IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.,
1000 US Highway 202 South
Raritan, NJ 08869,

Plaintiff,

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. 1:24-cv-3188

BRIEF OF AMICUS CURIAE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PLAINTIFF JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.

TABLE OF CONTENTS

TABLE OF CASES AND AUTHORITIES ii

CORPORATE DISCLOSURE STATEMENT 1

INTEREST OF AMICUS CURIAE 1

INTRODUCTION AND SUMMARY OF ARGUMENT 1

ARGUMENT 4

I. The Section 340B statute requires drug manufacturers to offer certain pharmaceuticals to covered entities at or below a specified, discounted rate 4

II. Due to legislative amendments and HRSA guidance, the 340B Program has evolved and increased in size and scope since its inception 5

III. The growth of the 340B Program has imposed substantial costs on manufacturers, employers, and other stakeholders in the pharmaceutical industry 8

IV. J&J proposed its Rebate Model to ameliorate Program dysfunction, effectuate the aims of section 340B, and bring transparency and accountability to a laudable program 10

V. The D.C. Circuit and the Third Circuit have rejected HRSA's recent attempts to block manufacturers' policies aimed at limiting unlawful diversion and duplicate discounting 12

VI. HRSA's determination that J&J's Rebate Model violates Section 340B is arbitrary, capricious, and contrary to law 13

A. HRSA's conclusion that the Rebate Model contravenes Section 340B's "shall offer" provision is contrary to law 13

B. HRSA's differential treatment of rebate and replenishment models is arbitrary and capricious 17

C. HRSA's rejection of the rebate model appears to further a pattern arbitrarily disfavoring manufacturers and thereby endangering access to potentially life-saving treatments 19

CONCLUSION 20

COMBINED CERTIFICATIONS 22

TABLE OF CASES AND AUTHORITIES

Cases:

Astra, USA, Inc. v. Santa Clara Cnty.,
563 U.S. 110 (2011) 1

Baltimore Gas & Elec. Co. v. FERC,
954 F.3d 279 (D.C. Cir. 2020) 17

Christensen v. Harris Cnty.,
529 U.S. 576 (2000) 13

Christopher v. SmithKline Beecham Corp.,
567 U.S. 142 (2012) 16

Colo. Interstate Gas Co. v. FERC,
850 F.2d 769 (D.C. Cir. 1988) 17

Grayscale Invs., LLC v. Sec. & Exch. Comm'n,
82 F.4th 1239 (D.C. Cir. 2023) 18

Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food & Drug Admin.,
3 F.4th 390 (D.C. Cir. 2021) 17

Leocal v. Ashcroft,
543 U.S. 1 (2004) 17

Novartis Pharms. Corp. v. Johnson,
102 F.4th 452 (D.C. Cir. 2024) ..... *passim*

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95 F.4th 1136 (8th Cir. 2024) 1

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58 F.4th 696 (3d Cir. 2023) ..... *passim*

Yi v. Sterling Collision Ctrs., Inc.,
480 F.3d 505 (7th Cir. 2007) 16

Westar Energy, Inc. v. Fed. Energy Regul. Comm'n,
473 F.3d 1239 (D.C. Cir. 2007) 17

Statutes and Regulations:

5 U.S.C. § 706(2)(A) 13, 17

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42 U.S.C. § 256b(a)(5)(D) 5

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75 Fed. Reg. 10,272 (Mar. 5, 2010) 5

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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 (2023) 10

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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 Heal.th & 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 handful of companies at the expense of drug makers, patients, insurers, and employers, 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 discount prices to a select set of health care providers, known as "covered entities," which generally 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 Program

[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.

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 Johnson & Johnson (J&J) 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 summer 2024, to effectuate the aims of section 340B and bring transparency and accountability to a laudable Program, J&J proposed its shift from a discount model to a Rebate Model as a means of effectuating the 340B price. *See, e.g.*, Compl. ¶ 78. Although J&J's proposed Rebate Model is analogous in operation to replenishment models commonly employed by covered entities and is compliant with the plain text of the statute, HRSA rejected J&J's proposal.

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, 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, discounted 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 J&J: 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 program, 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 guidance documents interpreting and implementing the scheme." *Novartis*, 102 F.4th at 456.

In 1996, four years after section 340B's enactment, HRSA issued a guidance document 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 decision 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.* at 457. 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.[2] 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.[3]

As a result, the 340B Program is now dominated by large, for-profit enterprises, including publicly traded pharmacy chains.[4] Given the discounts the 340B Program affords—an 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.[5] In so doing, many covered entities engage in

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[2] 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.

[3] 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.

[4] 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.

[5] *See* Ellie Blalock et al., *The Pharmaceutical Supply Chain, 2013–2023*, Berkeley Rsch. Grp., 4 (January 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

arbitrage, declining to pass some or all of the savings on to their patients in underserved communities.[6]

Moreover, as HRSA's audits have uncovered, recent years have seen a troubling incidence of unlawful drug diversion and duplicate discounting.[7] 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.[8] According to J&J, its own audits have uncovered evidence of abuse, by "identify[ing] thousands of transactions in which [disproportionate share hospital (DSH)] covered entities received a 340B discount on a unit of drug for which a state Medicaid program also requested a Medicaid rebate, in violation of the prohibition against duplicate discounts." Compl. ¶ 59.

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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).

[6] 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 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").

[7] *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 (December 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).

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

Although covered entities are statutorily required to comply with manufacturer audits, *see* 42 U.S.C. § 256b(a)(5)(C), J&J's HRSA-sanctioned audits have been frustrated by lawsuits aimed to prevent J&J's efforts at ensuring Program compliance and providing transparency.[9]

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 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,

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[9] Indeed, five covered entities have sued HRSA in this District alone seeking to set aside the agency's approvals of J&J's audits.

[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.").

[11] *Id.*

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

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.

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]

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[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.*

[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

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.

IV. J&J proposed its Rebate Model to ameliorate Program dysfunction, effectuate the aims of section 340B, and bring transparency and accountability to a laudable program.

In summer 2024, J&J proposed its shift from a discount model to a Rebate Model as a means of better effectuating the aims of 340B, as well as fulfilling its obligations under the "shall offer" provision of the statute. *See, e.g.*, Compl. ¶ 78. As J&J explains, "[u]nder [its] Rebate Model, covered entities would purchase the applicable J&J medicines from wholesalers at commercial prices" and "would then obtain the 340B price" by receiving a rebate *after* the hospital-covered entity furnishes "claims data for each purchase" "indicating that a covered entity both purchased and dispensed a drug," Compl. ¶¶ 78, 80. At its core, the Rebate Model is designed to "offer[] a number of operational and logistical benefits that will further the integrity of the 340B Program,"

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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.

including more transparency, greater efficiency, and the elimination of diversion and duplicate discounting. Compl. ¶ 80

The Rebate Model is also analogous to existing replenishment models commonly used by covered entities. *See Novartis*, 102 F.4th at 457–58 (describing the replenishment model in depth). Like replenishment models, the Rebate Model effectuates the 340B ceiling price *post facto*, by requiring covered entities to initially purchase an eligible drug at an elevated commercial price prior to receiving a rebate (for the difference between the wholesale price and the 340B ceiling price). But unlike the replenishment model, covered entities that timely file claims data after they dispense covered drugs will receive "340B rebates *before* payment is due to wholesalers on the underlying purchase under standard payment terms." Compl. ¶ 79 (emphasis in original). Thus, the Rebate Model permits covered entities to realize the 340B price within an abbreviated timeframe: upon submission of a rebate claim, "J&J expects the claim to be validated immediately and paid within approximately seven to ten days." Compl. ¶ 79. Importantly, although HRSA has not formally approved the use of replenishment models, the agency has acquiesced in and conceded its use—including, most notably, in a declaration from HRSA's Director of the Office of Pharmacy Affairs, Krista Pedley, in recent litigation. *See* Pedley Decl. ¶¶ 5-9, *Sanofi-Aventis U.S.*, No. 3:21-cv-634 (D.N.J. June 24, 2021).

Here, although J&J's proposed Rebate Model is consistent with the replenishment model tacitly endorsed by HRSA, the agency nonetheless rejected J&J's proposal. Instead, HRSA asserts that the 340B statute requires J&J 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, J&J is precluded from using a Rebate Model under section 340B. Further, HRSA threatened enforcement action if J&J proceeded with its proposed model, including terminating the PPA.

HRSA's uncompromising response to J&J's limited rebate proposal is legally flawed and has widespread consequences. Indeed, HRSA's threatened sanctions, most notably, termination of J&J's PPA, would bar the company from further participation in Medicare—a financial death knell which would foreclose access to J&J's life-saving treatments for millions of vulnerable Medicare and Medicaid patients. But this is not the first time that HRSA has endeavored to thwart manufacturers' attempts to implement policies aimed at enhancing the integrity of the 340B Program. Unfortunately, the agency appears to have a pattern of interpreting and enforcing the 340B statute at the expense of manufacturers, employers, patients, and insurers.

V. The D.C. Circuit and the Third Circuit have rejected HRSA's recent attempts to block manufacturers' policies aimed at limiting unlawful diversion and duplicate discounting.

In 2020, several manufacturers adopted policies directed at reducing diversion and duplicate discounting, by limiting covered entities' reliance on contract pharmacies. *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.

In *Sanofi Aventis*, several manufacturers adopted policies to limit the use of contract pharmacies. 58 F.4th at 700. HHS responded by issuing an Advisory Opinion "declaring that Section 340B unambiguously requires drug makers to deliver 340B drugs to an unlimited number of contract pharmacies," and sending violation letters to the companies stating that their policies contravened section 3430B. *Id.*

On appeal, the Third Circuit disagreed with HRSA, finding that both the "shall offer" and "purchased by" provisions of 340B were silent about delivery and contract pharmacies, and thus there is no textual support for HRSA's contention that the statute requires unlimited delivery. *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).

In *Novartis*, the D.C. Circuit likewise "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.*

Consistent with *Sanofi Aventis* and *Novartis*, this Court should reject HRSA's current effort to hinder J&J's attempt to bring transparency and accountability to the 340B Program.

VI. HRSA's determination that J&J's Rebate Model violates Section 340B is arbitrary, capricious, and contrary to law.

A. HRSA's conclusion that the Rebate Model contravenes Section 340B's "shall offer" provision is contrary to law.

HRSA's determination that the Rebate 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") (emphasis 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.

J&J's Rebate 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).

HRSA, however, further contends that the ACA amendment to the 340B statue—adding the "shall offer" provision, under which a PPA must "require that the manufacturer offer each

covered entity covered outpatient drugs for purchase at or below the applicable ceiling price," 42 U.S.C. § 256b(a)(1)—somehow renders rebates statutorily impermissible. This argument is unavailing. The 340B statute's reference to rebates abides, unaltered by the ACA amendment. *See id.* But more importantly, the Rebate Model is plainly *consistent* with the "shall offer" provision. Through its use of a rebate, J&J "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.* Indeed, this is the prevailing understanding of the term under various Medicare statutes and implementing regulations.[20] It is also consistent with the commonsense 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. J&J's Rebate Model 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.

[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)).

HRSA also urges that J&J'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, as J&J contends, the Secretary can only dictate a pricing mechanism through the PPA. *See* 42 U.S.C. § 256b(1)(a). Further, J&J has never sought, and HRSA has never provided in a PPA, explicit approval for the *discount* model which J&J has employed for three decades. *See* Compl. ¶ 23 (noting that J&J "has participated in the 340B Program for more than thirty years"). HRSA's acquiescence is best understood as assent to the lawfulness of 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 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.").

Finally, in its September 17 letter, HRSA, contends that section 340B prohibits the use of *any* pricing mechanism that obligates covered entities to procure 340B drugs at higher 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 failed 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 J&J's Rebate Model violates 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 rebate and 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 the Rebate Model and 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). HRSA's disparate treatment of the two models is especially capricious given the lack of

express statutory permission for replenishment models, on the one hand, and the clear statutory contemplation of rebates, on the other. *See* 42 U.S.C. § 256b(a)(1). HRSA's contention that "[t]here are fundamental differences between J&J's" Rebate Model and replenishment models is arbitrary and disregards the operational similarities between the two mechanisms in effectuating the 340B price. *See* Compl. Ex. 9 at 3. HRSA urges that "under a typical replenishment structure, a covered entity *generally makes an initial purchase at a higher price*, then subsequent, ongoing drug purchases are at the 340B price." *Id.* (emphasis added). "By contrast," HRSA's argument goes, "under the J&J proposal, covered entities would be forced to pay a higher price point up front for *every* purchase." *Id.* (emphasis in original). HRSA argues that "[t]his would create significantly higher up-front costs for covered entities." *Id.* But, under HRSA's own interpretation of the 340B statute, that is a distinction without a difference. As noted *supra*, the Rebate Model operates much as a 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 concedes, under the replenishment model, the initial purchase is still above the ceiling price. *See id.* (observing that "under a typical replenishment structure, a covered entity *generally makes an initial purchase at a higher price*, then subsequent, ongoing drug purchases are at the 340B price" (emphasis added)). 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 rebate—then, by that (flawed) reading, replenishment models would likewise contravene 42 U.S.C. § 256b(a)(1). HRSA simply cannot have it both ways, by (1) construing the "shall offer" provision as it does here to bar the use of rebates, and (2) simultaneously acquiescing in the widespread use of replenishment models. Furthermore, notwithstanding HRSA's apparent concern for covered entities' outlays, the statute

says nothing of "higher upfront costs." Rather, it merely 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). The Rebate Model does just that and thus is consistent with the "shall offer" provision.

HRSA's further attempt to distinguish replenishments from rebates fares no better. The agency obliquely urges that while "covered entities *voluntarily* choose to use replenishment processes," "J&J's proposal is *not* voluntary for covered entities." Compl. Ex. 9 at 3 (emphasis added). But that is beside the statutory point. The volitional quality of a rebate (or lack thereof) is irrelevant to whether a pricing mechanism complies with the "shall offer" provision. After all, the distribution conditions upheld in *Sanofi Aventis* and *Novartis* were not voluntary; they were imposed by the manufacturers on the covered entities. By failing to reasonably explain the disparate treatment that it accords J&J's Rebate Model vis-à-vis existing replenishment models, HRSA's conclusion that the former violates section 340B is arbitrary and capricious and thus must be set aside.

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

HRSA's rejection of J&J's Rebate Model evinces the agency's pattern of action disfavoring drug manufacturers and other stakeholders. As *Sanofi Aventis*, *Novartis*, and the instant case demonstrate, HRSA has exhibited a pattern of blocking good faith attempts by drug makers to comply with Rule 340B 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.

Finally, by threatening to terminate J&J's PPA and impose Civil Monetary Penalties, HRSA's response to J&J's proposed implementation of the Rebate Model is detrimental to millions of Medicare and Medicaid patients, who would be denied access to any of J&J's medicines were HRSA to follow through on its threats of enforcement. If HRSA's August 14, September 17, and September 27 letters are allowed to stand, these threatened enforcement actions could deprive millions of Americans access to potentially life-saving pharmaceuticals. HRSA's decision to block J&J 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.

Time and again, HRSA is willing to expend finite resources targeting manufacturers for trying to eliminate diversion and duplicate discounts, rather than directing its enforcement efforts at entities who may be violating the Program. Given the costs of developing breakthrough medicines, HRSA's apparently skewed enforcement priorities further compromise Program integrity and ultimately repress innovative pharmaceutical research. 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 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, employers, and insurers. 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 attempting to restore accountability and transparency to the Program through statutory approved rebates.

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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

Attorneys for Washington Legal Foundation

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 10, 2025

/s/ Jonathan J. Huber
Jonathan J. Huber