[ORAL ARGUMENT NOT YET SCHEDULED]

Nos. 21-5299, 21-5304

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NOVARTIS PHARMACEUTICALS CORP.
Plaintiff-Appellee,
v.

CAROLE JOHNSON, in her official capacity as Administrator, U.S. Health Resources and Services Administration, *et al.*,

Defendants-Appellants.

UNITED THERAPEUTICS CORP.

Plaintiff-Appellee,
v.

CAROLE JOHNSON, in her official capacity as Administrator of U.S. Health Resources and Services Administration, *et al.*,

Defendants-Appellants.

On Appeals from the United States District Court
for the District of Columbia

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).

Plaintiffs' policies violate the statute because, by their plain terms, they restrict 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 opening brief explained, 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. Plaintiffs have 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 those restrictions, plaintiffs demonstrate that their interpretation of the 340B statute is incorrect. In essence, they contend 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* Novartis Br. 21; United Therapeutics Br. 29-30.

That is not a tenable interpretation of the statute. Plaintiffs do 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). Plaintiffs 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 our opening brief explained (at 6-7), 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 arrangement 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 plaintiffs' 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)).

Novartis wrongly asserts that the Court may not consider this contemporaneous unenacted bill. Novartis Br. 42. 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).

Plaintiffs retreat to the assertion that contract-pharmacy arrangements are "ripe for abuse." Novartis Br. 1; *see also* United Therapeutics Br. 3. 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 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 plaintiffs' professed concern that they may be required to ship discounted drugs "to the moon." Novartis Br. 55; United Therapeutics Br. 47. 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 our opening brief, the statute does not allow manufacturers to do so.

II. Plaintiffs' Policies Violate The 340B Statute

It follows from these principles that plaintiffs' policies violate the 340B statute and thus are the basis for enforcement action. By plaintiffs' own account, their policies impose restrictions on covered entities' access to the statutorily discounted price if they dispense 340B drugs through a contract pharmacy.

A. Novartis has generally refused to honor a hospital's contract-pharmacy arrangement unless the contract pharmacy is located within 40 miles of the hospital. *See* Novartis Br. 14. By contrast, the 340B statute imposes no geographic restrictions. Novartis purports to derive its policy from a Medicare regulation concerning "provider-based status" for facilities and organizations that are "not located on the campus of a potential main provider," 42 C.F.R. § 413.65(e), but that regulation has no bearing on the 340B Program.

Novartis notes that patients can still fill prescriptions at non-contract pharmacies, Novartis Br. 46-47 (citing 61 Fed. Reg. at 43552), 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). Novartis also notes that a drug manufacturer can "request standard information" from covered entities and employ other "customary business practice[s]," Br. 39 (citing 59 Fed. Reg. 25110, 25114 (May 13, 1994)), but the Novartis policy is not a request for standard information or a customary business practice. Instead, it is a policy targeted at the 340B Program that impedes covered entities' use of contract pharmacies.

B. United Therapeutics announced that the company "is not legally obligated to honor any 340B contract pharmacy orders." JA808. Under its policy, the company "will accept" an order from a covered entity "only if the contract pharmacy was utilized by the covered entity for a valid 340B purchase of a United Therapeutics covered outpatient drug during the first three full quarters of the 2020 calendar year." JA803. Covered entities that have had neither a contract pharmacy during that period nor an in-house pharmacy are permitted to designate only a single contract pharmacy and must submit specified claims data. JA808-09. Any covered entity that tries

to purchase 340B drugs for their patients outside of those restrictions "will simply be rejected." JA809. For the reasons discussed above and in our opening brief, these restrictions contravene the manufacturer's obligations under the 340B statute.

C. At bottom, plaintiffs' argument rests on the premise that their unilateral policies are proper because nothing in the 340B statute "*prohibit[s]* manufacturers from placing *any* conditions on covered entities." United Therapeutics Br. 28; *accord* Novartis Br. 21.

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, JA361-62, are depleting the resources that clinics need to operate, JA754-55, and are preventing people from obtaining the medications they need to live, JA307. *See also* Opening 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.

United Therapeutics (at 5) argues that it is required only to "[o]ffer eligible drugs to covered entities at the 340B *price*. No more." *See also* United Therapeutics Br. 32 ("Congress explicitly restricted manufacturers' ability to set the terms of the offer in only one respect—the price."). That position 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, United Therapeutics could presumably require covered entities in Alaska, Puerto Rico, and Guam, to pick up all their 340B drugs from United Therapeutics' headquarters in Silver Spring, Maryland. And if the covered entities need to have the drugs shipped to their physical locations, United Therapeutic

could charge the wholesale price. Or, on the same logic, United Therapeutics 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 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 plaintiffs' evasion of its central requirements.

III. Plaintiffs' Remaining Arguments Lack Merit

Plaintiffs' remaining objections to the HHS enforcement letters are meritless.

Plaintiffs argue that HHS previously restricted covered entities to only a single contract pharmacy and failed to explain a change of position in the enforcement letters at issue here. *See* Novartis Br. 55-56; *see also* United Therapeutics Br. 11. But it is common ground that HHS lacks substantive authority to regulate a covered entity's contract-pharmacy arrangements. *See* Novartis Br. 7 ("Because HHS has only limited rulemaking authority over the 340B Program, it lacks the authority to issue a legislative rule regarding contract pharmacies." (quotation marks omitted)); *see also* United Therapeutics Br. 37 (similar). Accordingly, HHS emphasized at the outset of the 340B Program that its guidelines regarding contract-pharmacy arrangements for covered entities were nonbinding. *See, e.g.*, 61 Fed. Reg. at 43550 (explaining that "these guidelines create no new law and create no new rights or duties"). The enforcement letters are premised on violations of the statute alone, rather than on agency guidance.

Novartis also asserts (at 55) that HHS's enforcement letter misstated the details of Novartis's policy. But there is no doubt that HHS understood

the substance of Novartis's policy, which Novartis discussed with HHS at length, *see* JA51-58.

Finally, Novartis asserts in conclusory fashion (at 46) that it is "par for the course" for manufacturers to require covered entities to comply with varying conditions. But Novartis points to nothing remotely comparable that has removed billions in savings from the 340B Program's intended recipients, JA361-62, threatened the continued operations of covered entities, JA754-55, and deprived patients of necessary drugs like insulin at the statutorily discounted price, JA307.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and remanded with instructions to grant summary judgment in favor of the federal defendants.

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3,192 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.

/s/ Daniel Aguilar
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