IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.,

Plaintiff,

v.

DOROTHY FINK, in her official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

and

DIANA ESPINOSA, in her official capacity, and HEALTH RESOURCES AND SERVICES ADMINISTRATION,

Defendants.

Civil Action No. 1:24-cv-3188

MEMORANDUM IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case involves a simple question of statutory construction: Does the statute establishing the 340B prescription drug pricing program, 42 U.S.C. § 256b, permit drug manufacturers to offer statutorily required price reductions through a rebate rather than a discount? The answer is definitively yes. The 340B statute directs that "[t]he Secretary [of Health and Human Services] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account *any rebate or discount*, as provided by the Secretary) to the manufacturer" by eligible purchasers, known as covered entities, "does not exceed" a "ceiling price" calculated by the manufacturer through a statutory formula. 42 U.S.C. § 256b(a)(1) (emphasis added). The "agreement" referenced in the statute, a form contract known as the Pharmaceutical Pricing Agreement ("PPA"), does not, and indeed cannot, preclude manufacturers from offering that ceiling price through a rebate. Accordingly, manufacturers retain discretion to adopt a rebate mechanism for offering the ceiling price to covered entities.

Despite the plain statutory text, the Health Resources and Services Administration ("HRSA") rejected a plan by plaintiff Johnson & Johnson Health Care Systems Inc. ("J&J") to offer the 340B price for certain sales through a rebate model rather than through a discount. In a series of final action letters to J&J, as well as a policy pronouncement on its website, HRSA definitively has concluded that J&J must obtain "Secretarial approval" before offering the 340B price on these sales through a rebate.[1]

But the 340B statute does not vest Defendants with that authority. Rather, the statute authorizes the Secretary, at most, to provide guidance in the PPA on how a manufacturer should

[1] Pursuant to Federal Rule of Civil Procedure 25(d), J&J has substituted the successors of the Health and Human Services ("HHS") Secretary and HRSA Administrator in this case's caption.

"tak[e] into account" the manufacturer's own, discretionary choice of pricing mechanism. 42 U.S.C. § 256b(a)(1). By its plain meaning, that language authorizes HRSA to provide in the PPA how manufacturers may account for rebates or discounts, such as by directing use of appropriate records, recordkeeping procedures, or accounting mechanisms to document rebate payments (*i.e.*, "taking [rebates] into account"). Moreover, even if HRSA were correct that the 340B statute vests the Secretary with discretion to direct a pricing mechanism (it does not), the 340B statute makes clear that the *only* vehicle through which HRSA could possibly implement such a mandate is the PPA. The statute contains no other authority to prohibit a pricing mechanism; as this Court has held, "[w]ithin section 340B, Congress specifically authorized rulemaking in three places" only. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 41-42 (D.D.C. 2014) (Contreras, J.). Whether manufacturers must use discounts or rebates to provide 340B pricing to covered entities is not among them, and "HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program." *Id.* at 42. As such, HRSA's regulatory letters and policy pronouncement rejecting J&J's planned use of rebates to effectuate 340B pricing violate the 340B statute.

HRSA's actions also violate the Administrative Procedure Act ("APA"). Again assuming that HRSA has authority to mandate or prohibit a pricing mechanism, which it does not, that is an exercise of legislative authority that could be carried out only through notice-and-comment rulemaking. In its letters to J&J and the policy pronouncement on its website, HRSA declared that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1)," and threatened to terminate J&J from the 340B program if it proceeds with a rebate model. These declarations purport to bar J&J from unilaterally adopting a rebate model on pain of severe sanctions. HRSA has thus attempted to adopt a legislative rule that is both in excess of its statutory powers and promulgated without observing procedures required by law.

HRSA's treatment of J&J's rebate model is also fundamentally at odds with its acquiescence in covered entities' adoption of "replenishment models" for 340B purchasing over a decade ago. The details of replenishment models vary, but they operate similarly to rebate models in that covered entities make initial purchases at commercial prices, and thereafter receive replacement units at reduced 340B pricing. Yet in its letters rejecting J&J's rebate model, HRSA failed to reconcile its tacit consent to covered entities' voluntary adoption of replenishment models—which are contemplated nowhere in the 340B statute—with its harsh rejection of J&J's materially similar, statutorily-authorized rebate model. Nor did HRSA sufficiently reconcile its current rejection of J&J's rebate model with HRSA's prior determination that certain covered entities could use rebate models (as some covered entities do today) or with J&J's contention that a rebate model was necessary to comply with the Inflation Reduction Act's Medicare Drug Price Negotiation Program, for which key obligations take effect on September 1, 2025.

For these reasons, the Court should: (i) declare that J&J may proceed with its plan to offer the 340B price to covered entities through a rebate; (ii) declare that HRSA violated the APA by (a) adopting its "Secretarial approval" policy without statutory authority and through unlawful procedure, and then (b) applying that unlawful policy to J&J; and (iii) vacate HRSA's unlawful policy and its letters applying that policy to J&J.

STATEMENT OF FACTS

I. STATUTORY AND REGULATORY FRAMEWORK

A. The 340B Drug Pricing Program Caps Drug Prices for Certain Covered Entities that Provide Healthcare to Underserved Populations

Section 340B of the Public Health Service Act establishes a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations.

Astra USA, Inc. v. Santa Clara Cnty., 563 U.S. 110, 113 (2011). The statute defines "covered entity" to include 15 carefully drawn and narrow categories of healthcare providers. 42 U.S.C. § 256b(a)(4)(A)-(O).

Under the 340B statute, in order for a pharmaceutical manufacturer's products to be reimbursed under Medicare Part B, and for a state Medicaid program to receive "Federal Financial Participation" for those products, the manufacturer must enter into a Pharmaceutical Pricing Agreement ("PPA") with HHS. *See* 42 U.S.C. § 256b(a)(1). The PPA requires manufacturers, among other things, to "offer each covered entity covered outpatient drugs for purchase" at a calculated reduced price (the ceiling price) "if such drug is made available to any other purchaser at any price." *Id.*; *see* AR36-AR47.[2] This is known as Section 340B's "must-offer" requirement. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023).

Congress enacted Section 340B in 1992 to address an unintended consequence of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388. Among other things, the 1990 Act established the Medicaid Drug Rebate Program ("MDRP"), which altered pricing rules that had previously enabled some manufacturers to voluntarily provide lower prices on their drugs to safety net providers. The intent of the 340B Program was to restore the pre-1990 status quo, making reduced prices available again to covered entities but now exempting those lower prices from impacting the manufacturer's rebate obligations under the Medicaid rebate program. *See* H.R. Rep. No. 102-384, pt. 2, at 10-12 (1992) (House committee report explaining that the 340B Program would "remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals").

[2] "AR" citations refer to the Administrative Record produced by Defendants, ECF No. 17.

Over time, however, covered entities realized that they could arbitrage their ability to purchase drugs at steep discounts under the 340B Program to generate "revenue from serving insured patients: they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi Aventis*, 58 F.4th at 699; *see Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024) (covered entities generate revenue from the "spread between the discounted price and the higher insurance reimbursement rate"). In other words, covered entities benefit from the spread between a 340B drug's acquisition cost (*i.e.*, the reduced 340B price) and a higher rate at which insurance companies reimburse for the product. Eligibility to purchase drugs at 340B prices thus confers an extremely valuable benefit on covered entities, who have "a financial incentive to catalog as many prescriptions as possible as eligible for [a 340B] discount." *Novartis Pharms.*, 102 F.4th at 457-58. As a result, the program incentivizes covered entities to provide services to *insured* patients rather than vulnerable populations most in need of affordable care. *See, e.g.*, Rory Martin et al., IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* 5 (Aug. 30, 2024) (*Unintended Consequences*), https://bit.ly/3XFDWh8.

In enacting Section 340B, Congress sought to balance its goal of increasing patient access against the need to "assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384, pt. 2, at 16. To that end, the 340B statute places two important restrictions on covered entities. First, covered entities may not obtain 340B pricing on units of drugs that are also subject to the payment of a rebate under Medicaid (known as a "duplicate discount"). 42 U.S.C. § 256b(a)(5)(A). Second, covered entities may not resell or otherwise transfer 340B drugs to a person who is not a patient of the covered entity (known as "diversion"). *Id.* § 256b(a)(5)(B). A

covered entity that "knowingly and intentionally" engages in diversion must pay monetary penalties. *Id.* § 256b(d)(2)(B)(v)(I).

In addition, the 340B statute authorizes HRSA and manufacturers to conduct audits of covered entities' compliance with the diversion and duplicate discounting prohibitions:

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

Id. § 256b(a)(5)(C).

In addition to regulating covered entities, the 340B statute also authorizes HRSA to pursue enforcement actions against manufacturers who are not compliant with program requirements. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B ceiling price]" are subject to civil monetary penalties ("CMPs"). *Id.* § 256b(d)(1)(B)(vi)(III). The amount of the penalty is decided on a case-by-case basis, with a maximum of "$5,000 for each instance of overcharging," *id.* § 256b(d)(1)(B)(vi)(II), an amount that has been administratively adjusted for inflation up to the current maximum of $6,813, 88 Fed. Reg. 69,531, 69,535 (Oct. 6, 2023). HRSA has interpreted the phrase "instance of overcharging" to mean "any order for a covered outpatient drug, by NDC [a unique product identifier for each prescription drug product], which results in a covered entity paying more than the [340B] ceiling price." 42 C.F.R. § 10.11(b). In addition, "[e]ach order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered." *Id.* § 10.11(b)(1). HRSA initiates a CMP action by issuing a referral to HHS's Office of the Inspector General. *See* 42 C.F.R. § 1003.150 (delegating HHS Secretary's authority to assess CMPs).

B. The 340B Statute Allows Manufacturers to Select a Mechanism for Offering Reduced-Priced Drugs to Covered Entities

The key provision of the 340B statute for the purposes of this case directs 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 … does not exceed" the "ceiling price." 42 U.S.C. § 256b(a)(1). Importantly, the statute does not specify a single mechanism that manufacturers should use to furnish reduced prices to covered entities; instead, it specifies both "rebate[s]" and "discount[s]." *Id.* Likewise, the PPA—the "agreement" referred to in the statute—does not specify the pricing mechanism to be used. Nor has HRSA attempted to direct a pricing mechanism through other means, other than releasing guidance discussing use of rebate models by one category of covered entity. *See infra* at 8-9.

Rather, from its original enactment, the 340B statute was understood to afford manufacturers discretion over how best to make the 340B price available to covered entities. In 1992, the House Energy and Commerce Committee issued a report on a bill that became part of the Veterans Health Care Act of 1992 ("VHCA"), Pub. L. 102-585, 106 Stat. 4943, which established the 340B Program. H.R. Rep. No. 102-384, pt. 2 (1992). The report made clear that the legislation contemplated manufacturers using different mechanisms, including rebates, for providing 340B pricing to covered entities. The Committee specifically stated that "manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions (*whether through a discount, rebate, or other mechanism*) to these 'covered entities' on covered outpatient drugs." *Id.* at 12 (emphasis added); *see id.* at 16 ("The Committee bill does not specify whether 'covered entities' would receive these favorable prices *through a point-of-*

purchase discount, through a manufacturer rebate, or through some other mechanism." (emphasis added)).

In addition to the House report, the Senate sponsor of the legislation explained in a floor speech that the bill would require manufacturers to enter agreements "to provide rebates or discounts" to covered entities. 138 Cong. Rec. 34279, 34293 (1992) (statement of Sen. Alan Cranston); *see id.* at 34294 (repeatedly referring to provisions addressing "rebate or discount agreement[s]"). Those remarks reinforced what the statute's plain text already made clear: Congress intended to establish rebates as an acceptable mechanism through which manufacturers could offer the 340B price to covered entities. In fact, HRSA so recognized in its very first 340B Program guidance document in 1993, which stated that the VHCA "is an attempt to provide Federal purchasers with a process whereby they will receive drug discounts *or rebates*." 58 Fed. Reg. 27,289, 27,290 (May 7, 1993) (emphasis added). That flexibility for manufacturers again reflected Congress's purpose: to restore reduced pricing that manufacturers had *voluntarily* provided to safety net entities before the establishment of the MDRP in 1990. *See* H.R. Rep. No. 102-384, pt. 2, at 12. Granting manufacturers discretion on the form such price reductions would take under 340B is consistent with the discretionary basis on which those reductions were offered before 1990.

Subsequent HRSA guidance further confirmed that HRSA understood the 340B statute to allow for the use of rebates. In 1997, HRSA proposed guidance discussing a rebate option for providing 340B pricing to State AIDS Drug Assistance Programs ("ADAPs"). 62 Fed. Reg. 45,823 (Aug. 29, 1997). Citing the 1992 committee report, the guidance set forth HRSA's understanding that "section 340B does not specify whether entities should receive the section 340B pricing 'through a point of purchase discount, through a manufacturer rebate, or through some

other mechanism.'" *Id.* at 45,824 (quoting H.R. Rep. No. 102-384, pt. 2, at 16). The final guidance, issued in 1998, confirmed that HRSA was not "propos[ing] a specific mechanism for accessing [340B] rebates" in order to "allow maximum flexibility" between the state ADAPs and manufacturers. 63 Fed. Reg. 35,239, 35,239, 35,241 (June 29, 1998).

In 2010, as part of the Affordable Care Act, Congress amended Section 340B in several respects, including by adding its so-called "must-offer" provision, which directs that each 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). Importantly, nothing in the amendment purported to eliminate rebates as a permitted mechanism for "offering" drugs for purchase at 340B prices. Congress did not remove or alter the preexisting statutory language that HRSA had read as allowing the use of rebates as a 340B pricing mechanism. *See id.* (retaining the "rebate or discount" language as the first sentence of the paragraph). That language remains unchanged to the present day. And, also to the present day, HRSA permits rebate models with respect to ADAPs, which ADAPs continue to use.

C. The 340B Program Has Evolved Dramatically Since Its Inception

Since its establishment in 1992, the 340B Program has expanded dramatically, becoming the second-largest federal prescription drug program in the United States. AR73. The program has also changed considerably over time. Among other things, 340B entities have entered into thousands of so-called "contract pharmacy" arrangements, under which 340B covered entities "contract with outside pharmacies" for the distribution of 340B-discounted drugs. *Novartis Pharms.*, 102 F.4th at 455. Because patients or their insurers often pay commercial prices for drugs purchased at contract pharmacies, these arrangements enable generation of revenue from the "spread between the discounted [340B] price and the higher insurance reimbursement rate." *Id.* at

457.[3] That revenue is then shared between the for-profit pharmacies, pharmacy benefit managers that own them, third-party administrators, and covered entities, which each have "a financial incentive to catalog as many prescriptions as possible as eligible" for the program, and no obligation to pass on or share the revenue generated with patients. *See id.* at 457-58.

Covered entities' use of contract pharmacies has exploded over time; between 2010 and 2019, the number of contract pharmacies dispensing 340B drugs ballooned from 1,300 to 23,000. 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) (2020 GAO Report), https://bit.ly/3ZG0ctH. The contract pharmacy industry is now dominated by a handful of multi-billion dollar for-profit pharmacy chains and PBMs, including CVS Health, Walgreens, Cigna (via Express Scripts), UnitedHealth Group (via OptumRx), and Walmart. Adam

[3] Various studies have analyzed the resulting financial windfall for pharmacy benefit managers and pharmacies and the lack of patient benefit. *See, e.g.*, Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, Food & Drug L. Inst. (2022), https://bit.ly/3XK1cdG ("Consequently, PBMs are gaining a greater share of overall 340B contract pharmacy business .... In 2018 alone, hospitals and pharmacies together made $13 billion in 340B profits. The bulk of the pharmacy take goes to corporations like CVS."); Ted Okon, *Hospitals And For-Profit PBMs Are Diverting Billions in 340B Savings From Patients In Need*, STAT (Jul. 7, 2022), https://bit.ly/4dksUn7 ("[O]ne Wall Street analysis estimates that $2.58 billion in 340B savings were siphoned away in 2021 by PBM-controlled pharmacies operated by Walgreens, Caremark, Express Scripts, and OptumRx. That's $2.58 billion in 340B discounts that patients never benefit from."). With respect to DSH covered entities in particular, studies have shown that many are not using the savings they receive from the 340B Program to fund programs that would benefit underserved patients, and that the majority of DSH covered entities are not providing more care to disadvantaged patients than the average acute-care hospital. One analysis found that 69% of 340B DSH covered entities provide charity care at rates lower than the national average. AIR 340B, *Charity Care at 340B Hospitals is on a Downward Trend* 2, 6 (Oct. 2023), https://bit.ly/4eicWep. Similarly, an HHS Office of the Inspector General report found that almost half of the DSH covered entities it surveyed required uninsured patients to pay the full, non-discounted price for their medications at their contract pharmacies, even though the hospitals purchased those drugs at the reduced 340B price. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 14 (Feb. 4, 2014), https://bit.ly/3XKxkOf (finding seven of the 15 DSH covered entities surveyed required uninsured patients to pay the full cost of their prescriptions).

J. Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), https://bit.ly/3ZH23yG.

Alongside this explosion of growth for contract pharmacies, abuse of the 340B program by covered entities has become rampant and well documented. For example, the Government Accountability Office found in 2020 that, across 1,242 audits HRSA conducted of covered entities from fiscal year 2012 through 2019, HRSA made 546 findings related to diversion and 429 findings related to duplicate discounts. AR217 (citing 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. 14, 2020), https://www.gao.gov/assets/gao-21-107.pdf). HRSA audits in fiscal year 2022 found evidence of duplicate discounting for at least 28 of 199 covered entities audited, and for at least 25 of 159 covered entities in fiscal year 2023 audits. AR217 (citing HRSA, *Program Integrity: FY22 Audit Results*, https://bit.ly/4ekBOlN (last updated July 24, 2024); HRSA, *Program Integrity: FY23 Audit Results*, https://bit.ly/4dpSxTs (last updated Sept. 20, 2024)).

Aggravating these concerns is the emergence of so-called "replenishment models" for 340B purchasing. More than a decade ago—and without prior approval from HRSA—covered entities shifted away from systems in which contract pharmacies physically kept 340B-priced drugs in separate inventories from regular-priced inventory. Instead, they adopted "replenishment models," in which contract pharmacies make the initial purchase of a product at its (non-discounted) commercial price, dispense the product to an individual who is later determined to be a patient of the 340B entity, and then receive a replacement unit at 340B-discounted prices to "replenish" the pharmacy's stock. *See Novartis Pharms.*, 102 F.4th at 457-58 (describing emergence and operation of replenishment models); *see also* Decl. of Krista M. Pedley ¶¶ 5-9,

Sanofi-Aventis U.S., LLC v. HHS, No. 3:21-cv-634 (D.N.J. June 24, 2021) (Pedley Decl.), ECF No. 93-2 (HRSA description of replenishment models). The D.C. Circuit recently described replenishment models as follows:

> The mechanism for distributing covered drugs [under the 340B Program] also has evolved. While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Novartis Pharms., 102 F.4th at 457-58; *see also PhRMA v. Morrisey*, --- F. Supp. 3d ---, No. 2:24-cv-00271, 2024 WL 5147643, at *2, *8 (S.D. W. Va. Dec. 17, 2024) (describing the replenishment model as "the controlling drug distribution model in West Virginia"). Thus, replenishment models work after the fact to reconcile transactions made initially at a commercial price to the 340B discount, analogous to a rebate mechanism.

HRSA has acknowledged the widespread usage of replenishment models in litigation, *see* Pedley Decl. ¶¶ 5-9, *Sanofi-Aventis U.S.*, No. 3:21-cv-634 (D.N.J. June 24, 2021), and in 2015 guidance, 80 Fed. Reg. 52,300, 52,305 (Aug. 28, 2015) (later withdrawn). However, HRSA has never affirmatively authorized covered entities to utilize replenishment models, nor has it undertaken any process to approve or reject them. Instead, HRSA has acquiesced to their widespread adoption, without ever asserting that its permission was required.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. J&J Observes Rapidly Increasing 340B Purchasing and Evidence of Program Abuse, but Covered Entities Stymie J&J's Attempts to Audit

Over the past few years, J&J has observed concerning trends in the volume of purchases of its drugs at 340B prices. AR157, AR160-AR161. Across its portfolio, purchases of J&J's 340B drugs have increased at a rate at least twice as fast as its overall sales, and 340B purchases of certain of its products have increased even faster. AR160; *see* AR52-AR53. From the second quarter of 2023 to the second quarter of 2024, for example, 340B purchases of J&J's drug STELARA increased by 56%—about five times as fast as STELARA's overall sales. AR160. Likewise, 340B purchases of J&J's drug XARELTO increased by 33%—about eight times as fast as XARELTO's overall sales. AR160. These significant 340B purchase increases have occurred even though the population of patients either uninsured or living in poverty—the patients who should be benefiting from 340B discounts—has actually declined by almost half, from 15.7% of the U.S. population in 2013 to 8.7% in 2021. *See* Martin et al., *Unintended Consequences*, at 8. For example, one review found that, for every $10 the top-performing quintile of 340B hospitals collect in profit, just $1 is invested in charity care. *See* Neal Masia, *Comparing the Financial Health and Charitable Care of 340B and Non-340B Hospitals* 3, 13 (2023), https://bit.ly/3BikgIx.

In April 2024, J&J contacted several covered entities that J&J's data showed had significantly increased their 340B purchasing of certain J&J products over the past year; in some cases, 340B purchasing grew by more than 120% in a 6-month period. AR161. J&J also found evidence demonstrating that purchases by several of these covered entities had resulted in duplicate discounts—in some cases, hundreds of such examples—in violation of the 340B statute. AR241; *see* AR53. J&J attempted to engage in good-faith discussions with these entities so that J&J could better understand the drivers of their substantial increases in utilization and attempt to confirm

whether their purchases had resulted in duplicate discounts or diversion. AR162-AR163. Unfortunately, most entities offered little substantive response. AR163-AR164.

In May and June 2024, J&J submitted letters to HRSA requesting approval to conduct audits of certain entities and explaining J&J's concerns with each entity it sought to audit. AR162; *see* AR53. In June and July 2024, HRSA approved J&J's request to audit 11 covered entities. AR162. J&J's external independent auditor then began notifying the covered entities of the HRSA-approved audits. AR162.

Most of the covered entities refused to cooperate with J&J's auditors—in violation of their statutory obligation to participate in HRSA-approved audits, 42 U.S.C. § 256b(a)(5)(C). AR164; *see* AR53-AR54. Five covered entities filed litigation against HRSA in this district seeking to invalidate its approvals of the audits. *See Or. Health & Sci. Univ. v. Johnson, et al.*, No. 1:24-cv-02184-RC (D.D.C. filed July 24, 2024); *MaineGeneral Med. Ctr. v. Johnson, et al.*, No. 1:24-cv-02187-RC (D.D.C. filed July 24, 2024); *Univ. of Rochester v. Johnson, et al.*, No. 1:24-cv-02268-RC (D.D.C. filed Aug. 1, 2024); *Children's Nat'l Med. Ctr v. Johnson, et al.*, No. 1:24-cv-02563-RC (D.D.C. filed Sept. 6, 2024); *Univ. of Wash. Med. Ctr. v. Becerra, et al.*, No. 1:24-cv-02998-RC (D.D.C. filed Oct. 22, 2024).[4]

B. J&J Considers Offering 340B Pricing Through a Rebate Model and Presents a Proposal to HRSA

In the summer of 2024, J&J moved forward with initial steps toward adopting a rebate model to effectuate 340B pricing. J&J contacted HRSA on June 27, 2024 to request a meeting to discuss the rebate model concept. AR49. At the meeting, which was held on July 24, 2024, J&J explained that it is deeply committed to the 340B program and wants to ensure 340B discounts are

[4] J&J has moved for leave to file amicus briefs in each of these cases detailing J&J's good-faith efforts to cooperate with these entities in the audits and the ways in which those efforts have been rebuffed.

offered to eligible covered entities. AR157; *see* AR52-AR54. Yet because of the current structure of the 340B program, J&J explained, it has little to no visibility into the claim-level data necessary to validate 340B claims—in particular, whether covered entities are unlawfully obtaining duplicate discounts on 340B-priced drugs. AR157, AR166; *see* AR53-AR54.

J&J also explained the challenges it faces in attempting to comply with its obligations under the "maximum fair price" ("MFP") component of the Inflation Reduction Act ("IRA"), Pub. L. No. 117-169, 136 Stat. 1818 (2022). *See* AR167. J&J explained that, under the IRA, covered entities are entitled to the lesser of the 340B price or the MFP for drugs selected for "negotiation" under the IRA. AR59. The Centers for Medicare and Medicaid Services ("CMS") had previously selected two J&J products, STELARA and XARELTO, for the MFP for calendar year 2026. AR54; *see* AR73. The IRA includes a non-duplication provision that exempts manufacturers from providing both the 340B ceiling price and the MFP on the same drug unit. AR59. As a result, effectuating the MFP requires identifying when 340B-priced drugs are dispensed to Medicare beneficiaries. AR59. However, CMS has not yet developed a mechanism enabling manufacturers to identify those claims. AR59.

Offering the 340B price through a rebate, J&J explained, would be an effective means for J&J to fill the gap left by CMS, enabling J&J to identify Medicare claims in real time and implement the IRA's non-duplication provision. AR54; AR167-AR168; *see* AR59. Indeed, time is of the essence for this issue. Under CMS guidance, J&J must submit a plan for effectuating the MFP to CMS—which must include its procedures for administering the non-duplication provision—by September 1, 2025. *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and*

2027, § 90.2.1 (Oct. 2, 2024), http://bit.ly/3Y719J0. In addition, offering the 340B price through a rebate would improve the integrity of the 340B program for all parties by helping to mitigate the risk of duplicate discounts, which HRSA's own audits demonstrate occur frequently. AR167; *see* AR192.

In light of the challenges J&J faces in meeting its obligations under the IRA, as well as the disproportionate increases in J&J's 340B sales, the resistance to audits J&J has experienced, and its lack of visibility into data necessary to determine the legitimacy of claims for 340B pricing, J&J informed HRSA that it was contemplating a shift to a rebate model (the "Rebate Model"). AR167-68. Under J&J's Rebate Model, Disproportionate Share Hospitals (DSH), one type of covered entity particularly prone to the abuse that J&J identified, would purchase the applicable J&J medicines (STELARA and XARELTO) from wholesalers at commercial prices, similar to the replenishment models used today, and then receive a rebate to realize the 340B ceiling price promptly after submitting commercially standard claims data for each purchase. AR169.

At the end of the meeting, HRSA asked J&J to submit a letter describing its proposed Rebate Model in detail, including the legal basis for the Rebate Model. AR55. J&J submitted the letter to HRSA on July 31, 2024. AR55. In addition to detailing its Rebate Model's wide range of practical benefits for administering the program and the IRA and maintaining program integrity, J&J explained that it has clear statutory authority to utilize such a model. AR56-AR57. In particular, J&J noted that the 340B statute unequivocally contemplates "rebate[s]" as a mechanism for manufacturers to offer the 340B price to covered entities, in addition to "discount[s]." AR57 (citing 42 U.S.C. § 256b(a)(1)). The letter also reminded HRSA that its proposed guidance concerning ADAPs acknowledged that the 340B statute does not specify whether price reductions should be effectuated through a discount or rebate. AR57.

As for J&J's ability to select a Rebate Model, the letter cited recent decisions from the Third and D.C. Circuits confirming that the 340B statute leaves manufacturers with discretion to impose reasonable conditions with respect to the offering of 340B drugs, including requiring covered entities to submit standard claims data gathered for 340B purchasing. AR58 (citing *Novartis Pharms.*, 102 F.4th 452; *Sanofi Aventis*, 58 F.4th 696). J&J explained that the same reasoning and conclusions apply even more strongly in this context, where the statute expressly contemplates both rebate and discount models as options for manufacturers to implement the 340B program's ceiling price requirement. AR58.

The letter concluded by describing the modest scope of the Rebate Model J&J intended to implement. AR62. Specifically, J&J reported that, beginning on October 15, 2024, it would apply the Rebate Model only for purchases by DSH covered entities of the two products that CMS had selected for the MFP for calendar year 2026, STELARA and XARELTO, with notice provided to covered entities by August 15, 2024, 60 days in advance of the launch. AR62. J&J explained that it believed the 60-day advance period would provide sufficient time for DSH entities to adjust to the Rebate Model. AR62. Moreover, J&J noted that it planned to offer training and support during and after the notice period to ensure covered entities have the ability to become familiar with the Rebate Model's operation, including a 45-day period for submission of claims data following dispensing of a drug. AR62. J&J further explained that the Rebate Model would utilize standard claims data that covered entities already collect in the normal course of business—under policies approved by the D.C. Circuit, *see Novartis Pharms.*, 102 F.4th at 463—and data elements that covered entities currently submit to payers in the reimbursement process. AR58, AR61. To further support the Rebate Model, J&J also informed HRSA that it planned to offer a grace period until

February 28, 2025, during which DSH covered entities could submit rebate claims outside of the 45-day window. AR62.

C. HRSA Rejects J&J's Rebate Model Proposal

On August 14, 2024, HRSA responded to J&J's July 31 letter. AR64. In addition to posing more than two dozen questions to J&J concerning the operation of the Rebate Model, the August 14 Letter also set forth HRSA's determination that J&J lacks authority to adopt the model without HRSA's prior approval. AR66. The letter asserted that the 340B statute directs 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' shall not exceed the statutory ceiling price formula." AR66 (quoting 42 U.S.C. § 256b(a)(1)) (emphasis added by HRSA). Communicating an interpretation of the text, the letter then stated: "To date, the Secretary has not provided for such rebate as proposed by J&J. Therefore, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program, which require the approval of a rebate model such as J&J has proposed." AR66.

On August 16, 2024, J&J responded to HRSA's August 14 letter. AR69. In addition to answering HRSA's questions, J&J noted that HRSA's response was "a definitive and final expression of HRSA's interpretation that the 340B statute vests HRSA with discretion to determine whether manufacturers may utilize a rebate model." AR73. J&J expressed its disagreement with that view and reiterated its legal basis for implementation of its Rebate Model. AR72-AR74. In particular, J&J observed that "HRSA's final action in this regard is not consistent with the statutory text or history." AR73. The statutory provision that HRSA's August 14 letter quoted, J&J explained, refers to HRSA's PPAs with manufacturers, and J&J's PPA contains no term addressing

the mechanism to be used for offering 340B pricing on J&J products to covered entities. AR73.[5] As a result, J&J retains discretion to employ the ceiling price mechanism of its choosing, including its Rebate Model. AR74. J&J also informed HRSA that, in light of HRSA's letter, and as a show of good faith, J&J would delay its planned August 15, 2024 announcement of the rebate model transition to August 23, 2024. AR84. On August 22, 2024, J&J sent HRSA a copy of the revised notice it would be issuing to covered entities, and then issued its announcement as scheduled on August 23. AR176; *see* AR575.

In the days surrounding J&J's August 23 announcement, several trade associations for large hospital systems issued public statements criticizing the Rebate Model and calling for HRSA to take action against J&J. AR565-AR579. To correct the numerous mischaracterizations of the Rebate Model and the 340B statute in these statements, J&J sent an additional letter to HRSA on September 12, 2024. AR190. Among other things, the September 12 Letter reiterated the basis for J&J's clear legal authority under the 340B statute to implement the Rebate Model. AR191-AR195. J&J also noted that, to the extent the statute authorizes HRSA to direct a pricing mechanism at all, it must do so through the PPA, and may not declare in a guidance document or through any other administrative procedure that manufacturers may not use rebate models. AR192-AR194.

On September 17, 2024, then-HRSA Administrator Carole Johnson sent a letter to J&J, which HRSA posted on its website the same day. AR201. The letter referred to J&J's planned implementation of its Rebate Model and reported HRSA's final, consummated determination on its legality: "By way of this correspondence, HRSA provides warning that this unapproved rebate

[5] J&J additionally noted that by its terms and structure, the 340B statute does not grant HRSA discretion to mandate a pricing mechanism, even through the PPA. AR74 n.2.

proposal violates J&J's obligations under the 340B statute, and HRSA expects J&J to cease implementation of it." AR202. Citing the statute, the letter declared that "[t]he Secretary has not 'provided' that the rebates described in J&J's notice should be 'tak[en] into account' in the 'amount required to be paid' for Stelara and Xarelto by disproportionate share hospitals." AR203. In a footnote, HRSA challenged J&J's argument that a PPA amendment is the only regulatory procedure by which HRSA could direct a pricing mechanism. AR202 n.1.

HRSA's letter also asserted that "J&J's rebate proposal would require disproportionate share hospitals to purchase Stelara and Xarelto at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs." AR203. "This, too, violates Section 340B(a)(1) of the PHS Act," HRSA asserted. AR203. In effect, HRSA appeared to contend that rebate models are *per se* impermissible because they result in covered entities being "required to pay" prices above the ceiling price. *See* AR203. The letter then admonished that "[b]ecause J&J's rebate proposal, if implemented, violates J&J's obligations under the 340B statute, it subjects J&J to potential consequences," including termination of J&J's PPA and the imposition of CMPs. AR203. HRSA concluded by declaring—in definitive and unequivocal terms—that HRSA "expects J&J to cease implementation of its rebate proposal immediately and to inform HRSA no later than September 30, 2024, in order to provide adequate notice to covered entities." AR204.

J&J sent a letter in response on September 19. AR205. The letter expressed surprise that HRSA viewed J&J's Rebate Model as inconsistent with the 340B statute in light of the clear statutory permissibility of rebate models. AR208. J&J also specifically responded to HRSA's assertion that it is unlawful to use any pricing mechanism that requires covered entities to purchase 340B drugs at commercial prices before receiving a payment effectuating the ceiling price.

AR209. HRSA's position, J&J explained, flatly contradicts both the text and history of the 340B statute, which make clear that rebates are a permitted pricing mechanism for the program. AR209. J&J also responded to HRSA's rejection of its arguments on the PPA, reiterating that it is clear from the text of the statute that if HRSA has any discretion to direct a pricing mechanism (which it does not), it could be exercised only through the PPA. AR209. After emphasizing the Rebate Model's numerous benefits for program administration and integrity, the letter concluded by asking for a meeting with HRSA to continue discussions before HRSA's September 30 requested response date. AR210-AR211.

HRSA did not respond to J&J's good-faith offer to meet. Instead, HRSA sent a one-page reply on September 27 that confirmed its final determination on the impermissibility of J&J's rebate model, as well as HRSA's authority to direct a pricing mechanism by letter, and set out stark legal consequences for J&J if it proceeded contrary to HRSA's interpretation of the statute. AR212-AR214. If J&J did not notify HRSA by September 30, 2024 that J&J would cease implementation of the Rebate Model, HRSA decreed, "HRSA will begin the process outlined in J&J's Pharmaceutical Pricing Agreement related to terminating the agreement," and "will initiate a referral to the HHS Office of Inspector General pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)," *i.e.*, a CMPs proceeding. AR214. The letter reiterated HRSA's final, consummated position that "the 340B statute requires Secretarial approval of any rebate mechanism," and asserted that J&J had not requested such approval. AR214.

J&J responded to HRSA on September 30 confirming that, in light of the drastic legal consequences HRSA had threatened, J&J had no choice but to suspend implementation of its Rebate Model. AR215. J&J once again reiterated its view that the 340B statute unequivocally permits rebates as a pricing mechanism and that HRSA may direct a mechanism, if at all, through

the PPA. AR216. J&J also reminded HRSA of the resistance J&J had faced in seeking to begin its numerous HRSA-approved audits of covered entities, further demonstrating the need for a Rebate Model to address serious concerns about program integrity. AR217. J&J concluded by reiterating that it remained interested in meeting to continue discussing the Rebate Model. AR218. J&J followed up on that request by email on October 2, 2024, and HRSA eventually agreed to a meeting, which took place on October 21, 2024. *See* AR225-AR230.

At the October 21 meeting, J&J maintained its legal position that it has authority to proceed with its Rebate Model without HRSA pre-approval, but focused primarily on the substantive features and benefits of the model, including that no other solution allows for compliance with the IRA's requirements concerning duplicate discounts. AR236-AR239. Specifically, only the Rebate Model would allow J&J to deliver to covered entities the lower of the 340B ceiling price and the MFP, as required by the IRA, and to prevent duplication across the two types of discounts. *See* AR239; *see also supra* at 15-16.

Following the meeting, while again preserving its legal position that HRSA pre-approval was not required, J&J sent an email to HRSA inquiring whether HRSA would approve J&J's implementation of the Rebate Model as proposed. AR232. Noting that time was of the essence, J&J requested that HRSA provide a response by October 28, 2024. AR232. When HRSA failed to do so, J&J emailed HRSA on October 29, 2024, communicating that, in light of the lack of response, J&J understood that HRSA's position remained unchanged from its prior letters to J&J, and J&J would proceed consistent with that understanding. AR247-AR248. HRSA did not respond, but later confirmed its definitive interpretation of the statute with a policy pronouncement posted on its website, affirming HRSA's view that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." AR48.

D. J&J Proceeds with Litigation Against HRSA

On November 12, 2024, J&J sent HRSA an email stating: (1) J&J understands HRSA's August 14, September 17 and September 27, 2024 letters to reflect the agency's final determination on whether HRSA has the authority to preapprove rebate models and whether J&J's proposed Rebate Model is consistent with the 340B statute; and (2) J&J would be filing suit the same day challenging HRSA's final determinations, as set out in the August 14, September 17 and September 27 letters, that J&J may not proceed with its Rebate Model without HRSA's approval and that J&J's Rebate Model is not permissible under the 340B statute. AR251-AR252. J&J filed its complaint in this action later the same day. ECF No. 1. The parties filed a consent motion for a briefing schedule on cross-motions for summary judgment on December 27, 2024, which the Court entered on December 30, 2024. ECF No. 10.

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56, summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "But when assessing a summary judgment motion in an APA case, 'the district judge sits as an appellate tribunal.'" *PhRMA v. HHS* (*Orphan Drug I*), 43 F. Supp. 3d 28, 35 (D.D.C. 2014) (Contreras, J.) (quoting *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)). "'The entire case on review is a question of law, and only a question of law.' The district court's review 'is based on the agency record and limited to determining whether the agency acted arbitrarily or capriciously,' or in violation of another standard set out in section 10(e) of the APA." *Id.* (first quoting *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993); then quoting *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009)).

That provision of the APA generally directs the Court to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2); *see, e.g.*, *Vanda Pharms., Inc. v. FDA*, 123 F.4th 513, 520 (D.C. Cir. 2024). "Where the question is whether the agency action was consistent with statutory authorization, [a court's] task is to determine whether the agency acted consistently with the 'best reading' of the statute." *Vanda Pharms.*, 123 F.4th at 521 (quoting *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024)). In conducting that inquiry, courts "must exercise [their] 'independent judgment' and 'apply[] all relevant interpretive tools.'" *Env't Def. Fund v. EPA*, 124 F.4th 1, 11 (D.C. Cir. 2024) (quoting *Loper Bright*, 603 U.S. at 393, 400); *see also, e.g.*, *Servier Pharms. LLC v. Becerra*, No. 24-cv-2664, 2025 WL 27352, at *9 (D.D.C. Jan. 3, 2025) (applying *Loper Bright*). "This judicial inquiry includes a determination as to whether the statute in question 'delegates discretionary authority' to the agency and whether the agency 'engaged in reasoned decisionmaking within [the] boundaries' of that statutory delegation." *Vanda Pharms, Inc.*, 123 F.4th at 521 (quoting *Loper Bright*, 603 U.S. at 395).

In reaching their own independent judgment on the best reading of a statute, courts may in some instances consider "the 'interpretations and opinions' of the relevant agency, 'made in pursuance of official duty' and 'based upon … specialized experience.'" *Loper Bright*, 603 U.S. at 388 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 139-40 (1944)); *see also, e.g.*, *Pac. Gas & Elec. Co. v. FERC*, 113 F.4th 943, 951 (D.C. Cir. 2024) (citing *Loper Bright*, 603 U.S. at 385, 402). "'The weight of such a judgment in a particular case' … would 'depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.'" *Loper Bright*, 603 U.S. at 388 (quoting *Skidmore*, 323 U.S. at 140); *see also, e.g.*,

Lissack v. Comm'r, 125 F.4th 245, 259 (D.C. Cir. 2025) ("agency interpretations are not controlling" but may "'constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance'" (quoting *Skidmore*, 323 U.S. at 140)).

ARGUMENT

The Court should declare that J&J may use a rebate model to provide the 340B ceiling price to covered entities, without prior approval from HRSA, and that HRSA's purported rejection of J&J's Rebate Model was unlawful.

As an initial matter, the text, structure, purpose, and history of the 340B statute make clear that manufacturers may use rebate models to effectuate 340B pricing. The statutory text expressly provides that both a "rebate" and a "discount" are means of furnishing the ceiling price to covered entities. 42 U.S.C. § 256b(a)(1). The statute also does not empower HRSA to mandate a pricing mechanism or to bar manufacturers from selecting the pricing mechanism of their choice.

And even if the statute did vest HRSA with discretion to specify a pricing mechanism, that discretion may be exercised only through the PPA. HRSA purported to exercise that discretion here—and adopt a substantive rule that binds J&J and serves as the basis for a threatened, severe enforcement action—through letters to J&J and an online policy pronouncement. That is unlawful twice over: once under the 340B statute, which permits rebates as a pricing mechanism; and again under the APA, which requires agencies to use notice-and-comment rulemaking for enacting legislative rules. Further, HRSA's inconsistent treatment of replenishment models, which HRSA tacitly approved, and J&J's proposed rebate model, which HRSA harshly rejected, demonstrates the capriciousness of HRSA's decision-making.

Simply put, HRSA's unlawful actions should not prevent J&J from taking reasonable steps to timely fulfill its obligations under the IRA and to further 340B program integrity. The Court

should declare that J&J may proceed with its Rebate Model and should vacate HRSA's contrary letters and website statement.

I. THE 340B STATUTE UNQUESTIONABLY ALLOWS REBATE MODELS, WHICH MANUFACTURERS CAN SELECT AT THEIR DISCRETION

A. Rebate Models Are Permitted by the Statute

At the outset, there can be no serious dispute that the 340B statute permits manufacturers to use rebate models. The text of the statute is clear in this regard: "The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account *any rebate or discount*, as provided by the Secretary) …." 42 U.S.C. § 256b(a)(1) (emphasis added). Plainly, Congress contemplated both discounts and rebates as available mechanisms for effectuating 340B price reductions.

Though courts need not "resort to legislative history" to interpret "statutory text that is clear," *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 335 (D.C. Cir. 2020) (citation omitted), the legislative history of the 340B statute reaffirms the conclusion that flows from the statute's plain language. The key House committee report on the 340B bill explained that the legislation "does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism." H.R. Rep. No. 102-384, pt. 2, at 16; *see also id.* at 12 (explaining that "manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions (whether through a discount, rebate, or other mechanism) to these 'covered entities' on covered outpatient drugs"). And the bill's Senate sponsor repeatedly stated in a floor speech that the agreements would require manufacturers "to provide rebates or discounts" to covered entities. 138 Cong. Rec. 34293 (1992) (statement of Sen. Alan Cranston); *see id.* at 34294 (repeatedly referring to provisions addressing

"rebate or discount agreement[s]"). Unsurprisingly, HRSA's first 340B guidance readily acknowledged that the 340B program was "an attempt to provide Federal purchasers with a process whereby they will receive drug discounts *or rebates*." 58 Fed. Reg. at 27,290 (emphasis added).

As noted, HRSA doubled down on that understanding in the 1997 guidance it proposed for state ADAPs participating in 340B. 62 Fed. Reg. at 45,823-24. Relying on the 1992 committee report, the proposed ADAP guidance confirmed that "section 340B does not specify whether entities should receive the section 340B pricing 'through a point of purchase discount, through a manufacturer rebate, or through some other mechanism.'" *Id.* at 45,824 (quoting H.R. Rep. No. 102-384, pt. 2, at 16). HRSA further acknowledged that "Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)." *Id.* In its final ADAP guidance the following year, HRSA allowed manufacturers "maximum flexibility" in how they structured the rebate programs and would not propose "a specific mechanism." 63 Fed. Reg. at 35,239, 35,241.

B. HRSA's Interpretation of the 340B Statute Is Erroneous

HRSA's letters, and the policy pronouncement later posted on its website, assert that manufacturers must seek permission and obtain "Secretarial approval" before adopting a rebate model. *See* AR214; AR48. That position is inconsistent with the statute, which merely authorizes Defendants to direct in the PPA that manufacturers must use appropriate records, recordkeeping procedures, or accounting mechanisms to account for the rebates or discounts they choose to provide.

The relevant statutory text again states: "The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking

into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs … purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed" the ceiling price. 42 U.S.C § 256b(a)(1). Importantly, the phrase "as provided by the Secretary" modifies the *entire* preceding phrase "taking into account any rebate or discount," not only the words "any rebate or discount," as HRSA's letters suggest. The Supreme Court's decision in *Cyan, Inc. v. Beaver County Employees Retirement Fund*, 583 U.S. 416 (2018), is instructive. The Court there rejected the government's reading of a statute providing that "[a]ny covered class action brought in any State court involving a covered security, as set forth in subsection (b) of this section, shall be removable." *Id.* at 437 (quoting 15 U.S.C. § 77p(c)). The government asserted that the modifier "as set forth in subsection (b) of this section" applied only to the immediately preceding phrase "involving a covered security." But the Court disagreed, explaining that "the most natural way to view the modifier is as applying to the entire preceding clause," which is "concise and 'integrated'" and "hangs together as a unified whole." *Id.* at 440 (quoting *Jama v. ICE*, 543 U.S. 335, 344 n.4 (2005)).

So too here. The modifier "as provided by the Secretary" is most naturally read to apply to the entire rest of the parenthetical—"taking into account any rebate or discount"—rather than just the immediately preceding words "any rebate or discount." *See id.* Indeed, Congress's placement of the parentheses around the full phrase "taking into account any rebate or discount," and not just around "any rebate or discount," underscores that Congress intended that full phrase to operate as "a unified whole." *Id.*; *see also Maple Drive Farms Ltd. P'ship v. Vilsack*, 781 F.3d 837, 847 (6th Cir. 2015) (explaining "[n]o intelligent construction of a text can ignore its punctuation," including when material is "contained in parentheses" (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 161 (2012)).

Read consistent with these principles, the phrase "as provided by the Secretary" thus authorizes the Secretary, at most, to provide in the PPA *how* a manufacturer should "tak[e] into account" the manufacturer's chosen pricing mechanism to ensure that the "amount required to be paid" by the covered entity does not exceed the ceiling price. For example, the PPA could provide that manufacturers must account for rebates by sending reconciliation forms with each rebate payment to identify the drug purchases to which the rebate payment applies. The PPA could also require that manufacturers obtain claims information from purchasers to confirm that the rebate amounts a manufacturer will pay are accurate and will effectuate the ceiling price. *Id.* As for discounts, the Secretary could "provide[]" in the PPA that manufacturers must maintain certain accounting records to document discounts that are offered.[6]

HRSA's contrary interpretation that the 340B statute requires "Secretarial approval" before manufacturers may use rebate models, AR203, selectively excerpts the language of the parenthetical in an "[un]natural way," *Cyan*, 583 U.S. at 440; does not give meaning either to the words "taking into account" or the surrounding punctuation, *see Maple Drive Farms*, 781 F.3d at 847; and is not "the best reading of the statute," *Loper Bright*, 603 U.S. at 400; *see also, e.g.*, *Vanda Pharms., Inc.*, 123 F.4th at 524. Moreover, the statutory language as written would be an implausible way for Congress to convey the authority Defendants claim to have. *See Wash. All. of Tech. Workers v. DHS*, 50 F.4th 164, 185 (D.C. Cir. 2022) (rejecting statutory interpretation that was "awkward at best," "implausible," and "counterintuitive"). If Congress had intended to vest the Secretary with discretion to *decide* the pricing mechanism manufacturers must use, it could and would have said so directly. *See, e.g.*, *EB5 Holdings, Inc. v. Jaddou*, 717 F. Supp. 3d 86, 104

[6] HRSA could not impose conditions that effectively preclude manufacturers from selecting rebate models, however. *See Novartis Pharms.*, 102 F.4th at 463 (limiting HRSA's discretion to restrict manufacturers' ability to utilize conditions for 340B sales).

(D.D.C. 2024) ("[I]f that *was* in fact Congress's intent, it is safe to assume that Congress would have expressed that intent much more clearly.").

Faced with that reality, HRSA's interpretation in its letters and website statement effectively rewrites the 340B statute to say something Congress did not. Again, the statute as written by Congress provides as follows:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

42 U.S.C. § 256b(a)(1). The text as HRSA's interpretation rewrites it would read something like the following:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid ~~(taking into account any rebate or discount, as provided by the Secretary)~~ to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). **The amount to be paid hereunder shall take into account either a discount or rebate, but only if such pricing mechanism is authorized by the Secretary by regulation.**

The far more natural and best reading of the statutory text is that it authorizes Defendants to provide in the PPA that a manufacturer must account for rebates or discounts by using appropriate records, recordkeeping procedures, or accounting mechanisms. *See, e.g.*, *Pac. Gas & Elec. Co.*, 113 F.4th at 950-51 (rejecting a "[r]eading … at odds with the most natural reading of the statutory provision"); *Servier Pharms. LLC*, 2025 WL 27352, at *17 (finding unpersuasive a reading that "would strain the text" and accepting one "that makes better sense of the statutory text as a whole").

C. HRSA Lacks Authority to Mandate a Pricing Mechanism

It is "incumbent upon [HRSA] to demonstrate that some statute confers upon it the power it purported to exercise." *California Indep. Sys. Operator Corp. v. FERC*, 372 F.3d 395, 398 (D.C. Cir. 2004). Yet for the reasons just explained, the statutory language HRSA relies on provides no authority to reject manufacturers' rebate models. Nor does any other provision of the 340B statute confer such authority—just as this Court found with respect to a different HRSA action in the *Orphan Drug I* case, 43 F. Supp. 3d 28. There, the Court concluded that HHS and HRSA had no statutory authority for a rule purporting to mandate discounts for certain purchases by covered entities of so-called orphan designated drugs, which were expressly exempted from the 340B Program by statute. 43 F. Supp. 3d at 39-40 (citing 42 U.S.C § 256b).

HHS in *Orphan Drug I* argued that five statutory provisions empowered it to adopt the challenged orphan drug rule, but this Court disagreed. *See id.* at 39-40. The Court first reviewed and dispatched with four of the five provisions, none of which arose under the Public Health Service Act or the 340B Program and thus "clearly d[id] not confer any rulemaking authority upon HHS for the orphan drug rule." *Id.* at 40. The Court then carefully examined the entire 340B statute and found that "[w]ithin section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions." *Id.* at 41 (quoting 42 U.S.C. § 256b(d)(1)(B)(i)(I)). Stepping through each of those areas, the Court concluded that none "confer[s] orphan drug rulemaking authority upon the agency." *Id.* at 45. "The rulemaking authority granted HHS by Congress under the 340B program" has been "specifically limited," the Court explained, "and HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B

program." *Id.* at 42; *see also PhRMA v. HHS* (*Orphan Drug II*), 138 F. Supp. 3d 31, 36 (D.D.C. 2015) (Contreras, J.) (reiterating *Orphan Drug I*).

Precisely the same conclusion—now bolstered by the D.C. Circuit's recent affirmation that "[t]he [HHS] Secretary lacks rulemaking authority over the section 340B program," *Novartis Pharms.*, 102 F.4th at 459—applies to HRSA's attempted actions on J&J's Rebate Model here. None of the narrow, "specific grants of rulemaking authority" that this Court identified in *Orphan Drug 1* as included in the 340B statute empowers HRSA to reject a manufacturer's choice of a rebate model. *Orphan Drug I*, 43 F. Supp. 3d at 39. As with the unlawful orphan drug rule, HRSA's rule requiring Secretarial approval of manufacturer rebate models has nothing to do with "the establishment of an administrative dispute resolution process," "standards of methodology for calculation of ceiling prices," or "the imposition of monetary civil sanctions." *Orphan Drug I*, 43 F. Supp. 3d at 41. Defendants thus cannot rely on these authorities "to sustain rulemaking for an entirely different purpose under the statute." *Id.* at 45.[7] As this Court held unequivocally, "Congress has not given HHS [or HRSA] broad rulemaking authority … and '[w]here Congress has established a clear line, the agency cannot go beyond it….'" *Orphan Drug I*, 43 F. Supp. 3d at 45 (quoting *City of Arlington v. FCC*, 569 U.S. 290, 307 (2013)). The Court should therefore vacate HRSA's rejection of J&J's Rebate Model and its policy requiring Secretarial approval of manufacturer rebate models. *See Hikvision USA, Inc. v. FCC*, 97 F.4th 938, 944 (D.C. Cir. 2024) ("In the absence of statutory authorization for its act, an agency's action is plainly contrary to law and cannot stand." (quoting *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002)).

[7] HRSA has not cited these authorities in its letters to J&J or in the policy pronouncement on its website, so any attempt to invoke them now would be barred in any case. *See Vinyl Inst., Inc. v. EPA*, 106 F.4th 1118, 1126 (D.C. Cir. 2024) (citing the "bedrock principle of administrative law" that "agency action is upheld only 'upon the validity of the grounds upon which the [agency] itself based its action'" (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943)).

The Court should further find that, because no provision of the 340B statute either prohibits manufacturers from choosing a rebate model or authorizes HRSA to impose such a prohibition, J&J is free to offer the ceiling price to covered entities via a rebate or discount at its discretion. As the *Sanofi* and *Novartis* decisions from the Third and D.C. Circuits make clear, where the 340B statute does not "prohibit[]" manufacturers "from adopting their policies" imposing reasonable conditions on 340B purchases, such policies "are lawful." *Sanofi Aventis*, 58 F.4th at 703-04 (finding that the 340B statute "imposes only a price term for drug sales to covered entities, leaving all other terms blank"); *Novartis Pharms.*, 102 F.4th at 460-61 (holding that the statute "preserves" manufacturers' ability to impose "reasonable conditions," including "request[ing] standard information" from covered entities)*; see also* 59 Fed. Reg. 25,110, 25,114 (May 13, 1994) (HRSA guidance providing that manufacturers may "request standard information" and utilize "customary business practices" with covered entities). These authorities underscore and reinforce that J&J's Rebate Model accords with the 340B statute.

D. Even If HRSA Had Discretion to Mandate a Pricing Mechanism, It Must Do So in the PPA

Alternatively, even if HRSA were correct that the best reading of the statute is that the Secretary has discretion to direct a pricing mechanism, which it is not, the *only* regulatory vehicle through which HRSA could possibly implement such a mandate is the PPA.

Starting with the 340B statute's text and structure, the provision containing the parenthetical phrase that gives Defendants their supposed authority, "(taking into account any rebate or discount, as provided by the Secretary)," discusses *only* the contents of the PPA. Indeed, that subsection of the statute is titled "Requirements for agreement with Secretary." 42 U.S.C. § 256b(a). The entirety of paragraph (1) describes such requirements for the PPA:

> The Secretary *shall enter into an agreement* with each manufacturer of covered outpatient drugs *under which* the amount required to be paid (taking

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

42 U.S.C. § 256b(a)(1) (emphasis added). Read in context, the parenthetical phrase refers to the terms of the PPA. It strains credulity to argue that Congress would bury language establishing an independent source of agency authority to act on pricing mechanisms within a paragraph that addresses the structure and contents of the PPA. *See Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 643 (D.C. Cir. 2021) (explaining that Congress "does not … hide elephants in mouseholes" (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 467-68 (2001))). Plainly, even if the statute authorized the Secretary to "provide[]" for the ceiling price mechanism manufacturers must use (it does not), the Secretary could do so only through a term in the PPA. 42 U.S.C. § 256b(a)(1).

Again, courts need not "resort to legislative history" where, as here, the "statutory text … is clear." *Eagle Pharms.*, 952 F.3d at 339 (citation omitted). But to the extent the 340B statute's legislative history is considered, it supports the same conclusion. The 1992 House report, for example, states that, under the bill, "manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to *enter into an agreement* with the Secretary of HHS to provide price reductions (*whether through a discount, rebate, or other mechanism*) to these 'covered entities' on covered outpatient drugs. H.R. Rep. No. 102-384, pt. 2, at 12 (emphases added). In addition to confirming that a rebate model is an available mechanism

for furnishing 340B pricing to covered entities, that passage signals that, to the extent Congress intended to authorize HHS to direct a pricing mechanism (which it did not, *see* sections I.B-C, *supra*), HHS would need to exercise that authority only through the PPA. *See id.* The report similarly explains that, although "[t]he Committee bill does not specify whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism.… [t]he Committee expects that the Secretary of HHS, *in developing these agreements*, will use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'" *Id.* at 16.[8]

Nothing in the legislative history suggests that Congress empowered the Secretary to prohibit rebate models or require discounts through any means other than the PPA. Yet the PPA, a form agreement on HRSA's website, contains no term addressing the pricing mechanism manufacturers must use. Defendants' failure to include such a term in the more than thirty years of the 340B program's existence—and manufacturers' discretionary adoption of discount models without HRSA (or Congress) indicating disapproval of that structure, *see* section II.B, *infra*—makes clear that manufacturers retain discretion to select among mechanisms, including rebates and discounts, for their administration of the program. As this Court held in *Orphan Drug I*, "[w]here Congress prescribes the form in which an agency may exercise its authority ... [the court] cannot elevate the goals of an agency's action, however reasonable, over that prescribed form." 43 F. Supp. 3d at 38 (quoting *Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1364 (D.C.

[8] This language in the House committee report is inconsistent with the plain and unambiguous text of the statute and should receive no weight in determining its meaning. *See Milner v. Dep't of Navy*, 562 U.S. 562, 574 (2011) ("clear statutory language" prevails over "committee reports"); *cf. Morley v. CIA*, 719 F.3d 689, 691 (D.C. Cir. 2013) (Kavanaugh, J., concurring) ("[W]e should heed the statutory text of FOIA, not committee reports."). At a minimum, however, the report supports the conclusion that the PPA is the only possible mechanism through which Defendants could direct a pricing mechanism if the statute provided authority to do so.

Cir. 1990)). If Defendants could mandate or prohibit a pricing mechanism at all (which they cannot), they could only do so through the PPA. HRSA's attempts to announce such a policy through letters to J&J and a statement on its website are accordingly unlawful and void.

E. Rebate Models Do Not Violate the "Must-Offer" Requirement

In its correspondence with J&J, HRSA also asserted that the "must-offer" provision of the 340B statute, which Congress added in 2010, prohibits manufacturers from adopting a pricing mechanism in which covered entities purchase 340B drugs at commercial prices and then receive a rebate to effectuate the ceiling price. AR202-AR203. On HRSA's telling, "J&J's rebate proposal would require disproportionate share hospitals to purchase Stelara and Xarelto at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs." AR203. In other words, HRSA's view is that a manufacturer that relies on rebates to effectuate 340B price reductions necessarily fails to "offer" the 340B ceiling price. *See* AR202-AR203.

That interpretation, which HRSA has never before asserted, fails on several grounds. First, by effectively precluding the use of any rebate model, the interpretation would render superfluous the statute's reference to "any *rebate* or discount." 42 U.S.C. § 256b(a)(1) (emphasis added); *see, e.g.*, *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1068 (D.C. Cir. 2018) ("We presume that Congress did not 'include words that have no effect.'" (quoting Scalia & Garner, *supra*, at 176-77)). If Congress had intended to revoke its authorization of rebate models when it added the "must-offer" provision in 2010—the assumption apparently underlying HRSA's claim—it surely would have done so by amending the provision expressly providing for a rebate mechanism. Yet that language remained unchanged. HRSA cannot now "rewrite a statute's plain text" to make it correspond with a particular policy preference. *Eagle Pharms.*, 952 F.3d at 335 (quoting *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 498 (D.C. Cir. 2009) (Kavanaugh, J.)). Second, HRSA's reading is notably inconsistent with its rebate guidance for state ADAPs, which remains

in effect and continues to be applied. *See* 63 Fed. Reg. at 35,239, 35,242. Third, HRSA's interpretation clashes with recent interpretations of the "must-offer" provision by the D.C. and Third Circuits, which confirm that the 340B statute allows manufacturers to adopt "reasonable conditions" with respect to the offering of 340B drugs and that HRSA cannot impose restrictions unless authorized to do so by statute. *Novartis Pharms.*, 102 F.4th at 459-61; *Sanofi Aventis*, 58 F.4th at 703-05.

Fourth, interpreting the "must-offer" provision to require discounts fails as a matter of ordinary meaning. The statute provides that the PPA "shall 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) (emphasis added). "Price" means "[t]he cost of acquiring or producing something." *Price*, Black's Law Dictionary (12th ed. 2024). Under the plain language of the statute, the "price" of J&J drugs for covered entities under J&J's Rebate Model is the ceiling price, however effectuated. Indeed, it is commonly understood that "[t]he transaction price of a prescription drug … includes discounts and rebates." *PhRMA v. David*, 510 F. Supp. 3d 891, 898 (E.D. Cal. 2021). Manufacturers routinely "*offer*[] lower *prices* … through *rebates* or discounts." *Cash & Henderson Drugs, Inc. v. Johnson & Johnson*, 799 F.3d 202, 206 (2d Cir. 2015) (emphasis added); *see also, e.g., FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (explaining that drug manufacturers may offer "cash rebates" to wholesalers that result in a wholesaler "acquir[ing] the drugs for *prices* less than the listed [wholesale acquisition cost]" (emphasis added)). Stated simply, an offer to purchase a drug and then receive a rebate is an offer to purchase the drug at the price after the rebate. J&J's Rebate Model therefore does not result in covered entities paying more than the ceiling price. *See also Novartis Pharms.*, 102 F.4th at 460-61 (discussing definitions of "offer," "purchase," and "price" under the 340B statute).

That understanding also aligns with HHS's implementation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"). Under AKS safe-harbor regulations, a "discount" is "a reduction in the amount a buyer … is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5). A rebate, in turn, is "any *discount* the terms of which are fixed and 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." *Id.* § 1001.952(h)(4) (emphasis added). In other words, a "rebate" is a type of "reduction in the amount a buyer … is charged for an item." *Id.* § 1001.952(h)(5). The purchaser is still "charged" the reduced amount, regardless of whether the reduction is pre- or post-offer. *See also, e.g.*, 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I) ("best price" under Medicaid Drug Rebate Program "shall be inclusive of cash discounts, … volume discounts, and rebates"); 42 C.F.R. § 447.505(b) (implementing Medicare regulation defining "[b]est price" to include "applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly"); 42 U.S.C. § 1395w-102(d)(1)(B) (Medicare Part D statute providing that "negotiated prices … shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs"); 42 C.F.R. § 423.100 (defining "[p]rice concession" for Part D as "any form of discount, direct or indirect subsidy, or rebate received by the Part D [plan] sponsor … that serves to decrease the costs incurred under the Part D plan").

As these parallel provisions and regulations reinforce, the 340B statute's "must-offer" provision by its plain terms is satisfied when a covered entity receives a rebate that reduces the net price for an eligible drug purchase to the ceiling price. HRSA's newfound interpretation of the must-offer provision, which would preclude the use of any rebate model *at all*, is contrary to law.

II. HRSA UNLAWFULLY REJECTED J&J'S REBATE MODEL

HRSA's rejection of J&J's Rebate Model was unlawful on several grounds. As described in section I.C, *supra*, HRSA lacks statutory authority to mandate a pricing mechanism, so any attempt to do so is *ultra vires*, in excess of statutory jurisdiction, and not in accordance with law. *See* 5 U.S.C. § 706(2)(A), (C). Even if the 340B statute did grant Defendants discretion to approve or prohibit pricing mechanisms (which it does not), Defendants could do so only through the PPA, not through letters to manufacturers or policy pronouncements on HRSA's website. *See* section I.D, *supra*. HRSA's final actions disapproving J&J's Rebate Model accordingly violated the 340B statute. HRSA's actions also violated the APA: assuming in the alternative that HRSA has authority to mandate or prohibit a pricing mechanism, that is an exercise of legislative authority that requires notice-and-comment rulemaking. Further, HRSA's treatment of J&J's Rebate Model, in comparison to how HRSA has approached the replenishment models in widespread use by covered entities, is arbitrary and capricious.

A. HRSA's Rejection of J&J's Rebate Model Announced a Legislative Rule Without Required Procedure

HRSA's letters to J&J and website statement violated the APA because HRSA tried to adopt and enforce a legislative rule without using notice-and-comment rulemaking. "An agency action that purports to impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements—is a legislative rule." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (Kavanaugh, J.); *see also, e.g.*, *Elec. Energy, Inc. v. EPA*, 106 F.4th 31, 40 (D.C. Cir. 2024) (explaining that, to determine whether a regulatory action is a legislative rule, "we look to whether the action binds private parties or the agency itself with the force of law" (cleaned up)).

Repeating the position it took in its letters to J&J, HRSA has declared on its website that "implementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1)." AR48. That statement unequivocally "tell[s] regulated parties what they must do or may not do in order to avoid liability," and thus imposes a legally binding prohibition on J&J, barring adoption of its Rebate Model absent HRSA approval. *Nat'l Mining Ass'n*, 758 F.3d at 252. And HRSA's threats to terminate J&J from the 340B program if it proceeds with the Rebate Model, AR203; AR214, demonstrate that HRSA views violations of its announced policy as the basis not only for pursuing enforcement, but for seeking the most severe sanctions possible. HRSA has thus purported to adopt a policy that binds J&J, yet it failed to use notice-and-comment, "the hallmark of a legislative rule." *Orphan Drug I*, 43 F. Supp. 3d at 46; *see Nat'l Mining Ass'n*, 758 F.3d at 250 ("Legislative rules … may be promulgated only after public notice and comment."). HRSA's declaration of its policy through its letters and website statement, and application of the policy to J&J, therefore violated the APA and should be vacated. 5 U.S.C. § 706(2)(D) (directing reviewing courts to hold unlawful and set aside agency action taken "without observance of procedure required by law").

HRSA's failure to exercise its alleged discretion consistent with the APA here makes its rejection of J&J's Rebate Model unlawful—as would be any attempt to adopt the same policy through a PPA amendment without notice-and-comment rulemaking. In short, HRSA action to specify a mechanism under 42 U.S.C. § 256b(a)(1) is an exercise of purported legislative authority and an application of discretion supposedly delegated by Congress to adopt binding requirements for regulated parties. When an agency promulgates a policy "with the intent to exercise its delegated legislative power by speaking with the force of law," the policy is a legislative rule and notice-and-comment is required. *Nat'l Council for Adoption v. Blinken*, 4 F.4th 106, 114 (D.C.

Cir. 2021) (citation omitted); *see also, e.g.*, *CSL Plasma Inc. v. U.S. Customs & Border Prot.*, 628 F. Supp. 3d 243, 261-62 (D.D.C. 2022) ("A legislative rule … 'supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy.'" (quoting *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014))).

Contrary to HRSA's assertion in its September 17, 2024 letter to J&J, AR202 n.1, nothing in the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), suggests a different result. The Court there stated that "PPAs simply incorporate statutory obligations and record the manufacturers' agreement to abide by them," *id.* at 118, which remains true; the form PPA on HRSA's website, and the addendum HRSA released in 2016, simply parrot the statutory text, *see* AR36-AR47; *see also* 80 Fed. Reg. 63,560, 63,560 (Oct. 20, 2015) (HRSA notice announcing PPA addendum "to incorporate the administrative requirement for manufacturer integrity provisions directly addressed in the Affordable Care Act"); 81 Fed. Reg. 20,649, 20,649 (Apr. 8, 2016) (final PPA addendum notice). To date, the PPA has simply echoed the statutory text and "serve[d] as the means by which drug manufacturers opt into the statutory scheme." *Astra USA*, 563 U.S. at 118.

If HRSA attempts to use alleged authority (under the incorrect assumption it has such authority) to mandate or prohibit a pricing mechanism through the PPA, that would constitute the promulgation of a legislative rule, premised on a claimed delegation of authority, that announces a binding interpretation of the statute. *See Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710, 716 (D.C. Cir. 2015) ("A legislative rule '*modifies* or *adds* to a legal norm based on the agency's *own authority*' flowing from a congressional delegation to engage in supplementary lawmaking." (quoting *Syncor Int'l. Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997))). Under the APA, courts must respect "delegations of authority" to agencies, but must also "police the outer

statutory boundaries of those delegations, and ensure that agencies exercise their discretion consistent with the APA." *Loper Bright*, 603 U.S. at 404. That includes enforcing the requirement of notice-and-comment for legislative rules, *Nat'l Council for Adoption*, 4 F.4th at 114, and ensuring that properly promulgated rules are "reasonable and reasonably explained," *Env't Def. Fund*, 124 F.4th at 11 (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021))—which in turn requires the agency to credibly explain any decisions to treat similar situations differently. *See* section II.B, *infra*.

B. HRSA's Inconsistent Treatment of Rebate and Replenishment Models Raises Serious Questions About the Agency's Decision-making

HRSA's decisions to reject J&J's Rebate Model, and to prohibit use of any rebate model "without Secretarial approval," AR214, are fundamentally at odds with the approach that HRSA has taken in response to the emergence and broadscale utilization of replenishment models by covered entities. "It is a fundamental principle of administrative law that agencies must treat like cases alike." *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1242 (D.C. Cir. 2023). Even though replenishment models share many of the same features and operate in materially the same manner as J&J's proposed Rebate Model, HRSA has treated requests by manufacturers to adopt rebate models in a dramatically different fashion from how it has responded to covered entities' adoption of replenishment models—or, more accurately, has *not* responded.

Under a replenishment model, drug units are purchased at wholesale acquisition cost ("WAC"), and the 340B price is realized once the covered entity's third-party administrator determines that a sufficient number of units have been dispensed to 340B-eligible patients and then places an order to replenish the stock of the drug at the 340B price. *See* Pedley Decl. ¶¶ 5-9,

Sanofi-Aventis U.S., LLC, No. 3:21-cv-634 (D.N.J. June 24, 2021);[9] *Novartis Pharms.*, 102 F.4th at 457-58. J&J's Rebate Model is similar in critical respects—drug units are purchased at WAC and the 340B price is realized after the initial sale. In replenishment models, the 340B price is effectuated subsequent to the product dispense to the patient by replenishing with a replacement unit whereas, with the Rebate Model, the 340B price is effectuated subsequent to the product dispense to the patient by providing a rebate.

Despite these and other key commonalities, none of HRSA's correspondence rejecting J&J's Rebate Model adequately explained why HRSA treated the Rebate Model differently from the replenishment models that covered entities have used for over a decade. In its September 17, 2024 letter to J&J, HRSA tried to distinguish replenishment models from rebate models by asserting that, under the "typical replenishment structure," the covered entity purchases the initial unit at WAC and then subsequent units are replenished at the 340B price. AR203. But that is materially the same as how J&J's Rebate Model will work. The covered entity will purchase a unit at WAC and then obtain a rebate seven to ten days after submitting data supporting the 340B purchase. AR208-AR209. The rebate plays the same role as the replenishment unit in ensuring that the prior purchase nets the 340B price.

HRSA's failure to sufficiently explain its inconsistent treatment of replenishment models and J&J's Rebate Model fatally undermines its decision-making. "[W]hen an agency takes inconsistent positions ... it must explain its reasoning." *District Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (quoting *Gulf Power Co. v. FERC*, 983 F.2d 1095, 1101 (D.C. Cir. 1993)). For basic reasons of fairness, HRSA "cannot treat similarly situated entities

[9] The Court may "properly take judicial notice of proceedings and filings in other courts." *Strike 3 Holdings, LLC v. Doe*, 964 F.3d 1203, 1213 (D.C. Cir. 2020).

differently unless it 'support[s] th[e] disparate treatment with a reasoned explanation and substantial evidence in the record.'" *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014) (quoting *Burlington N. & Santa Fe. Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005)). The superficial distinctions HRSA's September 17 letter draws between replenishment models and J&J's Rebate Model fail to satisfy that standard.

That is especially true for the September 17 letter's assertion that replenishment models are distinct from rebate models in that "covered entities voluntarily choose to use replenishment processes," whereas "J&J's proposal is not voluntary for covered entities." AR203. HRSA has acquiesced in covered entities' use of replenishment models for more than a decade, *see, e.g.*, 80 Fed. Reg. at 52,305 (2015 proposed guidance acknowledging use of replenishment models), but has never affirmatively authorized their use or provided any limitations or guidelines, let alone granted manufacturers an opportunity to reject the use of replenishment models. HRSA's position thus inexplicably treats one class of program stakeholders—covered entities—more favorably than another set of stakeholders—manufacturers. Courts have long held that "agency action 'is at its most arbitrary when it treats similarly situated people differently'" without "an adequate explanation." *Nasdaq Stock Market LLC v. SEC*, 38 F.4th 1126, 1141 (D.C. Cir. 2022) (first quoting *Etelson v. Off. of Pers. Mgmt.*, 684 F.2d 918, 926 (D.C. Cir. 1982); then quoting *Burlington N. & Santa Fe Ry. Co.*, 403 F.3d at 776).[10]

[10] HRSA continued this differential treatment in its evaluation of J&J's Rebate Model. The Administrative Record reveals that HRSA met with representatives of a hospital association on October 2, 2024, and asked the association to submit information on a number of topics, including "[t]he potential added administrative costs of implementing a rebate model" and "[t]he extent to which manufacturer administrative barriers effectively create a denial of discounts that covered entities are eligible for." AR586. HRSA has yet to ask manufacturers corresponding questions about, for example, the administrative costs manufacturers shoulder in order to supply drugs to

If the 340B statute permits covered entities to implement replenishment models without HRSA consent, as HRSA has apparently decided, then surely it follows that the 340B statute permits manufacturers to implement rebate models without HRSA consent. This is especially so given that the text of the 340B statute expressly references rebates as a means of effectuating 340B prices but nowhere mentions replenishment models. Congress's broader purpose in enacting the 340B statute reinforces this conclusion. The aim of the law was to restore the status quo before the Medicaid Drug Rebate Program was enacted in 1990; at that time, manufacturers *voluntarily* offered reduced pricing to safety net providers. *See* H.R. Rep. No. 102-384, pt. 2, at 12. Granting manufacturers discretion on the form the restored price reductions would take post-340B is consistent with the discretionary basis on which those price reductions were offered pre-1990. HRSA's contrary approach of giving manufacturers no say at all as to pricing mechanism—while simultaneously forcing them to accept covered entities' unprecedented and unilateral adoption of replenishment models—is not consistent with either the 340B statute or the APA, which does not countenance such arbitrary, inconsistent, and inadequately explained agency action.

CONCLUSION

For the foregoing reasons, J&J respectfully requests that the Court grant its Motion for Summary Judgment, declare that J&J may utilize its Rebate Model for the 340B program and that HRSA's rejection of the Rebate Model was unlawful, and vacate and set aside HRSA's letters announcing that rejection decision and its website policy pronouncement requiring Secretarial approval for implementation of 340B rebate models.

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covered entities and their contract pharmacies using replenishment models, or the extent to which replenishment models enable unlawful diversion or duplicate discounting.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on February 3, 2025, I filed the foregoing with the Clerk of the Court using the ECF System, which will send notification of such filing to the registered participants identified on the Notice of Electronic Filing.

/s/ Jeffrey L. Handwerker
Jeffrey L. Handwerker