IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, *et al.*,

Plaintiffs

v.

XAVIER BECERRA, in his official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201,

and

CAROLE JOHNSON, in her official capacity, and HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857,

Defendants.

Civil Action No. 24-CV-3220 (DLF)

BRIEF OF AMICUS CURIAE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PLAINTIFF ELI LILLY AND COMPANY AND LILLY USA, LLC'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

Statutes

Other Authorities

CORPORATE DISCLOSURE STATEMENT

Consistent with Local Rule 26.1, Washington Legal Foundation states that it is a non-profit 501(c)(3) organization. It has no corporate parent and is not owned in whole or in part by any publicly held corporation.

INTEREST OF AMICUS CURIAE[1]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus urging courts to properly construe 42 U.S.C.§ 256b (Section 340B). *See Pharm. Rsch. And Mfrs of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023); *Astra, USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011).

INTRODUCTION AND SUMMARY OF ARGUMENT

Lowering health care costs, including reducing the cost of prescription drugs for uninsured, low-income, and vulnerable patients, is a laudable goal. Government-sponsored arbitrage, especially when such arbitrage inures to the benefit of a select handful of private companies at the expense of drug makers, patients, and other stakeholders, is not.

When Congress enacted the 340B Drug Pricing Program as part of the Veterans Health Care Act of 1992, it had noble aims. It sought to provide prescription drugs at reduced prices to a select set of health care providers, known as "covered entities," which ostensibly serve low-income, uninsured, and rural patients, with the understanding that those discounts would be passed on to patients or used to expand services to the poor and underserved. The size and scope of the

[1] No party's counsel authored any part of this brief. No one, apart from WLF and their counsel, contributed money intended to fund the brief's preparation or submission.

Program was also modest for its first decade or so. But by 2022, 340B accounted for more than $53 billion in prescription-drug sales at 340B discount prices (from roughly $2.4 billion in 2005). The rise in the size of 340B is caused by several factors, including broader Program eligibility for hospitals due to Medicaid expansion; rapid hospital consolidation; expansion of contract pharmacy arrangements; and the addition by Congress of new types of covered entities. The result is that the 340B Program has become the second-largest federal prescription drug program (second only to Medicare Part D). In the process, it has become arguably the most obvious example of government-sponsored price arbitrage. An example may help illustrate the point.

As a condition of participating in Medicare Part B and Medicaid, a manufacturer enters into an agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) requiring the company to offer its new drug for sale to a covered entity at a price at or below a ceiling price of a penny per unit. *See* 42 U.S.C. § 256b(a)(1). (This is no exaggeration, as in some cases, the ceiling price "can be as low as a penny per unit," *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024).) Because the covered entity does not maintain an in-house pharmacy, it contracts with a third-party pharmacy to dispense the medication to its patients. The covered entity and contract pharmacy, however, are not obligated to dispense the drug at the penny ceiling price. Rather, they can impose a substantial markup with each transaction. Nothing in the 340B statute prohibits their doing so. Moreover, the covered entity need not actually pass any percentage of savings along to its patients. While it is reasonable to question why large hospitals, pharmacies, and pharmacy benefit managers (PBMs) are permitted to turn a substantial profit on pharmaceuticals that are subject to *manufacturer* price controls, this arbitrage appears lawful under the statute.

What is not permitted under the 340B statute is "diversion" (i.e., reselling a 340B drug to a person who is not a patient of the entity), and "duplicate discounts" (i.e., receiving both the 340B discount and a Medicaid rebate). But according to audits by the Health Resources and Services Administration (HRSA), manufacturers, and other entities, the 340B Program has been beset by widespread diversion and duplicate discounting. Even so, HRSA has failed to adequately police covered entity noncompliance. And so, consistent with their statutory rights and duties, drug manufacturers like Eli Lilly ("Lilly") have stepped in to fill the void. While HRSA should welcome efforts by manufacturers to implement safeguards aimed at ensuring the legitimacy of covered entities' claims data, HRSA has instead repeatedly attempted to block such statutorily permissible reforms.

In late August 2024, to effectuate the aims of section 340B and bring transparency and accountability to a laudable Program, Lilly informed HRSA of its intent to announce a proposed shift from a discount model to a rebate (or so-called "cash-replenishment"[2]) model as a means of effectuating the 340B price. *See* ECF No. 15-1 at 22; *see also* ECF. No. 1-3. Although Lilly's proposed cash-replenishment/rebate model is both (a) analogous in operation to product-replenishment models commonly employed by covered entities and (b) compliant with the plain text of the statute, HRSA rejected Lilly's proposal. ECF No. 15-1 at 22–24; ECF No. 1-5 at 1.

This case raises important questions about the scope of HRSA's authority, the reasonableness of its various interpretations of 340B, and the lawfulness of its decision making,

[2] As Lilly notes in its Motion for Summary Judgment, the company "adopted the phrase 'cash replenishment' when describing its rebate model to highlight the fact that [the] product replenishment" model commonly used by covered entities "is already a functional rebate." ECF No. 15-1 at 18 n.12. This brief will thus use the terms "cash-replenishment" and "rebate" interchangeably.

especially as it pertains to drug manufacturers. According to HRSA, a drug manufacturer must receive pre-approval from the agency before employing a 340B pricing model. But this claim is belied by the text of 340B, which requires no such pre-approval. Moreover, HRSA's argument goes against its own historical 30-year practice of tacitly approving various 340B-compliant pricing models without requiring pre-approval. Considering the text of 340B, HRSA's general practices in interpreting and enforcing 340B over the past 30 years, and its failure to reasonably explain its differential treatment of rebate and replenishment models, HRSA's actions in this case are arbitrary and capricious and must be set aside.

ARGUMENT

I. The section 340B statute requires drug manufacturers to offer certain pharmaceuticals to covered entities at or below a specified, reduced rate.

The 340B statute requires the HHS Secretary to "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 . . . purchased by a covered entity . . . does not exceed an amount" referred to as the "ceiling price," 42 U.S.C. § 256b(a)(1). As amended by the Affordable Care Act ("ACA"), section 340B further provides that each agreement, known as Pharmaceutical Pricing Agreement ("PPA"), "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.* This is known as the "shall offer" provision. *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023).

The 340B statute thus imposes only two requirements on pharmaceutical manufacturers such as Lilly: if they make a drug "available to any other purchaser at any price," they: (1) must "offer" that drug to "covered entities" (2) for "purchase" at or below the "ceiling price" established

in a PPA. 42 U.S.C. § 256b(a)(1). To safeguard the Program's integrity, Section 340B also prohibits "diversion," and "duplicate discounts." *Id.* § 256b(a)(5)(A)(i), (B). But under 340B, participating healthcare providers are permitted to "buy low and sell high," purchasing medicines at the steep discount, while charging patients prevailing market rate prices and often receiving insurance reimbursements that far exceed the purchase price. The 340B drug pricing Program therefore operates as a government-regulated price arbitrage mechanism, in which certain healthcare providers can purchase prescription drugs at a statutory discount and profit by selling those drugs at the prevailing market rate.

Finally, the statute includes robust compliance provisions, permitting both HRSA and pharmaceutical manufacturers to audit covered entities to ensure compliance with the 340B Program's bar on diversion and duplicate discounts. *See* 42 U.S.C. § 256b(a)(5)(C). "If the Secretary finds that a covered entity" engaged in either unlawful practice, "the manufacturer may recover damages from the covered entity in administrative proceedings." *Novartis*, 102 F.4th at 456 (citing *id.* § 256b(a)(5)(D)). The Secretary is also empowered to impose further penalties on covered entities for engaging in knowing, intentional, or systematic diversion. 42 U.S.C. § 256b(d)(2)(B)(v).

II. Due to legislative amendments and HRSA guidance, the 340B Program has evolved and increased in size and scope since its inception.

Although the Secretary of HHS "lacks rulemaking authority over the section 340B [P]rogram," HRSA has issued non-binding "guidance documents interpreting and implementing the scheme." *Novartis*, 102 F.4th at 456.

In 1996, four years after section 340B's enactment, HRSA issued guidance providing "that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457 (citing 61 Fed. Reg. 43,550, 43,555 (Aug. 23,

1996)). HRSA's suggestion to confine contracting to a single pharmacy was informed by a concern that the involvement of more third parties poses an increased risk of unlawful diversion and double discounting. In 2010, however, HRSA reversed course, issuing a new guidance permitting covered entities to "contract with an unlimited number of outside pharmacies . . . regardless of whether the entities have in-house pharmacies." *Id.* (citing 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010)).

The 2010 guidance precipitated an explosion in the use of third-party contract pharmacies and thus "prompted a significant expansion in the section 340B [P]rogram." *Id.* The Government Accountability Office ("GAO") has found that, from 2010 to 2019, the number of contract pharmacies used by covered entities increased from 1,300 to 23,000.[3] The volume of 340B purchases has correspondingly skyrocketed. *See id.* (according to one analyst's estimates, 340B purchases "jumped from roughly $6.9 billion in 2012 to $24.3 billion by 2018" (citing Adam Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—as Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019)). In 2023, "discounted purchases under the 340B program reached a record $66.3 billion—an astounding $12.6 billion," or 23.4 percent, increase over 2022.[4]

As a result, the 340B Program is now dominated by large, for-profit enterprises, including publicly-traded retail-pharmacy chains.[5] Given the discounts the 340B Program affords—an

[3] U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, 2 (Jan. 27, 2020) [hereinafter 2020 GAO Report], https://www.gao.gov/assets/gao-20-212.pdf.

[4] Adam Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html.

[5] Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html.

average of about 57 percent off list price and, in some cases, requiring drugs be offered to covered entities for as little as a penny—many covered entities and contract pharmacies appear to rely upon manufacturers' supply of 340B-discounted drugs as an added revenue stream by selling those drugs at steep profit margins, often as high as 72 percent.[6] In so doing, many covered entities engage in arbitrage, declining to pass some or all of the savings on to their patients in underserved communities.[7]

Moreover, as HRSA's audits have uncovered, recent years have seen a troubling incidence of unlawful drug diversion and duplicate discounting.[8] Yet HRSA has failed to adequately police and detect covered entity noncompliance, despite an elevated risk of duplicate discounting, particularly with respect to Medicaid managed care claims.[9] And even though covered entities are statutorily required to comply with manufacturer audits, *see* 42 U.S.C. § 256b(a)(5)(C), because both covered entities and HRSA have frustrated such attempted oversight, the former often get off

---

[6] *See* Ellie Blalock et al., *The Pharmaceutical Supply Chain, 2013–2023*, Berkeley Rsch. Grp., 4 (Jan. 2025), https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf (noting "that 340B contract pharmacies enjoy a 72 percent profit margin on commonly dispensed brand 340B medicines" and that "[o]utside of 340B, pharmacy margins on brand drugs are typically in the single digits") (citations omitted)).

[7] Recent research has revealed a lack of investment in charity care, even by 340B hospitals. *See* Neal Masia, *Comparing the Financial Health and Charitable Care of 340B and Non-340B Hospitals*, Health Cap. Grp. 3, 12, 13 (2023), https://www.healthcapitalgroup.com/340b-hospitals-and-charity-care-2023 ("find[ing] that 340B participation is not associated with any increase in charity care for 340B hospitals, on average"; that, on the contrary, "340B hospitals with the highest operating margins in 2021 provided significantly less charity care than the non-340B hospitals with the highest operating margins"; and that "the top quintile of 340B hospitals based on operating margins earn $9.92 in profit for every dollar they spend on charity care compared to $7.51 for the top quintile of non-340B hospitals").

[8] *See* U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, 13 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (reporting a total of 1,536 findings of covered entity noncompliance between 2012 and 2019, including 546 instances of diversion and 429 instances of duplicate discounts).

[9] *See* 2020 GAO Report, *supra* note 2, at 23.

scot-free. One reason for the inability of manufacturers to properly police compliance is another HRSA guidance document that governs dispute resolution.

The 340B statute directs the HHS Secretary to promulgate regulations instituting an administrative dispute resolution ("ADR") mechanism. *Id.* § 256b(d)(3)(A). Although the Secretary has set forth such procedures, *see* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,643, to avail itself of the ADR process, a manufacturer must first audit a covered entity, *see* 42 C.F.R. § 10.21(a)(2). Under HRSA's guidelines, however, a manufacturer's audit, in turn, requires a threshold showing of "reasonable cause" for suspecting unlawful duplication or diversion. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 FR 65,406, 65,410 (Dec. 12, 1996). *See id.* Manufacturers are thus stuck in a catch-22: The information required to justify an audit of covered-entity 340B compliance—"reasonable cause" for suspecting noncompliance—naturally would be obtained *from an audit*, which manufacturers are not authorized to conduct until they have "reasonable cause."

III. The growth of the 340B Program has imposed substantial costs on manufacturers, employers, and other stakeholders in the pharmaceutical industry.

As noted *supra*, government-sanctioned arbitrage is now a feature of the 340B Program, permitting steep profits for some, and unlawful diversion and double discounting at times further increases that revenue. According to one analysis, "340B margins account for 77 percent of all revenue from the sale of brand medicines received by US pharmacies and providers (both 340B and non-340B entities)—up from just 14 percent in 2013."[10] Indeed, since 2013, "340B providers

[10] *See* Blalock et al., *The Pharmaceutical Supply Chain, 2013–2023*, *supra* note 5, at 4 ("Pharmacies and 340B providers—including eligible clinics and hospitals (and often hospitals' off-campus outpatient departments)—are increasingly leveraging the 340B program to raise profits on the sale and administration of brand medicines.").

and their contract pharmacies have seen margins on brand medicines increase by a factor of eighteen[.]"[11] Meanwhile, the corresponding "share of total gross expenditures for brand medicines retained by pharmaceutical manufacturers has declined steadily," such that "half of the total spending on brand medicines now flows to nonmanufacturer supply chain stakeholders including PBMs, insurers, providers, and the government."[12]

But on the other hand, manufacturers lose billions of dollars annually through participation in the 340B Program. As one analyst has reported, "[t]he compound average growth rate . . . of 340B purchases was 22.2% from 2018 through 2023," while during "the same period, manufacturers' net drug sales (excluding COVID-19 vaccines and therapeutics) grew at an average annual rate of only 4.3%."[13] Given that the total 340B Program sales reached $66.3 billion in 2023, "the list-to-340B gap—the difference between purchases at list prices and purchases at 340B discounted prices—grew to $57.8 billion . . . ."[14] That figure is "$5.5 billion higher than the 2022 gap," and "th[e] difference approximates the money collected by 340B covered entities."[15] The explosion in 340B purchases in recent years has, at any rate, dwarfed manufacturers' sales increases over the same period—while covered entities have pocketed over $50 billion as a result of the list-to-340B gap.[16] This has consequences for research and development ("R&D"), which is engaged in by the manufacturers.

---

[11] *Id.*

[12] *Id.* at 2, 6.

[13] Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022*, *supra* note 3 (citations omitted).

[14] *Id.*

[15] *Id.*

[16] *See id.*

Because of 340B *manufacturer* price controls, drug makers have less ability to invest in R&D. Notably, "less than half of every dollar spent on drugs in the United States goes to the companies actually innovating and manufacturing them."[17]

The 340B ceiling price is, by definition, a price cap for covered pharmaceuticals. As numerous studies have shown, by reducing revenues, price controls disincentivize pharmaceutical companies from investing in R&D, thereby stifling innovation and decreasing the number of new, potentially life-saving treatments brought to market.[18]

According to various estimates, "average R&D expenditures per new drug range from less than $1 billion to more than $2 billion," includ[ing] capital costs as well as expenditures on drugs that did not make it to market."[19] As a result, common sense dictates that fewer important medicines will be developed and brought to market.

---

[17] Trelysa Long & Stephen Ezell, *The Hidden Toll of Drug Price Controls: Fewer New Treatments and Higher Medical Costs for the World*, Info. Tech. and Innovation Found. (July 17, 2023), https://itif.org/publications/2023/07/17/hidden-toll-of-drug-price-controls-fewer-new-treatments-higher-medical-costs-for-world/.

[18] *See, e.g.*, *id.* (collecting studies finding that "prices and profits are strongly linked to pharmaceutical manufacturers' investments in R&D," including one study "estimat[ing] that cutting prices in the United States . . . by 40–50 percent would lead to between 30 and 60 percent fewer R&D projects," and another finding that "an increase of 10 percent in the growth of real drug prices is associated with an increase of 6 percent in the growth of R&D intensity" (citations omitted)); *see also id.* (noting that "pharmaceutical price controls disincentivize manufacturers from developing new medicines while incentivizing the production of generics"); *see generally* Rita Numerof, *The Hidden Costs of Healthcare Price Controls*, Forbes (Sept. 25, 2024), https://www.forbes.com/sites/ritanumerof/2024/09/25/the-hidden-costs-of-healthcare-price-controls/ (explaining the effect of marking-manipulating price controls on pharmaceutical R&D and the availability of innovative and life-saving treatments); Daniel E. Orr, *Congress Must Fix the Inflation Reduction Act Before Millions Lose Treatment for Rare Diseases*, 42 Yale L. & Pol'y Rev. Inter Alia 1, 8 (2023) (citing one economic analysis projecting "that because of IRA price controls, 40% fewer new drugs will come to market by 2035, including a loss of 14 new orphan drugs" (citation omitted)).

[19] *Research and Development in the Pharmaceutical Industry*, Cong. Budget Off., 14 (Apr. 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

IV. HRSA's acquiescence in covered entities' use of product-replenishment models has further contributed to the pervasion of third-party involvement and compromised the integrity of the 340B Program.

HRSA's acquiescence in covered entities' use of product-replenishment models for 340B purchases has further contributed to the pervasion of third-party involvement and compromised the integrity of the 340B Program. Under a product-replenishment model, covered entities and contract pharmacies initially purchase eligible drugs at a higher commercial price—known as the wholesale acquisition cost. *Novartis*, 102 F.4th at 457–58. The discounted 340B price is then realized *post facto*, once the covered entity accumulates enough eligible claims and then purchases a replenishment from a wholesaler at or below the drug's ceiling price. *Id.* The replenished 340B stock is then commingled with the regular wholesale stock and dispensed to an individual *regardless* of their status as a patient of a covered entity (a clear violation of 340B's no-diversion mandate).

Manufacturers (correctly) contend that replenishment models have enabled unlawful diversion and duplicate discounts. *Id.* at 458. As the D.C. Circuit has explained, with respect "to diversion, [the manufacturers'] concern is that pharmacies rely on manipulable algorithms to code whether prescriptions warrant the discount." *Id.* Moreover, the commingling of 340B and non-340B inventory under product-replenishment models increases the risk of diversion, as subsequent dispenses are inherently more difficult to track. *Accord* ECF No. 15-1 at 41 n.17. And with respect to "duplicate discounts, the [HHS] Inspector General found that some contract pharmacies do not track and exclude 340B-eligible prescriptions from Medicaid rebate claims, leading to impermissible duplication." *Novartis*, 102 F.4th at 458 (citing S. Wright, Off. of the Inspector Gen., OEI-05-13-00431, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program 13 (2014)).

Although HRSA has not formally approved the use of replenishment models, the agency has acknowledged and tacitly approved their widespread use—including, most notably, in a declaration from HRSA's Director of the Office of Pharmacy Affairs, Krista Pedley. *See* ECF No. 1-2 (Pedley Decl.) ¶¶ 5–11. Of course, HRSA is intimately aware of how contract-pharmacy arrangements operate under product-replenishment models. But in stark contrast to its present determinations on rebate/cash-replenishment models, HRSA has never contended either (a) that product-replenishment models' *post facto* effectuation of the 340B price is statutorily impermissible, or (b) that prior approval by the Secretary is a prerequisite to their adoption.

V. Lilly proposed its cash-replenishment model to ameliorate Program abuse, effectuate the aims of section 340B, and bring transparency and accountability to a laudable Program.

In August 2024, Lilly proposed its shift from a discount model to its cash-replenishment (rebate) model as a means of better effectuating the aims of 340B, while still fulfilling its obligations under the "shall offer" provision of the statute. *See, e.g.*, ECF No. 15-1 at 18–21. As Lilly explains, its "cash-replenishment model would substitute direct replenishments of cash to covered entities for the current replenishment of product" whereby a covered entity "would first purchase medicine at a commercial price," and "[a]fter identifying a transaction as eligible for the 340B price," a covered entity would then submit claims data to receive a cash payment effectuating the ceiling price. ECF No. 15-1 at 19. At its core, the cash-replenishment model is designed to offer several operational benefits that will enhance the integrity of the 340B Program. *See id.* at 19–21, 42–43. They include: emboldened transparency, as both Lilly and covered entities will be furnished identical data "on a claim-by-claim basis," thereby supplanting the opaque algorithms that typify product-replenishment models; greater efficiency, by permitting swifter payment and allowing covered entities to file claims for each dispense, rather than wait to accumulate eligible

prescriptions; streamlined cash flow, by remitting payment "directly to covered entities" instead of to third-party middlemen, and reduced diversion and duplicate discounting, by "channel[ing] . . . disputes into the audit and ADR processes," *Id.* at 20–21, 42 (internal quotation marks and citation omitted); *see also id.* at 37.

In several respects, Lilly's cash-replenishment model is analogous to existing product-replenishment models commonly used by covered entities. *See Novartis*, 102 F.4th at 457–58 (describing product-replenishment model in depth). Like product-replenishment models, Lilly's cash-replenishment/rebate model effectuates the 340B ceiling price *post facto*, by requiring covered entities to initially purchase an eligible drug at ordinary, commercial prices prior to receiving a cash replenishment covering the difference between the commercial price and the 340B ceiling price. *See* EFC No. 15-1 at 19. In this vein, existing product-replenishment models are functionally an in-kind rebate.

But there are notable differences between the two approaches. Unlike in a product-replenishment model, where replenishment units are not procured until a sufficient number of dispenses are accumulated or "package[d]," ECF No. 1-2 (Pedley Decl.) ¶ 8, by using claim-by-claim validation technology, Lilly "expects to be able to pay rebates to covered entities" promptly—on a weekly basis, ECF No. 15-1 at 42 (citation omitted). This approach would allow covered entities to "often receive rebates *before* they must pay wholesalers for a purchase, likely improving their cash flow compared to [product-replenishment models'] current full-package requirement." ECF No. 15-1 at 42 (citation omitted) (emphasis added); *compare id.*, *with* ECF No. 1-2 (Pedley Decl.) ¶ 8 (explaining that, under existing product-replenishment models, a third-party administrator "and/or contract pharmacy will 'accumulate' 340B-eligible dispenses of a specific . . . product towards a pre-set package size," rather than obtain replenishments after "a

single dispense"). Thus, Lilly's cash-replenishment model permits covered entities to realize the 340B price within an abbreviated timeframe—after validation of claims data submitted to a centralized platform—thereby aligning incentives, enhancing transparency, and preventing unlawful duplication. *See id.* at 38.

Notwithstanding these distinctions, the post-facto realization of the 340B ceiling price renders Lilly's model analogous to the existing product-replenishment models tacitly endorsed by HRSA. And yet, the agency has nonetheless rejected Lilly's proposal. ECF No. 1-5 at 1. In so doing, HRSA asserts that the 340B statute requires Lilly to obtain pre-approval from the Secretary before it can adopt a rebate model. Because the Secretary has not given such pre-approval, HRSA argues, "implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program . . ." *Id.*

HRSA's uncompromising response to Lilly's cash-replenishment proposal is legally flawed and has widespread consequences. But this is not the first time that HRSA has stopped manufacturers' attempts to implement policies aimed at enhancing the integrity of the 340B Program.

VI. The D.C. and Third Circuits have affirmed manufacturers' authority to "offer" medicine at 340B prices through reasonable means and conditions.

Federal courts of appeals have affirmed that the 340B statute only requires manufacturers to make a bona fide "offer" of their medicines at the 340B price—and that requirement leaves ample discretion for manufacturers to elect the method and means of that offer.

In 2020, several manufacturers exercised that discretion and adopted policies—in an effort to restore the 340B program's integrity—that limit the number of contract pharmacies that may purchase 340B medicines on behalf of a covered entity. *See Sanofi Aventis*, 58 F.4th at 700–01; *Novartis*, 102 F.4th at 458. Far from welcoming these attempts at greater 340B compliance, HRSA

repeatedly sought to frustrate the manufacturers' goals. Both the Third and D.C. Circuit countermanded HRSA's interference efforts.

In *Novartis*, the D.C. Circuit affirmed the basic proposition that manufacturers may impose conditions on the sale of their medicines, provided the offer they make remains "bona fide." *Id.* at 463–64. In particular, the court "reject[ed] HRSA's position that section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities." 102 F.4th at 459. The statute, the court explained, is "silent about delivery conditions," and "this silence preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Id.* In construing the "shall offer" provision, the court explained that, under black-letter contract law, "an offer often must contain some terms beyond the mere price to be definite enough to bind the contracting parties." *Id.* (citing Restatement (Second) of Contracts § 33 cmt. a; 1 Williston on Contracts § 4:22 (4th ed. 2023)). Finally, the statutory silence on delivery conditions "implies that manufacturers may impose distribution conditions by contract, not that they are prohibited from doing so." *Id.*

In *Sanofi*, the Third Circuit similarly concluded that, under the 340B statute, manufacturers remained free to impose reasonable conditions on their "offer" of 340B medicines. *Id.* at 703–04. The court held that "unless Section 340B '*prohibits*' drug makers from adopting their policies, *HHS cannot show that they have violated Section 340B.*" *Id.* at 704 (citing *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000)) (second emphasis added).

Both *Novartis* and *Sanofi* thus support the proposition that manufacturers may effectuate the 340B price through reasonable means and with reasonable conditions. That is particularly true in the case of a cash replenishment model, which enjoys explicit textual support in the 340B statute.

Accordingly, this Court should reject HRSA's current effort to hinder Lilly's attempt to bring transparency and accountability to the 340B Program through a cash-replenishment model.

VII. HRSA's determination that Lilly's cash-replenishment model violates Section 340B is arbitrary, capricious, and contrary to law.

A. HRSA's conclusion that Lilly's cash-replenishment model is inconsistent with Section 340B's "shall offer" provision is contrary to law.

HRSA's determination that the cash-replenishment model contravenes Section 340B's "shall offer" provision is arbitrary, capricious, and contrary to law. 5 U.S.C. § 706(2)(A). HRSA's position is contrary to law because the statutory text expressly contemplates the use of ***"rebate[s] or discount[s]"*** by manufacturers as permissible pricing mechanisms for offering covered entities the discounted 340B price. 42 U.S.C. § 256b(a)(1) (requiring the Secretary of HHS to "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 . . . ") (emphases added). Nor does the statute prescribe a particular pricing method. *See Sanofi Aventis*, 58 F.4th at 704.

Manufacturers thus have wide discretion to employ a pricing mechanism of their choosing—either discounts or rebates—for effectuating the ceiling price, so long as their approach is not expressly prohibited by the statute. *See id.* (explaining that "[u]nless Section 340B '*prohibits*' drug makers from adopting their policies, HHS cannot show that they have violated Section 340B" and that, absent such a prohibition, the manufacturers' "policies are lawful") (emphasis in original). Further, HRSA has long maintained "that manufacturers, in their contracts with covered entities, may 'include provisions that address customary business practice, request standard information, or include other appropriate contract provisions.'" *Novartis*, 102 F.4th at 456 (quoting Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity

Guidelines, 59 Fed. Reg. 25,110, 25,114 (May 13, 1994)). In short, the 340B statute delegates the intricate details of 340B transactions to the parties' free-market negotiations.

Lilly's proposed model stands on even firmer textual footing than the delivery conditions upheld in *Sanofi Aventis* and *Novartis*. In those cases, the courts concluded that Section 340B's silence on delivery and contract pharmacies foreclosed HRSA's asserted authority to prohibit imposing delivery conditions. *See Sanofi Aventis*, 58 F.4th at 703–04; *Novartis*, 102 F.4th at 460–61. Whereas here, not only does the statute ***not*** ***prohibit*** manufacturers from employing rebates, but—far from statutory silence—section 340B *expressly references* rebates as a permissible means of offering covered entities the 340B price. *See* 42 U.S.C. § 256b(a)(1). Similarly, as Lilly aptly notes, the statute's express reference to rebates is not confined solely to subsection (a)(1). *See id.* § (a)(5)(A) (provision "[p]rohibiting duplicate discounts *or rebates*" (emphasis added)); ECF No. 15-1 at 27 (citing *id.*).

Indeed, as a rebate, the cash-replenishment model is plainly *consistent* with the "shall offer" provision. Through its use of a rebate, Lilly "offer[s]" the drugs for "purchase at or below the applicable ceiling price," 42 U.S.C. § 256b(a)(1). "[P]rice" is best understood to be inclusive of "any rebate or discount." *Id.* This is the prevailing understanding of the term under various Medicare statutes and implementing regulations.[20] It is also consistent with the commonsense

[20] *See, e.g.*, 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I) (defining "best price" under Medicaid Drug Rebate Program as "inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and *rebates*," with certain exceptions (emphasis added)); 42 C.F.R. § 447.505 ("best price for covered outpatient drugs includes all prices, including applicable discounts, *rebates*, or other transactions that adjust prices either directly or indirectly" (emphasis added)); 42 U.S.C. § 1395w-102(d)(1)(B) (providing that "negotiated price" includes any "negotiated price concessions, such as discounts, direct or indirect subsidies, *rebates*, and direct or indirect remunerations, for covered part D drugs, and include[s] any dispensing fees for such drugs" (emphasis added)); *see also* 42 C.F.R. § 1001.952(h)(4) (Anti-Kickback Statute implementing regulation providing that "a rebate is any discount the terms of which are fixed and

understanding of consumer purchases. Suppose a student placed on an allowance is told that he is not permitted to spend more than $500 on a cellphone. Pursuant to a promotional program, the student purchases a new smartphone for $700 from his carrier and then receives a rebate for $200. It is fair to say the cell phone carrier *offered* the phone for purchase by the student at a price of $500. Nor did the rebate result in the student paying more than his $500 allotment, even though his credit card may have been initially charged $700 before the rebate was processed. Lilly's cash-replenishment is no different and is consistent with the "shall offer" provision. A covered entity is initially charged a higher commercial price and then receives a rebate which conforms the net price to the ceiling price.

HRSA also urges that Lilly's proposal violates section 340B because the statute requires manufacturers to obtain advance approval by the Secretary prior to implementing a rebate mechanism. But this interpretation is likewise contrary to the statute's text, under which the Secretary can only dictate a pricing mechanism through the PPA. *See* 42 U.S.C. § 256b(1)(a). Further, HRSA has never authorized *either* a discount *or* rebate model in Lilly's PPA. ECF No. 15-1 at 29. HRSA's failure to mandate pre-approval for Lilly's (and other manufacturers') longtime use of discounts confirms the lawfulness of this settled industry practice. *See Yi v. Sterling Collision Ctrs., Inc.*, 480 F.3d 505, 510–11 (7th Cir. 2007) (Posner, J.) (explaining that while "[i]t is possible for an entire industry to be in violation of [federal law] for a long time without [an agency] noticing," "a more plausible hypothesis is that the . . . industry has been left alone because" the agency believed its actions were lawful). This is particularly so when an agency's interpretive volte-face would work an "unfair surprise" on regulated parties with reliance

---

disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, *but which is not given at the time of sale*" (emphasis added)).

interests in the agency's prior practice and pronouncements, even if never formally adopted. *Cf. Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158 (2012) ("[W]here, as here, an agency's announcement of its interpretation is preceded by a very lengthy period of conspicuous inaction, the potential for unfair surprise is acute.").

HRSA's apparent position is that section 340B prohibits the use of *any* pricing mechanism that obligates covered entities to procure 340B drugs at ordinary commercial prices prior to receiving a concession effectuating ceiling price. But that construction would prohibit rebates *per se*, as any rebate, by definition, necessitates an initial purchase above the ceiling price. An interpretation of the 340B statute which forecloses the use of rebates would render superfluous the statutory reference to "any rebate or discount," 42 U.S.C. § 256b(a)(1). That cannot be correct. *See Leocal v. Ashcroft*, 543 U.S. 1, 12 (2004) ("[Courts] must give effect to every word of a statute wherever possible.").

HRSA cannot wield enforcement authority that Congress has declined to statutorily authorize. *See Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food & Drug Admin.*, 3 F.4th 390, 399 (D.C. Cir. 2021). Because HRSA lacks authority to dictate a pricing mechanism outside of a PPA or prohibit statutorily sanctioned rebates as a means of offering covered entities the 340B price, the agency's determination that Lilly's cash-replenishment model contravenes Section 340B is both contrary to law and "in excess of statutory . . . authority," and thus must be set aside. 5 U.S.C. § 706(2)(A).

B. HRSA's differential treatment of cash-replenishment/rebate and product-replenishment models is arbitrary and capricious.

"A fundamental norm of administrative procedure requires an agency to treat like cases alike. If the agency makes an exception in one case, then it must either make an exception in a similar case or point to a relevant distinction between the two cases." *Westar Energy, Inc. v. Fed.*

Energy Regul. Comm'n, 473 F.3d 1239, 1241 (D.C. Cir. 2007). As the D.C. Circuit has stressed, "'dissimilar treatment of evidently identical cases' is 'the quintessence of arbitrariness and caprice.'" *Id.* (quoting *Colo. Interstate Gas Co. v. FERC*, 850 F.2d 769, 774 (D.C. Cir. 1988)). And so, when "a party plausibly alleges that it has received inconsistent treatment under the same rule or standard," a court "must consider whether the agency has offered a reasonable and coherent explanation for the seemingly inconsistent results." *Baltimore Gas & Elec. Co. v. FERC*, 954 F.3d 279, 286 (D.C. Cir. 2020).

Here, HRSA has failed to reasonably explain its disparate treatment of Lilly's model and existing product-replenishment models, respectively; that explanatory deficit is quintessentially arbitrary and capricious, *see Grayscale Invs., LLC v. Sec. & Exch. Comm'n*, 82 F.4th 1239, 1245 (D.C. Cir. 2023). As noted *supra*, Lilly's rebate operates much as a product-replenishment model, requiring an initial purchase at a higher commercial price before the receipt of the rebate, which then brings the net price down to the ceiling price. Under either approach (rebate or replenishment), the 340B price is realized *after the fact* of the initial purchase.

As HRSA functionally concedes, under a product-replenishment model, the initial purchase is still above the ceiling price. *Cf.* ECF No. 1–2 (Pendley Decl.) ¶¶ 3, 5 (explaining that covered entities do not receive the "340B discount" until "after a drug is dispensed"). If HRSA's view is that the ceiling price must be offered at the earliest moment of purchase—and not upon the offer of the cash rebate—then, by that (flawed) reading, product-replenishment models would likewise contravene 42 U.S.C. § 256b(a)(1). HRSA simply cannot have it both ways, by (1) construing the section 340B statute as it does here to bar the use of rebates, and (2) simultaneously acquiescing in the widespread use of product-replenishment models. The 340B statute simply provides that manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below

the applicable ceiling price," 42 U.S.C. § 256b(a)(1). Lilly's proposed model does just that and thus is consistent with the "shall offer" provision.

By failing to reasonably explain the disparate treatment that it accords Lilly's rebate model vis-à-vis existing product-replenishment models, HRSA's conclusion that the former contravenes section 340B is arbitrary and capricious and thus must be set aside.

C. HRSA's rejection of the cash-replenishment model appears to further a pattern arbitrarily disfavoring manufacturers and thereby endangering access to potentially life-saving treatments.

HRSA's rejection of Lilly's cash-replenishment model—much like its rejection of other manufacturers' proposed rebate models—evinces the agency's pattern of action disfavoring drug manufacturers and other stakeholders. As *Sanofi Aventis*, *Novartis*, pending litigation involving other pharmaceutical manufacturers, *e.g.*, *Johnson & Johnson Health Care Sys. Inc., v. Becerra, et al.*, 1:24-cv-03188-RC (D.D.C.), and the instant case confirm, HRSA has exhibited a pattern of blocking good faith attempts by drug makers to comply with the 340B statute and further its professed intent. HSRA has not offered any reasonable basis for seemingly singling out drug makers and seeking to impede them from stanching financial losses and rededicating the 340B Program to its intended beneficiaries.

As Lilly notes, and as discussed above, the status quo renders it exceedingly difficult for manufacturers to exercise their statutory right to audit covered entities, rendering HRSA's ADR process a paper tiger as an enforcement mechanism. Simply put, covered entities, contract pharmacies, and third-party administrators, whose compensation is often tied to the number of eligible claims identified, have a perverse economic incentive to keep manufacturers in the dark, to evade a prospective audit and maximize their arbitrage. *See id.* This only further enables

Program abuse, undermines accountability, and neuters the 340B Program's ADR processes. *See id.* § 256b(d)(3)(A); 42 C.F.R. § 10.21(a)(2).

Finally, as Lilly notes, there is no question that HRSA's threatened termination of Johnson & Johnson's PPA and imposition of Civil Monetary Penalties—in response to that company's proposed rebate model—"applies to all manufacturers," as evinced by the agency's public pronouncement that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." HRSA, *340B Drug Pricing Program* (last updated Jan. 2025), https://www.hrsa.gov/opa. If HRSA were to follow through on its threats of enforcement, it would harm millions of Medicare and Medicaid patients, who would be denied access to all of Lilly's medicines. If HRSA's September 18 letter is allowed to stand, it will deprive millions of Americans access to potentially life-saving pharmaceuticals. HRSA's decision to block Lilly from selecting the (rebate) pricing mechanism of its choosing, as contemplated by the 340B statute, and restore accountability to the 340B Program, is arbitrary, capricious, and contrary to law and thus must be set aside.

HRSA has shown a willingness to expend finite resources blocking manufacturers' attempts to eliminate diversion and duplicate discounts, rather than directing its enforcement efforts at entities who may be violating the Program. This court should reject HRSA's latest, extra-statutory attempt to block a manufacturer from implementing permissible policies designed to effectuate the aims of section 340B, enhance transparency, and redirect savings to vulnerable patients.

CONCLUSION

Although its aims are laudable, the 340B Drug Pricing Program has veered from its original purpose to the detriment of drug makers, patients, and other stakeholders. This case cannot fix all

that needs fixing with the Program. But consistent with *Sanofi Aventis* and *Novartis*, this Court can provide some much-needed correction, by rejecting HRSA's attempts to punish drug makers for simply trying to restore accountability and transparency to the Program through statutorily-approved rebates.

Dated: February 14, 2025

Respectfully submitted,

/s/ Jonathan J. Huber

Jonathan J. Huber (DC Fed Bar No.: 1014590)
Nelson Mullins Riley & Scarborough LLP
101 Constitution Ave., NW | Suite 900
Washington, DC 20001
Phone: (202) 689-2966
Facsimile: (443) 392-9499
jonathan.huber@nelsonmullins.com

COMBINED CERTIFICATIONS

In accordance with the Federal Rules of Civil Procedure and the Local Rules of this Court, I hereby certify the following:

1. I am a member in good standing of the Bar of this Court.

2. This Brief complies with the page limitations of the Local Rules because it does not exceed 25 pages.

3. This Brief complies with the typeface and type-style requirements of the Local Rules because it is double spaced and has been prepared using Microsoft Word in a proportionally spaced 12-point font (Times New Roman) in the text and the footnotes.

4. The electronic file containing the Brief was scanned for viruses and is virus free.

Dated: February 14, 2025 */s/ Jonathan J. Huber*