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,
No. 21-81 (Barker, J.).

PRINCIPAL AND RESPONSE BRIEF FOR THE FEDERAL DEFENDANTS

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INTRODUCTION

Under Section 340B of the Public Health Service Act, as amended by the Patient Protection and Affordable Care Act (ACA or Affordable Care Act), drug manufacturers that choose to be reimbursed under Medicaid or Medicare Part B are subject to an unqualified statutory requirement. They must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). Congress considered but declined to enact a provision that would have confined these price discounts to covered entities that dispense drugs through in-house pharmacies. From the inception of the 340B Program, covered entities have relied on outside pharmacies (known as "contract pharmacies") to dispense the drugs purchased at the 340B price. 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996).

Dissatisfied with the terms of the 340B Program, drug manufacturers recently began adding new conditions of their own. Beginning in 2020, several of the world's largest manufacturers announced that they would no longer offer drugs to covered entities at or below the ceiling price when the covered entity relies on one or more contract pharmacies to dispense the drugs. The stated purpose of the new policies is to prevent duplicative discounts and drug diversion.

The Department of Health and Human Services (HHS) correctly informed Eli Lilly and other manufacturers that their new policies violate the 340B statute and are grounds for civil monetary penalties. Contrary to Eli Lilly's premise, Congress did not allow drug manufacturers to add provisos to their obligations under the 340B statute. That would be akin to letting the fox guard the henhouse. Congress was aware of the use of outside pharmacies, and chose not to restrict covered entities' use of contract pharmacies or allow drug manufacturers to impose such restrictions unilaterally.

The district court correctly recognized that the 340B statute "does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing * * * such that covered entities are prevented from accessing 340B pricing." SA46-47. The court was mistaken, however, in vacating HHS's enforcement letters and concluding that HHS had made a "change in position regarding its authority to enforce potential violations of the 340B statute." SA52. HHS has consistently explained, from the inception of the statute, that drug manufacturers may not impose unilateral conditions on covered entities that would prevent them from accessing the statutorily discounted price. And HHS has consistently recognized that its interpretive guidance is nonbinding: the

agency's express authority to impose penalties or take other enforcement actions must be grounded in a violation of the statute alone, as it was here.

STATEMENT OF JURISDICTION

Plaintffs-Appellants' jurisdictional statement is correct, but not complete to the extent that further explanation is necessary to explain this Court's jurisdiction over the federal defendants' cross-appeal. The district court entered partial final judgment on October 29, 2021. SA66. Plaintiffs filed a notice of appeal on November 10, 2021 (Dkt. No. 146), and defendants filed a cross-appeal on December 28, 2021 (Dkt. No. 151), which was within the 60 day period allowed under Federal Rule of Appellate Procedure 4(a)(1)(B). As plaintiffs note (Br. 4), this Court issued a limited remand for the district court to issue an amended judgment, which the district court issued on April 14, 2022. SA70-71. This Court explained that no additional notices of appeal were necessary from that amended judgment. Order, *Eli Lilly & Co. v. Becerra*, No. 21-3405 (7th Cir. Apr. 7, 2022).

STATEMENT OF THE ISSUES

Under Section 340B of the Public Health Service Act, as amended by the Affordable Care Act, drug manufacturers that participate in Medicaid and Medicare Part B shall "offer each covered entity covered outpatient

drugs for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). The questions presented are:

1. Whether the district court correctly held that the statute does not allow drug manufacturers to refuse to offer this price discount to a covered entity that uses one or more contract pharmacies to dispense the drugs that the covered entity purchases.

2. Whether the district court erred in vacating and remanding HHS's enforcement letter as arbitrary and capricious.

STATEMENT OF THE CASE

I. Statutory Background And Agency Guidance

A. The 340B Program

This appeal concerns the obligations of drug manufacturers that participate in Medicaid and Medicare Part B, and which accordingly receive reimbursement for their products under those programs. Congress directed that such manufacturers must comply with Section 340B of the Public Health Service Act, which was enacted in 1992 and codified at 42 U.S.C. § 256b. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992); *see also* 42 U.S.C. § 1396r-8(a)(1), (5) (cross-referencing 42 U.S.C. § 256b).

Under Section 340B, participating manufacturers "must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*,

563 U.S. 110, 115 (2011); *see* 42 U.S.C. § 256b(a)(1), (3), (4). Covered entities include, for example, black lung clinics, federally-qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, and other federally funded health care entities, 42 U.S.C. § 256b(a)(4), which "generally serve low-income or rural communities," *American Hospital Ass'n v. Becerra*, --- S. Ct. ---, 2022 WL 2135490, at *2 (June 15, 2022). The 340B Program enables covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992). Covered entities can use those cost savings "to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize[,] and expand services and formularies." 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996).

From the outset, Section 340B imposed obligations on both drug manufacturers and covered entities. With respect to manufacturers, the statute specified that the Secretary of Health and Human Services shall "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid * * * to the manufacturer for covered outpatient drugs * * * purchased by a covered

entity * * * does not exceed" a specified ceiling price. 42 U.S.C. § 256b(a)(1). The statute thus required manufacturers to sell drugs to covered entities at discounted prices.

With respect to covered entities, the statute prohibited requests for duplicate discounts and the diversion of drugs purchased under the 340B Program. To prevent duplicative discounts, the statute specified that a covered entity shall not request a discount for a drug that is already subject to a separate Medicaid rebate requirement. 42 U.S.C. § 256b(a)(5)(A). To prevent diversion, the statute specified that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

To promote transparency, the statute required a covered entity to permit both the Secretary and the manufacturer to audit the covered entity's records. 42 U.S.C. § 256b(a)(5)(C). The statute further provided that, if the Secretary finds that a covered entity is in violation of a requirement, the covered entity shall be liable to the manufacturer for the amount equal to the discount. *Id.* § 256b(a)(5)(D).

B. Covered entities' use of contract pharmacies to dispense drugs purchased under the 340B Program

From the inception of the 340B Program, many covered entities relied on outside pharmacies, which came to be known as "contract pharmacies," to dispense to their patients the drugs purchased at the discounted prices. Indeed, when the program was first implemented, only 5 percent (500 of 11,500) of covered entities had in-house pharmacies. *See* 61 Fed. Reg. at 43550.

When Congress was considering the legislation that established the 340B Program, it considered a bill that would have limited the discounts to drugs "purchased *and dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. Rep. No. 102-259, at 2 (1992) (emphasis added) (considering S. 1729, 102d Cong. (1992)). The emphasized language would have prevented covered entities from using outside pharmacies to dispense the drugs purchased at the discounted prices. Congress did not enact that restriction, however. Instead, Congress broadly required manufacturers to provide discounted prices for "drugs * * * purchased by a covered entity," regardless of whether covered entities used in-house or outside pharmacies to dispense the drugs that the covered entities purchased. 42 U.S.C. § 256b(a)(1).

Congress did not authorize HHS to restrict the use of contract pharmacies by covered entities. Congress gave HHS rulemaking authority with respect to only limited aspects of the 340B Program that do not include contract-pharmacy arrangements. *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464, at *34 (D.N.J. 2021), *appeals pending*, Nos. 21-3168, 21-3167, 21-3379, 21-3380 (3d Cir.). However, HHS periodically issued nonbinding guidelines on that topic. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties").

HHS's 1996 guidelines explained that a covered entity's use of a contract pharmacy was permissible and did not relieve a manufacturer of its obligation to sell the drugs at the discounted price. 61 Fed. Reg. at 43549-50. HHS noted that "[i]t would defeat the purpose of the 340B Program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B Program," because covered entities "would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.*

The 1996 guidelines advised that a covered entity contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. 61 Fed. Reg. at 43555. Starting in 2001, however, HHS began a pilot program under which covered entities used multiple contract pharmacies to increase their patients' access to 340B drugs. 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007). The pilot program's participants were subject to annual, independent audits "for drug diversion and duplicative discounts." *Id.* Based on the results of six years of auditing from the pilot program, HHS proposed new guidelines in 2007 under which covered entities could use multiple contract pharmacies "to provide broader access to 340B discounted drugs to eligible patient[s]." 72 Fed. Reg. at 1540. At the same time, HHS underscored the "particular importance" of the "requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute." *Id.*

After considering public comments, HHS finalized the proposed guidelines in 2010, shortly before Congress enacted the Affordable Care Act. 75 Fed. Reg. 10272 (Mar. 5, 2010). The 2010 guidelines indicated that covered entities could use multiple contract pharmacies as long as the covered entities complied with guidelines to prevent diversion and

duplicate discounts and adhered to policies regarding the definition of a "patient" of a covered entity. *Id.* at 10273.

C. The Affordable Care Act's amendments to the 340B Program

As part of the Affordable Care Act, Congress amended the 340B statute in a subtitle designed to provide "More Affordable Medicines for Children and Underserved Communities." Pub. L. No. 111-148, Title VII, subtitle B, 124 Stat. 119, 821 (2010).

Section 7101 of the Affordable Care Act, entitled "Expanded Participation In 340B Program," expanded the list of "covered entities" eligible to participate in the 340B Program. 124 Stat. at 821-22 (amending 42 U.S.C. § 256b(a)(4)). It added certain children's hospitals, critical access hospitals, rural referral centers, and sole community hospitals to the list of facilities that may purchase drugs from manufacturers at discounted prices.

Section 7102, entitled "Improvements To 340B Program Integrity," added a series of new provisions designed to improve compliance with 340B Program requirements by both drug manufacturers and covered entities. 124 Stat. at 823-27 (amending 42 U.S.C. § 256b(d)).

First, Congress directed the Secretary to improve oversight of manufacturers in various specified ways and authorized the Secretary to impose sanctions against manufacturers in the form of civil monetary

penalties, not to exceed $5,000 for each instance of overcharging a covered entity. 42 U.S.C. § 256b(d)(1).[1]

Second, Congress directed the Secretary to improve covered entities' compliance with the statute's prohibitions on diversion and duplicate discounts in various specified ways, such as by requiring covered entities to regularly update information on an HHS website. 42 U.S.C. § 256b(d)(2)(b). In addition, Congress significantly increased the penalties if covered entities violate program requirements. Congress authorized the Secretary to impose sanctions against covered entities—including monetary penalties, removal from the 340B Program, and referral to other federal agencies for appropriate action—for diversion, duplicate discounts, or other violations of program requirements. *Id.* § 256b(d)(2)(B)(v).

Third, Congress directed HHS to "promulgate regulations to establish and implement an administrative process for the resolution of" covered entities' claims that they have been overcharged and manufacturers' claims that covered entities violated certain statutory requirements. 124 Stat. at 826-27 (enacting 42 U.S.C. § 256b(d)(3)). Congress specified that the regulations should: (1) designate an HHS official or HHS decision-making

[1] *See also* 87 Fed. Reg. 15100, 15105 (Mar. 17, 2022) (adjusting penalty for inflation to $6,323).

body to be responsible for reviewing such claims; (2) establish deadlines and procedures as necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously; (3) establish procedures for covered entities to obtain relevant information from the manufacturer or third parties; (4) require that a manufacturer conduct an audit of a covered entity pursuant to 42 U.S.C. § 256b(d)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity; and (5) permit the consolidation or joinder of claims by multiple manufacturers against the same covered entity and by multiple covered entities against the same manufacturer. 42 U.S.C. § 256b(d)(3)(B)(i)-(vi). Congress provided that the administrative resolution of a claim or claims under the regulations shall be a final agency decision that is binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction. *Id.* § 256b(d)(3)(C).

The ACA's amendments to Section 340B did not restrict covered entities' longstanding use of contract pharmacies, nor did Congress authorize drug manufacturers or HHS to impose such a restriction. On the contrary, the ACA's amendments specified, without qualification, that the Secretary's agreement with a drug manufacturer "shall require that the manufacturer offer each covered entity covered outpatient drugs for

purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). *Accord* 59 Fed. Reg. 25110, 25111-12 (May 13, 1994) ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").

Section 7103 directed the Government Accountability Office (GAO) to report to Congress with recommendations for further improvements to the 340B Program. 124 Stat. at 827-28.

II. Factual Background

A. GAO reports on the growth of the 340B Program

In the decade since the Affordable Care Act's amendments, the GAO has submitted a series of reports to Congress on the 340B Program. These reports describe significant growth in the 340B Program and attribute that growth to a combination of factors, including the Affordable Care Act's expansion of the list of covered entities that can participate in the 340B Program, the enrollment of more facilities in the 340B Program, and covered entities' increased use of contract pharmacies to distribute the drugs they purchase.

The GAO reported that participation in the 340B Program grew from nearly 9,700 covered entities in 2010 to 12,700 covered entities in 2020. *See* GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms*

to Help Ensure Compliance with 340B Requirements 2 (2020).[2] The GAO reported that, between 2010 and 2017, the number of contract pharmacies increased from about 1,300 to about 20,000. *See* GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (2018).[3] Elaborating on the use of contract pharmacies, the GAO reported that, as of 2017, about one-third of the covered entities in the 340B Program used contract pharmacies, but the extent varied by type of entity. *See id.* at 16. For example, a higher percentage of hospitals (69.3%) used at least one contract pharmacy compared to federal grantees (22.8%). *See id.* And among the six types of hospitals eligible to participate in the 340B Program, the percentage that used at least one contract pharmacy ranged from 39.2% of children's hospitals to 74.1% of critical access hospitals. *See id.* Among the 10 types of federal grantees, the percentage with at least one contract pharmacy ranged from 3.9% of family planning clinics to 75.2% of federally qualified health centers. *See id.*

The GAO made a number of recommendations to improve HHS's oversight of contract-pharmacy arrangements, while at the same time

[2] https://www.gao.gov/products/gao-21-107
[3] https://www.gao.gov/products/gao-18-480

recognizing that HHS has limited authority to issue regulations governing the 340B Program. *See* GAO-18-480, at 47. For example, the GAO recommended that HHS require covered entities to register contract pharmacies for each site of the entity for which a contract exists. *See id.* at 46. The GAO did not recommend that HHS limit the number of contract pharmacies that a covered entity may use, however, nor did the GAO suggest that drug manufacturers themselves may impose restrictions on covered entities' use of contract pharmacies.

B. Drug manufacturers' new policies restricting covered entities' use of contract pharmacies

Beginning in 2020, a number of the country's largest drug manufacturers announced that they would cease shipping discounted drugs to contract pharmacies used by covered entities, unless various conditions were met. The claimed objective of these new policies is to prevent duplicative discounting and drug diversion.

The details of these policies differ by manufacturer. For example, plaintiffs Eli Lilly and Lilly USA (collectively Eli Lilly), informed HHS that it will "discontinue our practice of voluntarily honoring requests for 340B" prices for covered entities that are purchasing covered drugs to be dispensed by contract pharmacies. Suppl. App'x 129. Eli Lilly stated that the company might "approve[] an exception" to that policy if the covered

entity lacks an in-house pharmacy, *id.*, in which case the covered entity would be required "to submit additional paperwork designating a single contract pharmacy for delivery and [] engage in a process through which Lilly determines the eligibility of that pharmacy," SA12.[4] Eli Lilly stated that it would continue shipping its insulin products to contract pharmacies at the 340B price, but only if (1) the covered entity retains none of the savings and charges no dispensing or administrative fee (2) no insurer or payer is billed, and (3) the covered entity "provides claim-level detail" to Eli Lilly to "validate that the foregoing conditions have been satisfied." Suppl. App'x 130-31.

Drug manufacturer Novo Nordisk will not provide the 340B discounted price unless the covered hospital designates a single contract pharmacy, or if Novo determines "in its discretion" that the contract pharmacy poses a lesser risk of abuse to the 340B Program. *Sanofi-Aventis*, 2021 WL 5150464, at *5. Sanofi-Aventis will not provide discounted prices unless a covered entity uses an in-house pharmacy, has no in-house pharmacy and uses only a single contract pharmacy, or registers with and provides claims-level data to a third-party data-sharing

[4] In its complaint, Eli Lilly states that it will also ship 340B drugs to contract pharmacies wholly owned by covered entities. Dkt. No. 125, ¶ 80.

platform designated by Sanofi. *Id.* Novartis Pharmaceuticals will not provide discounted prices unless the covered entity is a federal grantee (as distinct from a hospital) or if the contract pharmacy is within 40 miles of the covered entity. *Novartis Pharm. Corp. v. Espinosa*, 2021 WL 5161783, at *3 (D.D.C. Nov. 5, 2021), *appeals pending*, Nos. 21-5299, 21-5304 (D.C. Cir.). United Therapeutics, AstraZeneca, and other manufacturers have adopted similar policies. *See id.* at *4; *see also AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587, at *1 (D. Del. Feb. 16, 2022), *appeal pending*, No. 22-1676 (3d Cir.).

As a consequence of these policies, numerous covered entities complained to HHS that they could no longer obtain eligible drugs manufacturered by Eli Lilly at the 340B discounted prices to dispense to their patients through contract pharmacies. For example, the organizations AIDS Response Effort and AIDS Support Group of Cape Cod notified HHS that they could no longer obtain cancer medications manufactured by Eli Lilly at the 340B price. Suppl. App'x 12-17, 21-29. HHS received similar complaints that covered entities could no longer obtain diabetes medications, insulin, and other medications manufactured by Eli Lilly at the 340B price. Suppl. App'x 30-107. When covered entities attempted to purchase Eli Lilly products at the 340B price, they were charged wholesale

prices higher than the statutory discounted price. *See, e.g.*, Suppl. App'x 110 (explaining that the covered entity was "charged [wholesale] price for the purchases" of covered 340B medications after Eli Lilly's new policy took effect).

Covered entities informed HHS that the manufacturers' new policies impair the covered entities' ability to serve their patients. For example, one federally funded health center, Medical Associates Plus, explained that its in-house pharmacies could only serve a minority of its 25,000 patients, who are a "medically underserved population." Suppl. App'x 113-14. It explained that most of its clinical locations do not have an in-house pharmacy, and those that do are only open during work-hours, making it difficult for many patients to access them. *Id.* The center explained that it "depends on its 340B Program savings and revenue to help support approximately 41% of" its expenses not covered by federal grants, and that the new policies will cause a "significant financial loss" that "will also result in reduction in other clinical and/or patient services." Suppl. App'x 116. . *See also* Suppl. App'x 117-21 (covered entity that serves thousands of patients across a 10,000 square mile area, including Michigan's upper peninsula, explains that manufacturers' policies will "significantly and irreparably harm[]" its patients).

Another federally funded health center, North Country HealthCare, informed HHS that it uses dozens of contract pharmacy locations to dispense needed medications to tens of thousands of its patients across northern Arizona. Suppl. App'x 122-24. Without contract pharmacies, many of the center's patients would have to travel over a hundred miles each way to reach one of the center's locations that operates an in-house pharmacy. Suppl. App'x 125. Illustrating its concern, the center noted that this travel was not realistically feasible for one of its uninsured diabetic patients, who was located "approximately 280 miles from our closest in-house pharmacy." Suppl. App'x 127. Starting in October 2020, that patient could no longer access Sanofi's insulin medication at his contract pharmacy. *Id.* Other insulin options, manufactured by Novartis and Eli Lilly—which had adopted similar policies—were "also not available at 340B pricing." *Id.* The center described the consequences in stark terms: "This patient's body is unable to make insulin. Without it he will die." *Id.* The center emphasized that many of its other patients "are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications." *Id.*

In all, HHS received thousands of pages from covered entities documenting their inability to receive and dispense medications at the

340B price after the various manufacturers implemented their new policies. *See generally* Suppl. App'x 3-6. That included documentation that covered entities could no longer order 340B drugs—including insulin—from Eli Lilly "due to the removal of the 340B pricing by the manufacturer," or that they would be charged above the statutory ceiling price for those drugs. Suppl. App'x 68, 73, 80. The new policies caused a precipitous decline in drug sales at the 340B prices. For example, in the month before announcing its new policy, Eli Lilly had sold 1.55 million units of drugs at the 340B prices—two months later, that number dropped by over 89% to just 170,000 units. Supp. App'x 133. Covered entities lost tens of millions in savings on Eli Lilly products that they had obtained under the 340B Program. In the month before Eli Lilly's new policy took effect, covered entities had saved $67.5 million—two months later, they only saved $3.8 million, losing almost 95% of the previous total savings. Supp. App'x 135. Based on such data, HHS calculated that covered entities had lost hundreds of millions in savings over just the few months after the new policies took effect, and would lose over $3.2 billion over the course of a full year. Supp. App'x 132.

C. HHS's enforcement actions

In December 2020, HHS's general counsel issued an advisory opinion stating that manufacturers are "obligated to deliver [their] covered

outpatient drugs to those contract pharmacies" used by covered entities "and to charge the covered entity no more than the 340B ceiling price for those drugs." App'x 5. However, HHS voluntarily withdrew that advisory opinion "in the interests of avoiding confusion and unnecessary litigation" after a district court declared that it rested on a statutory interpretation that was permissible but not compelled by the statute's text. *See* SA22; *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 61-62 (D. Del. 2021).

In May 2021, HHS took the enforcement action at issue here. HHS sent Eli Lilly and other manufacturers similarly worded letters notifying them that their new policies were in violation of 42 U.S.C. § 256b and resulted in prices above the ceiling price of the 340B Program. HHS's letter to Eli Lilly explained that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." App'x 2. The letter recognized that the manufacturer's claimed rationale for its new restrictions is to prevent diversion and duplicate discounts, and the letter explained that "[t]he 340B statute provides a mechanism by which a manufacturer can address these concerns." App'x 3. "Specifically, the manufacturer must (1) conduct an

audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A)" of the Public Health Service Act. *Id.* The letter directed the manufacturer to immediately resume offering its drugs at discounted prices to covered entities through their contract pharmacy arrangements, and to credit or refund covered entities for all overcharges. *Id.* The letter warned that, if the manufacturer continued its policy, HHS may seek civil monetary penalties of up to $5,000 for each instance of overcharging. *Id.* (citing 42 U.S.C. § 256b(d)(1)(B)(ii)).

III. The District Court's Rulings

In this district court action, Eli Lilly challenged HHS's enforcement letter and advisory opinion. SA2. The district court granted in part and denied in part the parties' cross-motions for summary judgment.

A. The district court's interpretation of the 340B statute

The district court agreed with HHS that "Congress in no way intended to allow regulated entities to unilaterally erect barriers," like Eli Lilly's new policies, which "frustrate the overarching purpose of the [340B] program." SA43. Accordingly, "drug manufacturers may not usurp [Congress's] role through unilateral extra-statutory restrictions." SA49.

The district court rejected Eli Lilly's argument that, because the 340B

statute does not refer explicitly to contract pharmacies, the statute leaves drug manufacturers free to refuse to offer the 340B discount to covered entities that rely on contract pharmacies to dispense the drugs purchased. SA41. The court explained that "Congress clearly utilized broad, generalized language" in establishing the manufacturers' duty to offer the price discount, SA45, and that "there is no such thing as a canon of donut holes, in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception." SA45-46 (quotation marks omitted). The court explained that, "since its enactment, the 340B statute has required drug manufacturers to" honor their obligations "as to the amount covered entities can be required to pay for 340B drugs, which cannot exceed the ceiling prices." SA46. Eli Lilly's policy that denies those prices "based solely on delivery location or dispensing mechanism * * * directly conflicts with the statutory requirement otherwise." *Id.*

The court underscored the practical impediments that Eli Lilly's policy imposes on covered entities. Because many 340B drugs are "controlled substances, they can be shipped only to locations that provide the proper legal infrastructure, including state licensing, DEA registration, staff pharmacists, etc., to accept" and dispense the medications. SA45 n.13.

The court noted that many covered entities lack "the capacity or authority to handle their own dispensing or to take delivery of Lilly's medications." *Id.* And even for those covered entities that may have an in-house pharmacy or a single contract pharmacy, it may be "impossible for all patients to fill their prescriptions each month" at those locations, especially for covered entities that "serve vulnerable populations scattered over large geographic areas." *Id.*

The court accordingly concluded that "Congress's use of broad language in enacting this statute * * * does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing to a particular delivery location of their choosing." SA46-47. Thus, the "most reasonable interpretation of the 340B statute" does not permit manufacturers to "impose unilateral restrictions" that would "frustrate Congress's manifest purpose in enacting the statute." SA47 (quotation marks omitted).

The court rejected Eli Lilly's other arguments in support of its interpretation. To the extent that Eli Lilly claimed that its policy was motivated by a desire to prevent violations of the 340B Program, the court noted that "Congress explicitly required manufacturers to address diversion and duplicate-discounting concerns" as part of the 340B statute's process

for administrative dispute resolution. SA47 n.14 (citing 42 U.S.C. § 256b(d)(3)(B)(iv)). And while contract pharmacy arrangements had grown in recent years, the court explained that Congress knew that covered entities relied on outside pharmacies "even at the time of the statute's enactment," but still chose to "use broad language to define obligations and entitlements under the statute." SA48. The court recognized that Congress was free to address these and other issues involving contract pharmacies—but emphasized that "drug manufacturers may not usurp" Congress's prerogative "through unilateral extra-statutory restrictions." SA49. Consistent with this analysis, the court held that the enforcement letter was "not only a permissible construction" of the statute, but also "best align[ed] with congressional intent." *Id.*[5]

B. The district court's vacatur of the enforcement letters and remand to HHS

The district court nonetheless vacated HHS's enforcement letter because the court believed that the enforcement action was premised on violations of the agency's interpretive guidance rather than on violations of the statute itself. Based on that assumption, the court declared that HHS

[5] The district court also held that Eli Lilly's challenge to the HHS advisory opinion was not moot, but concluded that remand to the agency was unnecessary since HHS had already withdrawn the advisory opinion. SA29-34.

had insufficiently explained a change of position that the court attributed to HHS, *i.e.*, why HHS now (ostensibly) believed that its guidance was enforceable when HHS had previously described the guidance as "non-binding" and recognized that it did not have authority "to issue enforceable regulations regarding contract pharmacy arrangements." SA53-54. The court vacated and remanded the enforcement letters to HHS for further explanation of the ostensible change in position. SA57-58.

The court rejected Eli Lilly's other claims. The court held that the enforcement letter was not subject to the Administrative Procedure Act's notice-and-comment requirements, SA36-37, and did not constitute a Taking or an unconstitutional condition on the receipt of federal benefits, SA50-52.

SUMMARY OF ARGUMENT

Drug manufacturers that wish to be reimbursed under the federally funded Medicaid and Medicare Part B programs are subject to a separate statutory requirement. Pursuant to Section 340B of the Public Health Service Act, such manufacturers must offer their drugs at discounted prices to specified "covered entities." When Congress enacted the Section 340B Program, it considered a bill that would have confined these price discounts to covered entities that dispense drugs through in-house pharmacies.

Congress declined to enact that bill, however, and covered entities have since the inception of the 340B Program relied on outside pharmacies (known as "contract pharmacies") to dispense the discounted drugs.

In 2020, drug manufacturers including Eli Lilly announced policies that dramatically curtailed the manufacturers' obligations under the 340B Program. Although the details of these policies vary, the manufacturers generally refuse to ship discounted drugs to covered entities' contract pharmacies unless specified conditions are met. For example, Eli Lilly will not provide discounted prices unless the covered entity wholly owns the pharmacy or designates only a single contract pharmacy subject to Eli Lilly's approval. SA12. As a consequence of the manufacturers' new policies, drug sales at the discounted prices plummeted. HHS correctly informed Eli Lilly and other manufacturers that their new policies violate the 340B statute and are grounds for civil monetary penalties.

I. The district court correctly held that drug manufacturers may not "unilaterally impose a wide variety of restrictions" that "control the availability of their 340B pricing to a particular delivery location of their choosing." SA45-47. As the court explained in its comprehensive opinion, that conclusion flows from the text, structure, history, and purpose of the 340B statute. Eli Lilly claims that its new policy is meant only to prevent

drug diversion. But Congress specifically addressed that concern through calibrated program-integrity provisions. Congress did not, however, restrict covered entities' use of contract pharmacies or allow drug manufacturers to impose such restrictions.

II. Although the district court correctly held that drug manufacturers cannot restrict covered entities' use of contract pharmacies, the court erred in vacating HHS's enforcement letter and remanding to HHS for further explanation. The remand and vacatur were based on an incorrect premise: that the enforcement letter was based on violations of HHS's guidance rather than on violations of the statute itself. HHS has consistently recognized that its guidance is non-binding; the enforcement letter at issue here rested on violations of the statute alone.

STANDARD OF REVIEW

The district court's summary judgment ruling is reviewed de novo. *Talignani v. United States*, 26 F.4th 379, 381 (7th Cir. 2022). Agency action is reviewed to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

ARGUMENT

I. The 340B Statute Requires Manufacturers To Sell Drugs To Covered Entities At The Discounted Price, Regardless Of Whether Covered Entities Use Contract Pharmacies To Dispense The Drugs Purchased

A. Drug Manufacturers Cannot Unilaterally Add Provisos To Their Statutory Obligations

Under Section 340B of the Public Health Service Act (42 U.S.C. § 256b), "manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011). Since the inception of the 340B Program, the statute has set forth the manufacturer's obligation in broad terms, requiring the Secretary to enter into an agreement with the manufacturer "under which the amount required to be paid * * * to the manufacturer for covered outpatient drugs * * * purchased by a covered entity * * * does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1). Likewise, when Congress expanded the 340B Program as part of the Affordable Care Act, it specified—without qualification—that the Secretary's agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* The bottom line requirement is straightforward: if drug manufacturers want to be

reimbursed for their drugs by the federally funded Medicaid and Medicare Part B programs, they also must sell their drugs to covered entities at a discounted price.

Contrary to Eli Lilly's premise, drug manufacturers cannot add provisos to that straightforward statutory requirement. Congress's choice to use "broad language in enacting this statute and specifically omitting any mention of where 340B drugs are to be delivered does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing" based on how the drugs are received and dispensed. SA46. There is "no 'such thing as a "canon of donut holes," in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception.'" SA45-46 (quoting *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020)). Instead, when "Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *White v. United Airlines, Inc.*, 987 F.3d 616, 621 (7th Cir. 2021).

Put another way, Congress created the 340B Program to ensure that covered entities could obtain discounted drugs under the conditions that *Congress* established. Accordingly, the statutory scheme must be construed to ensure that "everything necessary to making it effectual, or

requisite to attaining the end, is implied." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 193 (2012) (*Reading Law*). That necessarily precludes manufacturers from imposing their own conditions that would prohibit covered entities from otherwise obtaining drugs at a discounted price. Accordingly, Eli Lilly "may not unilaterally create and establish policies—whatever the underlying rationale"—that "dictate how many contract pharmacies a covered entity may designate to receive delivery of covered drugs." *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464, at *43 (D.N.J. 2021).

"Practical considerations strongly support [this] reading" of the statute, whereas Eli Lilly's interpretation "would frustrate Congress' manifest purpose." *United States v. Hayes*, 555 U.S. 415, 426-27 (2009). Congress established the 340B Program to provide covered entities with drugs at a discounted price, at a time when the vast majority of covered entities dispensed their drugs to patients through outside pharmacies. Yet under Eli Lilly's reading, drug manufacturers could have refused to provide the discounted price to all of the covered entities that relied on those pharmacies to distribute the drugs purchased. Under that interpretation, Section 340B "would have been 'a dead letter' * * * from the very moment

of its enactment," *id.* at 427, because manufacturers could have eliminated their obligation to sell discounted drugs to 95% of covered entities, *see* 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (explaining that only 500 of 11,500 covered entities had in-house pharmacies when the 340B Program was first implemented).

Such an interpretation is incompatible with basic tenets of statutory construction. The Supreme Court has repeatedly emphasized that it is a court's "job to avoid rendering what Congress has plainly done * * * devoid of reason and effect." *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 217-18 (2002). Accordingly, courts construe statutes to ensure that "a text's manifest purpose is furthered, not hindered." *Reading Law* 63 (collecting cases).

As the district court recognized, these pharmacy arrangements were "known to Congress as a common business practice" when Congress enacted the 340B statute. SA48. Contemporaneously with Congress's original consideration of the statute, Congress considered a bill that would have limited the discounts to drugs "purchased and *dispensed by, or under a contract entered into for on-site pharmacy services with*," a covered entity. S. 1729, at 9, 102d Cong. (Mar. 3, 1992) (emphasis added). But Congress did not enact that limit on the mechanism for dispensing drugs.

Instead, Congress made the discounts available to drugs "purchased by a covered entity," regardless of whether drugs are dispensed by in-house or contract pharmacies. 42 U.S.C. § 256b(a)(1); *accord Sanofi*, 2021 WL 5150464, at *37 (holding that "[b]ecause Congress *eliminated* a clear limitation on contract pharmacy arrangements * * * it likely did not intend *to prohibit* them altogether").

Eli Lilly nonetheless contends that because Section 340B has no *explicit* prohibition on adding conditions to the discounted price, Congress has implicitly permitted it to add on those conditions. But that "inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." *Burns v. United States*, 501 U.S. 129, 136 (1991) (holding that district court was required by the Federal Rules of Criminal Procedure to provide notice to criminal defendant of an upward departure from the sentence guidelines, even though that requirement was not made explicit in the rules) (abrogated on other grounds). Moreover, "the mere possibility of clearer phrasing cannot defeat the most natural reading of a statute; if it could (with all due respect to Congress), we would interpret a great many statutes differently than we do." *Caraco Pharm. Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

On Eli Lilly's logic, a drug manufacturer could offer their drugs to covered entities at the discounted price—but only if the covered entity agreed to purchase the manufacturer's drugs whenever possible, and never a competitor's. There is nothing in the 340B statute that explicitly prohibits such a unilateral condition. But the fact that Congress did not directly bar such a self-serving business practice does not mean that Congress *permitted* it. A contrary conclusion "not only would defy common sense, but also would defeat Congress' stated objective" of ensuring that covered entities could consistently—and without hindrance—obtain drugs at a discounted price. *See Quarles v. United States*, 139 S. Ct. 1872, 1879 (2019) ("We should not lightly conclude that Congress enacted a self-defeating statute."). As Eli Lilly acknowledges (at 31-32), its logic likewise would allow it to unilaterally force every covered entity in the country to pick up all their 340B drugs from Eli Lilly's headquarters in Indianapolis. Congress plainly did not allow drug manufacturers to undermine the 340B Program by erecting such barriers.

The district court thus correctly held that the "fairest and most reasonable interpretation of the 340B statute" prohibits Eli Lilly and other manufacturers from "impos[ing] unilateral restrictions on the distribution of the drugs that would frustrate Congress' manifest purpose." SA47

(quotation marks omitted); *accord Sanofi*, 2021 WL 5150464, at *43 ("Congress' use of general language * * * does not permit Plaintiffs to take specific actions, like their policies, just because those actions are not expressly prohibited by the broad text.").

B. Drug Manufacturers Cannot Supplement The Statute's Mechanisms For Preventing Diversion And Duplicative Discounts

Eli Lilly claims that its new policy is intended only to prevent the diversion of drugs that the 340B statute itself prohibits. Br. 34-35. But Congress specified in the statute the means to be used to prevent diversion and duplicative discounts.

From the inception of the 340B Program, Congress provided that covered entities "shall not resell or otherwise transfer" the discounted drug to non-patients, and provided that covered entities "shall not request payment" that would result in a duplicate discount in the form of a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A)-(B). Congress also mandated that covered entities must permit both HHS and drug manufacturers to conduct audits of the entity's records "that directly pertain to" these requirements. *Id.* § 256b(a)(5)(C). And Congress provided that a covered entity "shall be liable to the manufacturer" for the discount if HHS

determined, after notice and a hearing, that a covered entity had committed a statutory violation. *Id.* § 256b(a)(5)(D).

Congress expanded these measures when it amended the statute as part of the Affordable Care Act. Congress enacted a series of provisions explicitly designed to enhance program integrity, including provisions that guard against diversion and duplicative discounts and authorize substantial penalties for noncompliance by covered entities.

For example, Congress directed HHS to develop procedures by which the agency would obtain and verify information from covered entities on a regular basis to ensure their compliance with the 340B Program. 42 U.S.C. § 256b(d)(2)(B)(i)-(ii). Congress also required HHS to develop "more detailed guidance describing methodologies and options" to avoid duplicate Medicaid discounts, and to establish a "single, universal, and standardized" system for identifying covered entities so that HHS, manufacturers, and others could confirm it and "facilitate the ordering, purchasing, and delivery of covered outpatient drugs * * * including the processing of chargebacks for such drugs." *Id.* § 256b(d)(2)(B)(iii)-(iv). And Congress further provided that covered entities would face significant sanctions for intentional violations of the 340B Program, including monetary payments to affected manufacturers, disqualification from the 340B Program for

"systematic and egregious" violations, and potential referral to various federal agencies for additional measures. *Id.* § 256b(d)(2)(B)(v).

Congress thus addressed the risks of diversion and duplicative discounts through a calibrated statutory scheme. Congress did not, as Eli Lilly contends, implicitly authorize manufacturers to augment these carefully crafted provisions with policies that undermine the ability of covered entities to provide patients with 340B drugs through their contract pharmacies. *See supra* pp.19-20 (describing the precipitous drop in discounted sales that the manufacturers' new policies caused). To the contrary, Congress enacted numerous measures to ensure that manufacturers sold their drugs to covered entities at the ceiling price, that manufacturers would provide refunds when they overcharged, that HHS would audit manufacturers "to ensure the integrity of the drug discount program," and that HHS would impose money penalties of up to $5,000 "for each instance of overcharging a covered entity." 42 U.S.C. § 256b(d)(1)(B). Congress thus recognized that *both* manufacturers and covered entities must be well regulated in order to ensure compliance with the 340B Program. And if there is a dispute about compliance, Congress provided for an administrative dispute resolution process to address those concerns, *see id.* § 256b(d)(3), but did not permit manufacturers to make

such determinations on their own and impose whatever consequences they saw fit.

Nothing in this statutory scheme allows manufacturers to engage in self-help, impose the cost of proving compliance on the covered entities, or otherwise deny them the statutory discount. *Cf.* 42 U.S.C. § 256b(a)(5)(D) (penalty for a covered entity's noncompliance is an after-the-fact refund of the discounted amount to the manufacturer). Thus, even if Eli Lilly's policy "share[s] the same goals" as the statute, "[t]he fact of a common end hardly neutralizes conflicting means." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 379 (2000).

Instead of permitting manufacturer-imposed restrictions on access to the 340B price, the statute authorizes manufacturers to audit covered entities as the means to uncover diversion or duplicative discounts. 42 U.S.C. § 256b(a)(5)(C). Notably, Congress required manufacturers to bear the expense of such audits, rather than impose those costs on the covered entities. *Id.* Moreover, Congress has made an audit conducted pursuant to that statutory provision a prerequisite for a manufacturer's administrative claim against a covered entity. *Id.* § 256b(d)(3)(B)(iv).

Contrary to Eli Lilly's assertion, it cannot ignore this reticulated scheme for auditing and adjudicating potential violations by demanding

that covered entities instead designate a single contract pharmacy that Eli Lilly alone determines is "eligib[le]" to receive 340B drugs. SA12. As HHS explained at the inception of the 340B Program, a "manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions" because the program's enforcement "is a Federal responsibility." 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993). Accordingly, manufacturers may not require covered entities to "submit[] information related to drug acquisition, purchase, and inventory systems" as a condition of obtaining discounted drugs. *Id.* at 68925. So while a manufacturer can appropriately ask a covered entity for "routine information necessary to set up and maintain an account" as part of its "normal business policies," the manufacturer "may not enforce" its own *sui generis* requirements that a covered entity prove its "compliance with section 340B." 59 Fed. Reg. 25110, 25112 (May 13, 1994).

Moreover, it is not just Eli Lilly's policy that is at issue here. Many drug manufacturers have recently imposed their own new policies and restrictions on covered entities' ability to access drugs under the 340B Program. *See Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, --- F. Supp. 3d ---, 2021 WL 5150464 (D.N.J. 2021); *Novartis Pharm. Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5,

2021); *AstraZeneca Pharms. LP v. Becerra*, 2022 WL 484587 (D. Del. Feb. 16, 2022). Under plaintiff's logic, there is no reason for these manufacturer policies to follow the same criteria—and indeed these policies impose different substantive limitations and requirements on covered entities simply to obtain the same 340B price that was previously available. For example, Eli Lilly requires covered entities to have no in-house pharmacy and to designate a single contract pharmacy that Eli Lilly alone determines is "eligib[le]," SA12, while Novartis requires contract pharmacies to be within a 40-mile radius of the covered entity, *Novartis*, 2021 WL 5161783, at *3, while Novo Nordisk requires that covered entities designate a single contract pharmacy location, *Sanofi*, 2021 WL 5150464, at *5, while Sanofi requires the regular submission of claims data, *id.* Covered entities thus must seek to accommodate a web of restrictive manufacturer conditions simply to obtain the discounted drug price that Congress enacted the 340B Program to provide them.

That manufacturer-imposed burden increases costs for covered entities, diverts their time away from medical care, and seriously harms their patients. As the administrative record demonstrates, even in the limited time these new policies have been in place, covered entities have been unable to purchase drugs at the discounted price and patients have

struggled to obtain their needed medications from their pharmacies. *Supra* pp.17-20. The result is billions' worth of savings lost, and people's health put in jeopardy. Accordingly, HHS properly informed the manufacturers that their new policies violate the statutory scheme and must end.

C. Eli Lilly's Other Arguments Lack Merit

Eli Lilly suggests that if it is not allowed to place conditions on its sale of drugs in the 340B Program, then its sale of drugs at the discounted price through the program might constitute a Fifth Amendment Taking. *See* Br. 47-53. The district court rightly rejected this assertion. SA50-52. The 340B Program does not qualify as a physical taking because HHS does not acquire title to Eli Lilly's drugs, *United States v. Pewee Coal Co.*, 341 U.S. 114, 115-17 (1951) (plurality op.), obtain them for a third party, *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021), or compel Eli Lilly to surrender them, *Horne v. Department of Agriculture*, 576 U.S. 350, 364 (2015). Nor does it qualify as a regulatory taking. The only reason that Eli Lilly is subject to the 340B Program is because the company has willingly chosen to participate in (and profit from) the federally funded Medicaid and Medicare Part B programs. 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1), (5). Thus, although the statute requires Eli Lilly to sell some of its drugs at a discounted price, that is a voluntary choice it has made in order to

"receive[] a 'valuable Government benefit' in exchange," and does "not subject[] [Eli Lilly] to a taking." *Horne*, 576 U.S. at 366; *accord Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) (the "voluntary" relinquishment of property "in exchange for the economic advantages * * * can hardly be called a taking").

Eli Lilly's reliance on *Horne* (at 49) is thus misplaced. *Horne* explained that a farmer's ability to sell "produce in interstate commerce" was not a government benefit for purposes of this takings analysis. 576 U.S. at 366. Eli Lilly is of course free to sell its drugs in interstate commerce without participating in the 340B Program—the company does not do so, however, because it prefers to receive money from federal healthcare programs. As this Court has explained in rejecting a similar takings challenge in the Medicare context, "provider participation [in Medicare] is voluntary," and those who participate "made a voluntary choice to accept both the obligations and the benefits" of the program. *St. Francis Hospital Center v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983) (per curiam). And that "voluntariness forecloses the possibility that the statute could result in an imposed taking of private property." *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (collecting cases

and holding that conditions on receiving Medicare reimbursement are not takings).

Eli Lilly's reliance on *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) is similarly off the mark, as that case concerned the alleged violation of federalism principles through a statutory scheme that impermissibly coerced sovereign States to implement a federal program. *Id.* at 575. None of that is at issue here. Even if it were, the Supreme Court explained that "[n]othing in our opinion precludes Congress from offering funds" to expand Medicaid "and requiring that States accepting such funds comply with the conditions on their use." *Id.* at 585. And in all events, it is reasonable and appropriate for the 340B statute to prohibit manufacturer-created restrictions that "would assuredly render 340B drugs inaccessible to many covered entities." SA45 & n.13.

Eli Lilly reliance (at 35) on the so-called "major-questions doctrine" is wholly misplaced.[6] This is not a case where "an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy.'" *Utility Air Regulatory Group v. EPA*,

[6] Eli Lilly raises this argument for the first time on appeal, as it did not appear in its district court briefing. *See* Dkt. Nos. 89, 129. *See Mahran v. Advocate Christ Medical Center*, 12 F.4th 708, 713 (7th Cir. 2021) ("Arguments raised for the first time on appeal are deemed waived.").

573 U.S. 302, 324 (2014). Indeed, this case does not involve an agency's regulatory authority at all. As discussed below, the enforcement letter rests on violations of the 340B statute itself.

II. The District Court Erred In Partially Vacating The Enforcement Letters And Remanding To HHS

Having correctly held that the statute "does not permit drug manufacturers, such as Plaintiffs, to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities," the district court should have entered judgment in HHS's favor. SA71. Instead, the court vacated the enforcement letters and remanded to HHS to address what the court perceived as a "change in position regarding [HHS's] authority to enforce potential violations of the 340B statute." SA52.

That was error. HHS has consistently recognized that its guidance is unenforceable and that any enforcement action must be grounded in violations of the statute itself. There is no doubt that HHS has statutory authority to enforce the requirements of the 340B statute. *See* 42 U.S.C. § 256b(a)(5)(D), (d)(1)(B), (d)(2)(B), (d)(3) (statutory enforcement provisions). And that is precisely what the enforcement letter at issue here did.

Thus, there was no change in the agency's position to be explained. As the district court correctly noted, HHS has consistently described its

guidance as unenforceable. SA52-55. Indeed, HHS emphasized at the outset of the 340B Program that its guidelines regarding contract-pharmacy arrangements are nonbinding. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties"). HHS reiterated that nonbinding nature of its guidance when it advised covered entities to use a single contract pharmacy to dispense medications, *id.* at 43550, 43555, and when HHS later advised that covered entities could use multiple contract pharmacies to do so, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010) (explaining that "[t]his guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities").

At the same time, HHS has consistently interpreted *the statute* as prohibiting drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price. For example, as early as 1993, shortly after Congress enacted Section 340B, HHS explained that "[a] manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 58 Fed. Reg. at 68925. HHS thus explained that manufacturers "may not" require covered entities to demonstrate program eligibility, use drugs only for authorized services, keep drug pricing confidential, or "submit[]

information related to drug acquisition, purchase, and inventory systems." *Id.* at 68925; *see also, e.g.*, 59 Fed. Reg. at 25111-12 ("Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective.").[7] The enforcement letter at issue here applied the agency's longstanding view that manufacturers may not erect barriers that undermine covered entities' access to the 340B price.

[7] The GAO report discussed by the district court (SA55) was not an HHS document and concerned covered entity's oversight responsibilities, not whether drug manufacturers may impose unilateral restrictions on covered entities' access to the statutory discount.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed insofar as it vacated the enforcement letters and remanded to HHS. The judgment should otherwise be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a) (5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 9,435 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word 2016.

/s/ Daniel Aguilar
Daniel Aguilar

CERTIFICATE OF SERVICE

I certify that on June 24, 2022, I filed a copy of this brief with the Clerk of Court for the Seventh Circuit Court of Appeals through the Court's CM/ECF system, which will serve counsel for all parties.

/s/ Daniel Aguilar
Daniel Aguilar

CIRCUIT RULE 30(d) STATEMENT

I certify that all the materials required by Circuit Rules 30(a) and (b) are included in the appendix of appellants Eli Lilly & Co. and Lilly USA, LLC and need not be included in the brief of the federal defendants as cross-appellants under Circuit Rule 30(c).

/s/ Daniel Aguilar
Daniel Aguilar

STATUTORY ADDENDUM

TABLE OF CONTENTS

42 U.S.C. § 256b. Limitation on prices of drugs purchased by covered entities.

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that--

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs[1] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs[1] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions--

(1) In general

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) Covered drug

In this section, the term “covered drug”--

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered

entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the

interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term “covered outpatient drug” shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.