No. 22-1676

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

ASTRAZENECA PHARMACEUTICALS LP,

Plaintiff–Appellee,
v.

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

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Delaware (No. 21-27)

REPLY BRIEF FOR THE FEDERAL DEFENDANTS

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INTRODUCTION AND SUMMARY OF ARGUMENT

Congress enacted the 340B statute to provide discounted drugs to covered entities. Congress considered but declined to enact a provision that would have restricted covered entities' use of outside pharmacies known as "contract pharmacies" to dispense the discounted drugs. Nor did Congress authorize drug manufacturers to impose such restrictions for the ostensible purpose of preventing drug diversion or fraud. Instead, Congress established specific mechanisms to protect program integrity and assigned enforcement responsibilities to the federal government—not to drug manufacturers. "The statute therefore reflects a careful congressional focus not only on the goal * * * but also on the appropriate means to that end." *American Hospital Association v. Becerra*, 142 S. Ct. 1896, 1903 (2022).

AstraZeneca's policy violates the statute because, by its plain terms, it restricts covered entities' access to the 340B discounted price if covered entities dispense drugs to their patients through contract pharmacies. Accordingly, the judgment of the district court should be reversed.

ARGUMENT

I. The 340B Statute Does Not Allow Drug Manufacturers To Restrict Covered Entities' Use Of Contract Pharmacies

A. As our principal and answering brief in these consolidated cases explained (Defendants' Principal Brief), Congress enacted the 340B Program to ensure that "covered entities, dominantly, local facilities that provide medical care for the poor," are able to obtain and dispense covered drugs at a statutory discount. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 115 (2011). The Program works because the statute requires "manufacturers participating in Medicaid" and Medicare Part B to "offer discounted drugs to covered entities," *id.*, which include certain hospitals that "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support," *American Hospital Association v. Becerra*, 142 S. Ct. 1896, 1905-06 (2022).

The 340B statute imposes that obligation on manufacturers in general terms. Manufacturers must enter into an agreement with the Secretary of Health and Human Services (HHS) "under which the amount required to be paid" for drugs "purchased by a covered entity * * * does not exceed" the ceiling price. 42 U.S.C. § 256b(a)(1). And that 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.* Until recently, all had understood the obligation to be categorical — manufacturers must sell drugs subject to the 340B Program to covered entities at the discounted price. Selling those drugs at higher prices is not permitted. *Id.* § 256b(d)(1)(B)(vi)(II) (civil monetary penalties "for each instance of overcharging a covered entity").

Congress recognized the risk that covered entities might violate the requirements of the 340B Program. Accordingly, Congress authorized both HHS and drug manufacturers to conduct audits of covered entities at the Secretary's or the manufacturer's expense, as the means to ascertain whether a covered entity is unlawfully diverting drugs or requesting duplicative discounts. 42 U.S.C. § 256b(a)(5)(C). Congress further authorized the Secretary, but not drug manufacturers, to impose sanctions against a covered entity that is found to have violated the statute. *Id.* § 256b(a)(5)(D), (d)(2)(B)(v).

The statute also provides a mechanism for drug manufacturers—after conducting an audit as specified by the statute—to submit a dispute over a covered entity's compliance with statutory requirements, and that dispute will be resolved administratively, subject to judicial review. 42 U.S.C. § 256b(d)(3)(A). Congress made that system of dispute resolution subject

to reticulated requirements, *id.* § 256b(d)(3)(B)(i)-(vi), including rulemaking that HHS undertook at Congress's direction, 85 Fed. Reg. 80632, 80632-46 (Dec. 14, 2020).

Congress was equally aware of the risk that drug manufacturers might violate their obligations under the 340B statute and provided for various procedures to ensure that manufacturers do not charge more than the statutory ceiling price and to require refunds if they do overcharge. 42 U.S.C. § 256b(d)(1)(B)(ii). Congress made manufacturers subject to HHS audits to ensure compliance and subject to civil monetary penalties for overcharging. *Id.* § 256b(d)(1)(B)(v)-(vi).

Unsurprisingly, Congress did not authorize manufacturers to narrow their own obligations to sell discounted drugs or to add to this calibrated statutory scheme. The measures Congress put into place were developed by elected representatives, overseen by the Executive Branch, and subject to review by federal courts. *E.g.*, 42 U.S.C. § 256b(d)(3)(C); *see Law v. Siegel*, 571 U.S. 415, 424 (2014) (a statute's "meticulous" and "carefully calibrated exceptions and limitations * * * confirms that courts are not authorized to create additional exceptions."). Nothing in the 340B statute suggests that Congress thought it best for private, profit-driven drug manufacturers to determine the standards under which they must sell their drugs at

discounted prices. To the contrary, "[t]he enforcement of section 340B provisions is a Federal responsibility," and manufacturers "may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." 58 Fed. Reg. 68922, 68925 (Dec. 29, 1993).

B. AstraZeneca has nonetheless restricted covered entities' access to the statutory discounted price if those covered entities dispense drugs to their patients through contract pharmacies. In attempting to defend its restriction, AstraZeneca demonstrates that its interpretation of the 340B statute is incorrect. In essence, AstraZeneca contends that the 340B statute leaves manufacturers free to sell drugs to covered entities on whatever terms the manufacturers choose, including by refusing the 340B discount to covered entities that rely on even a single contract pharmacy to dispense the drugs purchased. *See* AstraZeneca Br. 4 ("[T]he statute does not impose contract pharmacy obligations on manufacturers.").

That is not a tenable interpretation of the statute. AstraZeneca does not dispute that when the 340B statute was enacted, nearly all covered entities relied on outside pharmacies to distribute drugs to their patients. At that time, only 5 percent (500 of 11,500) of covered entities had in-house pharmacies. *See* 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996). AstraZeneca

also do not dispute that this "reliance on outside pharmacies" was "known to Congress as a common business practice" when it created the 340B Program. *Eli Lilly & Co v. U.S. Department of Health and Human Services*, 2021 WL 5039566, at *20 (S.D. Ind. Oct. 29, 2021), *appeals pending*, Nos. 21-3128, 21-3405 (7th Cir.). When Congress was considering the legislation that established Section 340B, 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)). As Defendants' Principal Brief explained (at 7), the emphasized language would have prevented covered entities from using outside pharmacies to dispense the drugs purchased at the discounted prices.

But Congress did not enact that restriction. 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). The absence of an explicit statutory reference to contract pharmacies did not leave manufacturers free to undermine the 340B Program by refusing the discounted price to

covered entities that rely on contract-pharmacy arrangements. Thus, "reading the 340B statute 'as a whole'" and in light of "'the statutory context, structure, history, and purpose,' contract pharmacy arrangements are permissible as a drug dispensing mechanism." *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services*, 570 F. Supp. 3d 129, 201 (D.N.J. 2021), *appeals pending*, No. 21-3167, 21-3168, 21-3379, 21-3380 (3d Cir.).

The 340B statute cannot properly be read to allow manufacturers to impose the very restriction that Congress declined to enact. Under AstraZeneca's reading, manufacturers could negate their statutory obligation to offer the 340B discount simply by refusing to ship drugs to a covered entity's contract pharmacies. "Congress' rejection of the very language that would have" imposed that restriction "weighs heavily against" an interpretation that allows manufacturers to do so. *Hamdan v. Rumsfeld*, 548 U.S. 557, 579-80 (2006). "An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." *Cummings v. Department of the Navy*, 279 F.3d 1051, 1055 (D.C. Cir. 2002) (quoting *Burns v. United States,* 501 U.S. 129, 136 (1991)).

AstraZeneca wrongly asserts that the Court may not consider this contemporaneous unenacted bill. AstraZeneca Br. 45. But the issue here is not whether an unenacted bill may inform the "interpretation of a *prior* statute." *Id.* (emphasis added) (quoting *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994)). Here, Congress chose between two alternative legislative proposals. That choice is properly afforded "the weight of contemporary legislative history." *North Haven Board of Education v. Bell*, 456 U.S. 512, 535 (1982).

AstraZeneca resists that conclusion by pointing to different statutory provisions, neither of which concern AstraZeneca's obligations. Br. 32-33 (citing, 38 U.S.C. § 8126(h)(3)(a)(ii)). The first, 38 U.S.C. § 8126(h)(3)(A), defines "depot" in that statute to mean "a centralized commodity management system" that is a "federally owned and operated warehouse system" or a contracted system. That definition sheds no light on whether AstraZeneca can refuse to deliver 340B drugs to pharmacies that will dispense them to patients. *See Sanofi-Aventis*, 570 F. Supp. 3d at 200 (rejecting a similar attempted comparison between Section 340B and 38 U.S.C. § 8126(h)(3)(A)). The second, 42 U.S.C. § 256b(a)(8), directs HHS to establish a prime vendor program that covered entities can voluntarily

participate in. The prime vendor, Apexus,[1] can negotiate for additional discounts on 340B drugs and can establish a network of national, regional, and specialty distributors to aid the 340B Program.[2] Here, many covered entities that participate in the prime vendor program alerted Apexus that "AstraZeneca is blocking 340B prices for their drugs ordered by my covered entity that are shipped to my contract pharmacies" and "I am forced to pay [wholesale pricing] for these products." JA171; *see also*, *e.g.*, JA159-61, JA164-68, JA180-84, JA187-89, JA192-94 (similar). Thus, although § 256b(a)(8) allows the prime vendor to be involved in the "distribution of covered outpatient drugs" at the discounted price, that is no longer possible under AstraZeneca's unilateral policy.

AstraZeneca retreats to the assertion that contract-pharmacy arrangements cause "program abuses." AstraZeneca Br. 9. But as already discussed, Congress provided specific mechanisms to prevent abuse of the 340B Program, including by allowing manufacturers to audit a covered entity's records. 42 U.S.C. § 256b(a)(5)(C). Congress did not, however, allow drug manufacturers to restrict a covered entity's contract-pharmacy arrangements as an ostensible means to prevent abuse. "The statute

[1] About Apexus, https://perma.cc/W2T4-WJC2.
[2] PVP Authorized Distributors, https://perma.cc/PHL9-2U8Z.

therefore reflects a careful congressional focus not only on the goal * * * but also on the appropriate means to that end." *American Hospital Association*, 142 S. Ct. at 1903.

There is likewise no basis for AstraZeneca' professed concern that its delivery obligations would involve impossible logistics or otherwise be limitless. AstraZeneca Br. 29, 38. The drugs covered by the 340B Program must be dispensed pursuant to a prescription, *see* 42 U.S.C. § 256b(b)(2) (cross-referencing 42 U.S.C. § 1396r-8(k)(2)), which predominantly means dispensation in a pharmacy (or in certain circumstances, in a physician's office). The only issue before the Court is whether the 340B statute allows manufacturers to restrict a covered entity's access to the statutory discount based on the covered entity's use of contract pharmacies (rather than in-house pharmacies) to dispense the drugs. For the reasons explained above and in Defendants' Principal Brief, the statute does not allow manufacturers to do so.

II. AstraZeneca's Policy Violates The 340B Statute

It follows from these principles that AstraZeneca's policy violates the 340B statute and is thus the basis for enforcement action. By AstraZeneca's own account, its policy imposes restrictions on covered entities' access to the statutorily discounted price if they dispense 340B drugs through a

contract pharmacy. AstraZeneca "only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy." JA245. To implement that policy, AstraZeneca has "stop[ped] processing 340B" pricing for all "Contract Pharmacy arrangements" for all covered entities—the covered entities must "contact AstraZeneca to arrange for" a single contract pharmacy "to be eligible to receive 340B pricing." *Id.* That policy denies covered entities access to the 340B price unless they meet AstraZeneca's idiosyncratic conditions.

AstraZeneca notes that patients can still fill prescriptions at non-contract pharmacies, AstraZeneca Br. 53 (citing 61 Fed. Reg. at 43555), but fails to mention that "when a patient obtains a drug from a retail pharmacy other than the entity's contract pharmacy, the manufacturer *does not have to offer this drug at 340B pricing*." 61 Fed. Reg. at 43552 (emphasis added). The freedom to fill a prescription elsewhere is a costly one.

At bottom, AstraZeneca's argument rests on the premise that its unilateral policy is proper because the 340B statute regulates "with respect to one specific aspect of their drug sales—price"—and it is "unjustified" to read the statute as imposing any other "statutory obligation * * * in the first place." AstraZeneca Br. 33-34, 39 n.14.

That argument blinks at reality. In enacting the 340B Program, Congress was clear that drug manufacturers must provide discounted drugs to covered entities so that they could prescribe and dispense necessary medications to patients. Nothing in the statutory scheme, its history, or common sense suggests Congress simultaneously granted drug manufacturers the authority to place whatever restrictions they like on access to those drugs. The administrative record demonstrates that the manufacturers' policies have had devastating effect—the policies have eliminated billions in savings, JA263-66, are depleting the resources that clinics need to operate, and are preventing people from obtaining the medications they need to live, JA255-58. *See also* Defendants' Principal Br. 16-19. As far back as Chief Justice John Marshall, the courts have recognized that "where great inconvenience will result from a particular construction, that construction is to be avoided, unless the meaning of the legislature be plain." *United States v. Fisher*, 6 U.S. 358, 386 (1805). And there is no plain indication that Congress meant to grant each drug manufacturer free rein to impose its own preferred conditions and limitations before a clinic or hospital could obtain discounted drugs.

AstraZeneca's argument that it is required only offer drugs at the discounted price—and no more—has no limiting principle. Under that

theory, manufacturers could, as the manufacturer Eli Lilly has argued, require covered entities to pick up all drugs from the manufacturer's corporate headquarters. Opening Br. 31-32, *Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir. May 25, 2022) (asserting that "the seller is required to tender the goods at the *seller's* place of business, nowhere else"). Thus, on its logic, AstraZeneca could presumably require covered entities in Alaska, Puerto Rico, and Guam, to pick up all their 340B drugs from AstraZeneca's headquarters in Wilmington, Delaware. *See* 6 Del. C. § 2-308(a) ("[U]nless otherwise agreed the place for delivery of goods is the seller's place of business."). And if the covered entities need to have the drugs shipped to their physical locations, AstraZeneca could charge the wholesale price. Or, on the same logic, AstraZeneca could limit covered entities to a single pill per drug per month at the discounted price—because the statute does not explicitly address quantity. Although AstraZeneca disclaims any limitations on quantity (at 15), that is simply its current policy. On AstraZeneca's view of the statute, nothing would prohibit such restrictions.

Although the 340B statute does not expressly prohibit such attempts to circumvent the statutory requirements, that does not mean Congress authorized such policies. The Supreme Court has repeatedly rejected

similar arguments that attempt to evade carefully calibrated statutory schemes. For example, in *County of Maui v. Hawaii Wildlife Fund*, 140 S. Ct. 1462 (2020), the Court considered the Clean Water Act's requirement that polluters must have a federal permit if they add "any pollutant to navigable waters * * * from any point source," *id.* at 1469. The petitioner asserted that it did not need a permit because although it discharged partially treated sewage into the ocean, the sewage travelled through some groundwater first and therefore was not covered by the statute. *Id.* at 1468-69. The Supreme Court rejected that assertion, which "would risk serious interference with" the regulatory scheme. *Id.* at 1473. The Court noted that under petitioner's theory, a permit would be required for a pipeline that discharged sewage directly into the ocean, but a polluter could evade that requirement by "simply mov[ing] the pipe back, perhaps only a few yards, so that the pollution must travel through at least some groundwater before reaching the sea." *Id.* The Court declined to adopt petitioner's interpretation, which would "create such a large and obvious loophole in one of the key regulatory innovations of the Clean Water Act." *Id.*; *accord The Emily*, 22 U.S. 381, 390 (1824) (rejecting an interpretation that would facilitate "evasion of the law").

Similarly, in interpreting the Bankruptcy Code, the Supreme Court rejected a debtor's attempt to evade bankruptcy's priority distribution scheme through a dismissal order that paid lower-priority creditors and skipped over higher-priority creditors. *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 978 (2017). The Court explained that the priority distribution scheme "has long been considered fundamental to the Bankruptcy Code's operation," and the Court expected "more than simple statutory silence if, and when, Congress were to intend a major departure" from the scheme's operation. *Id.* at 984. Put differently, the Court "would expect to see some affirmative indication of intent if Congress actually meant to make" the debtor's actions "a backdoor means to achieve the exact kind of" activity that the Bankruptcy Code prohibits. *Id.* That same reasoning applies here, and the 340B statute prohibits AstraZeneca's evasion of its central requirements.

III. AstraZeneca's Remaining Arguments Lack Merit

AstraZeneca's remaining objections to the HHS enforcement letters are meritless.

AstraZeneca argues (at 55-56) that the enforcement letter is arbitrary and capricious because it does not adopt AstraZeneca's interpretation. As

explained above, AstraZeneca's interpretation is incorrect, and HHS acted appropriately in declining to adopt it.

AstraZeneca next argues (at 59-62) that HHS has changed positions regarding contract-pharmacy arrangements without sufficient explanation. *See also* AstraZeneca Br. 34 (asserting that HHS's position is "[n]ewly discovered"). But HHS has from the inception made clear that its guidance regarding contract pharmacies is nonbinding; thus, any enforcement action is premised on violations of the statute alone. As explained above, AstraZeneca's policy violates the statute and is thus the basis for enforcement action.

In any event, AstraZeneca does not meaningfully engage with HHS's explanation and citations to longstanding guidance that the 340B statute "prohibit[s] drug manufacturers from creating extra-textual barriers to a covered entity's ability to obtain drugs at the 340B price." Opening Br. 11. As HHS explained at the inception of the 340B Program, the program's enforcement "is a Federal responsibility" and 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 has never deviated from that understanding. And while HHS has stated in nonbinding guidance that covered entities may use one, 61 Fed. Reg. 43549,

or multiple contract pharmacies, 75 Fed. Reg. 10272 (Mar. 5, 2010), that guidance to covered entities has never given manufacturers carte blanche to impose restrictions on whether and how covered entities can purchase drugs at the statutory discount.

AstraZeneca intimates (at 51) that HHS previously did not permit covered entities to use contract pharmacies, citing 59 Fed. Reg. 25110, 25113 (May 13, 1994), but AstraZeneca misreads the guidance it cites. In response to comments that the statute does "not require manufactures to sell directly to a purchasing agent * * * or a contract pharmacy," HHS explained that covered entities "often use purchasing agents or contract pharmacies" and by "placing such limitations on sale transactions, manufacturers could be discouraging entities from participating in the program." *Id.* at 25111. Thus "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective," nor may manufacturers unilaterally require "entity compliance with Section 340B" as a precondition for selling drugs at the discounted price. *Id.* at 25111-12.

AstraZeneca's reliance (at 34) on the "major questions doctrine" is wholly misplaced.[3] 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*, 573 U.S. 302, 324 (2014). Indeed, this case does not involve an agency's regulatory authority at all. As discussed, the enforcement letter rests on violations of the 340B statute itself.

Finally, AstraZeneca asserts (at 49) that its policy "is fully consistent with" Congress's goal in enacting the 340B statute. AstraZeneca's policy has removed millions in savings from the 340B Program's intended recipients, threatened the continued operations of covered entities, and deprived patients of necessary drugs at the statutorily discounted price. Congress did not enact a statute that defeats itself.

[3] AstraZeneca raises this argument for the first time on appeal, as it did not appear in its district court briefing. *See* Dkt. Nos. 43, 65, 91, 95. *See Simko v. United States Steel Corp.*, 992 F.3d 198, 205 (3d Cir. 2021) ("[A]rguments raised for the first time on appeal are not properly preserved for appellate review.").

CONCLUSION

The district court's judgment should be reversed.

Respectfully submitted,

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August 2022

COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3,572 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Georgia 14-point font, a proportionally spaced typeface.

3. On August 11, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system.

4. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.

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/s/ Daniel Aguilar
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