 340B drugs. That the patient's provider receives the 340B benefit for those drugs serves Congress's intention of allowing the provider "to stretch scarce Federal resources as far as possible,"[69] and benefits the patients for whom the provider is able to expand services. Additionally, although not required to do so, more than half of the hospitals responding to the most recent 340B Health survey reported that they offer free or low-cost drugs to low-income and/or uninsured patients through contract pharmacies.[70] By restricting the use of

[68] *See, e.g.*, HHS Br. 18–19; *see also* Lilly Br. 12 (noting that "[c]overed entities now often contract with for-profit pharmacies located more than 1,000 miles away" without acknowledging that this occurs because covered entities' *patients* use those pharmacies and that those pharmacies may be mail-order specialty pharmacies) (emphasis omitted).

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

[70] 340B Health Survey, *supra* note 15, at 4.

contract pharmacies, Lilly and the other manufacturers have cut off patients' access to these discounts.

Contract pharmacies recoup a modest fee for dispensing 340B drugs, but (1) no matter the fee,[71] the *covered entity* is the one *purchasing* the drug; (2) the covered entity's patients benefit from increased access to 340B drugs; and (3) the covered entity is still getting the 340B benefit by receiving a discount from the manufacturer and reimbursement from the patient or third-party payer, which the contract pharmacy remits to the covered entity. Thus, the covered entity and its patients still benefit from the 340B program, as Congress intended.

To support its assertion that contract pharmacies do not benefit 340B providers and their patients, Lilly contorts the data by citing an article that focuses only on charity care.[72] But 340B hospitals provide substantial community benefits, and charity care tells just one piece of the story. It is more accurate to look at a hospital's total uncompensated care and their total community benefits rather than just its charity care numbers, as charity care alone does not account for the myriad programs and services that hospitals provide to their communities.[73]

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[71] *See supra* note 18.

[72] *See* Lilly Br. 13–14 (citing William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, Pioneer Health (Mar. 2022), https://pioneerinstitute.org/pioneer-research/340b-drug-discounts-an-increasingly-dysfunctional-program/).

[73] Am. Hosp. Ass'n, *supra* note 7, at 2.

When looking at the full picture, hospitals provided nearly $42 billion in uncompensated care in 2019; 340B hospitals accounted for roughly 68 percent of that number.[74] In 2017, 340B hospitals provided $64.3 billion in total benefits to their communities, including uncompensated care.[75] Those benefits increased to $68 billion in 2018, accounting for almost 14 percent of the hospitals' total expenses.[76] Examples of community benefits include financial assistance to patients in need and programs and services designed to meet specific health needs.

Contract pharmacies are also critical because more than half of 340B hospitals do not operate in-house retail pharmacies, and only one in five have their own specialty pharmacy.[77] Contract pharmacies are a necessary and beneficial component of the 340B program, allowing 340B providers to expand services to underserved populations.

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[74] *Id.*

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

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

[77] 340B Health Survey, *supra* note 15, at 4. Thirty-eight percent of disproportionate share hospitals, rural referral centers, and sole community hospitals, as well as 85 percent of critical access hospitals, do not operate their own retail pharmacies where patients can pick up their prescriptions. *Id.*

(b) *Lilly Understates the Impact of Drug Manufacturers' Policies on 340B Providers and Patients.*

340B providers are increasingly feeling the harmful impact of drug manufacturers' policies.[78] Between December 2021 and March 2022, when the number of manufacturers imposing restrictions increased from eight to 14, the financial impact on 340B hospitals more than doubled.[79] The median annualized impact on disproportionate share hospitals, rural referral centers, and sole community hospitals went from $1 million to $2.2 million, and 10 percent of those hospitals expect annual losses of $21 million or more.[80]

More than three-quarters of 340B hospitals reported that they will need to cut or adjust programs if these restrictions become permanent. This includes cuts to patient care services (80 percent), services in underserved areas (74 percent), and targeted programs to serve low-income patients that live in rural areas or are

[78] *E.g.*, Knox et al., *supra* note 11 ("[D]isproportionate share hospitals, rural referral centers, and sole community hospitals had lost on average 23% of their contract pharmacy revenue because of manufacturers' restrictions, while critical access hospitals had lost on average 39% [by late 2021]."); Gina Shaw, *Manufacturers' 340B Restrictions On Contract Pharmacies Draw Ire*, Pharmacy Practice News (May 10, 2021), https://www.pharmacypracticenews.com/Article/PrintArticle?articleID=63395 (outlining impacts on patients); *see also* HHS Br. 20 (noting 340B providers "would lose over $3.2 billion over the course of a full year.") (citing Suppl. App'x 132).

[79] 340B Health Survey, *supra* note 15, at 3.

[80] *Id.*

otherwise vulnerable (72 percent). A third of critical access hospitals reported that the restrictions put their hospitals at risk of closure.[81]

A recent survey shows that Lilly's policy of allowing 340B providers to use only a single contract pharmacy if the covered entity has no in-house pharmacy also imposes an impermissible burden on 340B hospitals and their patients, undermining the purpose of the 340B program. For example, 90 percent of hospitals surveyed reported that choosing one pharmacy location would limit the hospital's access to 340B discounts for eligible patients, and 54 percent reported concerns that patients would be forced to switch pharmacies, limiting the ability to flag drug interactions.[82]

3. *Lilly's Policy Increases the Burden on 340B Providers of Participating in the 340B Program, Undermining The 340B Program and Congress's Intent.*

By enacting then expanding the 340B program, Congress intentionally developed a regulatory scheme that drug manufacturers may not alter as they please. Yet Lilly's arguments—and policy—attempt to do just that. For example, "Lilly will deliver penny-priced insulin to multiple contract pharmacies as long as the covered entity agrees that *patients* will receive the full 340B discount [and] that no payer is billed for the insulin."[83] By requiring covered entities to give patients the full 340B

[81] *Id.* at 5.

[82] *Id.* at 7–8.

[83] Lilly Br. 15–16 (emphasis Lilly's).

discount, Lilly is not just requiring them to give up 100 percent of the intended benefit of the program; it is causing 340B providers to *lose* money, because there is a cost for dispensing the drug. This is the exact opposite of what Congress intended. Lilly may not usurp Congress's authority and refashion the program to require covered entities to use the 340B benefit how *Lilly* prescribes.

Moreover, Lilly briefly mentions that, "pending this appeal," the company will "permit 340B purchases through contract pharmacies if the covered entity agrees to furnish claims-level data associated with contract-pharmacy orders."[84] However, such a policy (also adopted by other companies) further undermines the 340B program by requiring certain 340B providers to limit the use of contract pharmacies or expend limited resources submitting sensitive claims data before receiving the 340B discounts to which they are entitled. Lilly claims that it will use the data "to monitor for and avoid duplicate discounts and to ensure the eligibility of certain contract pharmacy replenishment orders."[85] A recent GAO report, however, indicated that between 2012 and 2019, *only 23* of the 429 duplicate

[84] *Id.* at 24 n.7.

[85] Update to Eli Lilly and Company Contract Pharmacy Policy (Updated Policy) (Dec. 10, 2021), https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/340b/manf-letters/lilly-340b-announcement---updated-010321.pdf?la=en&hash=52F1C0625B00A6F28F4A5439CF834B343D185BCE.

discount audit findings related to contract pharmacies.[86] Moreover, state and federal laws effectively limit the use of 340B for Medicaid for most 340B hospitals.[87] In fact, 82 percent of 340B hospitals using contract pharmacies reported that they do not use contract pharmacies to dispense 340B drugs to Medicaid managed care patients, and only 80 of the 31,000 contract pharmacies used by covered entities involve the use of 340B drugs for Medicaid fee-for-service patients.[88] In any event, the data Lilly requires go far beyond what could potentially address duplicate discounts. Lilly is demanding from providers *all* contract pharmacy claims data for Lilly's products, not just Medicaid claims.[89]

For the 340B program to operate, *Amici* recognize and agree with HRSA's longstanding position that manufacturers are allowed to "request standard information."[90] But nothing about what Lilly and other companies are demanding of

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

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

[88] 340B Health Survey, *supra* note 15, at 8.

[89] *See* Updated Policy, *supra* note 85.

[90] Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,114 (May 13, 1994).

340B providers is standard,[91] and there is a significant difference between conditions that help make the 340B program possible and conditions that make it *harder* to participate in the program. The former furthers Congress's goals with the 340B program; the latter undermines and refashions the program to suit drug manufacturers' desires.

Covered entities have not in the past 30 years been required to provide this sensitive information to drug companies, and non-covered entities and covered entities using their own in-house pharmacy are *not* being asked to provide the data.[92] And HHS has consistently advised drug companies that they may not demand the information Lilly is demanding. In 1994, HHS notified pharmaceutical manufacturers that they "may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective"[93] and that "[m]anufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program."[94] The conditions Lilly's interim policy

[91] *See also* HHS Br. 38–39.

[92] *See* Updated Policy, *supra* note 85.

[93] 59 Fed. Reg. at 25,111–12.

[94] *Id.* at 25,1113; *see also* HHS Br. 45–46.

imposes on certain 340B providers, including *Amici's* members, are plainly disallowed.

CONCLUSION

For the foregoing reasons and those outlined in HHS's brief, the district court's judgment should be reversed insofar as it vacated the May 17, 2021 enforcement letter and should otherwise be affirmed.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 1, 2022, I caused a copy of this Brief of American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and Children's Hospital Association as *Amici Curiae* in Support of Appellees/Cross-Appellants to be served electronically via the Court's CM/ECF system on all counsel registered to receive electronic notices.

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