IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, *et al.*, *Plaintiffs*, v. DOROTHY FINK, *et al.*, *Defendants*.	Case No. 24-CV-3220 (DLF)

MEMORANDUM IN SUPPORT OF
ELI LILLY AND COMPANY'S AND LILLY USA, LLC'S
MOTION FOR SUMMARY JUDGMENT

CONTENTS

AUTHORITIES

Cases **Page(s)**

Statutes **Page(s)**

Rules, Regulations, and Guidance **Page(s)**

Other Authorities **Page(s)**

INTRODUCTION

The federal 340B drug-pricing program is broken. This case is about Lilly's lawful attempt to fix it, and the federal government's unlawful and irrational attempt to stop Lilly.

The 340B statute requires Lilly to sell its medicines at significantly reduced prices to certain healthcare providers. At issue is *how* Lilly makes the 340B price available. The statute expressly authorizes either up-front "discounts" *or* back-end "rebates." 42 U.S.C. § 256b(a)(1). The government has never mandated either option, and what's predominantly used today is a system of in-kind rebates. That system is opaque, enables widespread abuse, results in frequent errors, and makes it difficult, if not impossible, to comply with federal law. To solve these problems, Lilly decided to offer the 340B price by paying cash rebates instead. But the government unlawfully shut Lilly down before it could start—and without ever explaining why.

Not all healthcare providers are eligible for 340B pricing. Only certain providers called "covered entities" can buy at the 340B price, but today nearly 60% of all hospitals are in the program. These covered entities need not pass on the 340B price to patients. That creates an arbitrage opportunity: covered entities can buy medicines at vastly reduced prices and sell them for much more to patients and their insurers, including Medicare and Medicaid. And that opportunity has not escaped notice: Exploiting this "spread" can be so lucrative that an entire cottage industry of for-profit 340B middlemen has emerged to partner with covered entities in pursuit of those profits.

Congress recognized the 340B program's potential for abuse, so it enacted several statutory guardrails. Two are especially important here: Covered entities are supposed to dispense 340B-priced medicines only to their patients; that is, they cannot "divert" it to non-patients or for-profit partners. And covered entities cannot seek reimbursement from Medicaid for 340B-priced medicines that are subject to Medicaid rebates, which protects manufacturers from giving two mandatory price reductions for the same prescription.

To comply with these restrictions, covered entities initially had separate inventories—one for 340B-priced medicines and another for market-priced medicine. But that system proved inconvenient because it required identifying patients and their insurers when prescriptions are filled. To avoid those burdens, covered entities developed a system of in-kind rebates called a "product replenishment model." That system is nothing more than an elaborate shell game: Covered entities and their for-profit vendors first buy medicine at market prices and dispense it to anyone who shows up at the pharmacy counter. Later, third-party administrators use proprietary algorithms to *retroactively* identify dispenses to a 340B patient. Based on these identifications, they "replenish" their inventory at 340B prices, which they again proceed to dispense to anyone with a prescription. And then the cycle starts anew. The entire process takes place behind closed doors; the details of what purportedly triggered the 340B price, who is an eligible "patient," what happens to the "replenishment medicine," and who reaps the "spread" between the market price and the 340B price are unknown.

The result is as predictable as it is damaging: a system primed for fraud, waste, and abuse. The Government Accountability Office has noted, for more than a decade, that the current system results in unchecked—and illegal—duplicate discounts. And it has noted that the government agency tasked with overseeing the 340B program, the Health Resources and Services Administration (HRSA), has no interest in detecting or stopping illegal duplicates. Some estimate that illegal duplicates total more than *$2 billion* annually—and growing by more than 20% *every year*.

The way to prevent these unlawful duplicates is transparency. Lilly has contracted with Kalderos, a healthcare technology company, to provide the 340B price via a cash rebate—*i.e.*, by replenishing *cash* instead of *product*. Covered entities would continue to buy their medicines at market prices—just as they do now—and then electronically submit a claim through Kalderos's

system whenever a prescription is identified as 340B-eligible. Lilly would swiftly pay covered entities cash rebates to effectuate the 340B price, by direct deposit every week. That's it. That process would ensure *all* relevant parties, including Lilly, have the data they need to comply with federal law and resolve disputes if necessary. The transparency created by this data parity will help restore the integrity that the 340B program has now lacked for many years, fully realizing Congress's design.

Rather than embrace this 340B program improvement, HRSA has done everything it can to stop it. In a first for the 30-year-old program, the agency told Lilly that it must get preapproval for its cash-replenishment program—even though some covered entities *already* receive 340B prices via a cash rebate. And instead of providing that preapproval, HRSA threatened any manufacturer that begins paying cash rebates with the most dire punishment it can impose: removal from Medicaid and Medicare Part B, which would make Lilly's medicines unavailable for the country's most vulnerable patients. No manufacturer can rationally risk that outcome, so the status quo and all its drawbacks remain.

HRSA's decision is unlawful for at least two reasons. *First*, the 340B statute does not give HRSA (and it has never asserted) ad hoc preapproval power over the method for effectuating the 340B price. HRSA's role is to implement the 340B statute by signing agreements with manufacturers. HRSA's agreement with Lilly neither forbids the use of cash rebates nor requires Lilly to secure the agency's preapproval before doing so. And, as HRSA has previously acknowledged, the 340B statute expressly recognizes rebates as a valid method of providing the 340B price.

Second, HRSA's decision is arbitrary and capricious because it is neither reasonable nor reasonably explained. Although Lilly thoroughly explained to HRSA why its proposal complies with both the 340B statute and Lilly's PPA, while also addressing known program-integrity

concerns, HRSA rejected Lilly's proposal in a short, unreasoned letter. HRSA did not explain why it thinks Lilly's proposal is meaningfully different from the way manufacturers currently offer the 340B price—or from the cash-rebate systems that *already* exist for some covered entities. Nor could HRSA have done so if it had tried.

For each of these independent reasons, the Court should grant Lilly's motion for summary judgment.

STATEMENT OF FACTS

I. THE FEDERAL 340B PROGRAM

Before the 340B program, manufacturers voluntarily sold reduced-price medicines to the Department of Veterans Affairs and charitable hospitals. Milt Freudenheim, *Big Costs Imposed on Drug Makers*, N.Y. Times, Nov. 6, 1990, at D2, https://tinyurl.com/368umt5y. But when Congress enacted the federal Medicaid Drug Rebate Program in 1990, it inadvertently interfered with that practice. *See* H.R. Rep. No. 102-384(II), *9–10 (1992). The Medicaid Drug Rebate Program requires manufacturers to offer Medicaid discounts that match the lowest price they offer to other buyers—meaning that if a manufacturer were to continue to sell discounted medicines to the VA and those charitable hospitals, it could drastically increase the rebates owed to Medicaid. The Medicaid Drug Rebate Program thus disincentivized manufacturers from continuing to offer reduced-price medicines to entities serving under-resourced populations.

Congress sought to remedy that disincentive with the 340B program. Congress created the 340B program under the Veterans Health Care Act of 1992, codified as Section 340B of the Public Health Service Act, *see* 42 U.S.C. § 256b.[1] The program conditions federal coverage under Medicaid and Medicare Part B on the HHS Secretary's "enter[ing] into an agreement with [the]

[1] *See also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

manufacturer." 42 U.S.C. § 256b(a)(1). Such an agreement, known as a Pharmaceutical Pricing Agreement, or PPA, "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 117–18 (2011).

Under the 340B program, manufacturers must offer their medicines at bargain-bin prices to certain healthcare providers called covered entities. 42 U.S.C. § 256b(a)(1); *see also id.* § 256b(a)(4) (listing types of providers that can qualify as a covered entity). 340B ceiling prices represent "substantial discounts" from prevailing commercial rates. Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program* 6–7 (May 2015) (emphasis omitted), *available at* https://tinyurl.com/bdce5cbc. When Congress created the 340B program, there were only about 1,000 covered entities. Ryan P. Knox et al., *Outcomes of the 340B Drug Pricing Program: a Scoping Review*, 4(11):e233716 JAMA Health F., at 4 (Nov. 2023), *available at* https://pmc.ncbi.nlm.nih.gov/articles/PMC10665972/. By 2015, that figure swelled to include "more than 40% of US hospitals," *see id.*, and some analysts now place that estimate at roughly two-thirds of all U.S. hospitals.[2]

The 340B statute gives latitude in how to offer the required prices. It does so by requiring manufacturers to "enter into an agreement" (the PPA) "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). The statute thereby authorizes 340B prices to be offered by either a front-end "discount" or a back-end "rebate." Lilly's PPA, for its part, makes no mention of "rebate[s] or discount[s]"; it states that

[2] *E.g.*, Nicole Longo, Pharm. Rsch. & Mfrs. of Am., *By the Numbers: 340B Continues to Climb in Profits, Dwindle with Patient Support* (Sept. 13, 2023), *available at* https://tinyurl.com/24jddrdx.

the "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." AR 47.[3]

Given the significantly reduced prices available to covered entities under the 340B program, the 340B statute also carefully limits manufacturers' obligations: A manufacturer satisfies its "shall offer" requirement so long as it makes a "bona fide" offer to sell its medicines to covered entities at or below the ceiling price. This means in turn that a manufacturer may attach reasonable conditions to its offer, including those concerning data reporting. *See, e.g.*, *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459–61 (D.C. Cir. 2024) (rejecting HRSA's attempt to stop manufacturers from placing "reasonable conditions" on delivery); *see also Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 701, 706 (3d Cir. 2023) (affirming a manufacturer requirement that covered entities provide claims data).

Congress also created statutory guardrails to help "assure the integrity of the drug price limitation program." H.R. Rep. No. 102-384(II), *9–10 (1992). To that end, the 340B statute limits 340B pricing in two important respects. *First*, covered entities may not request payment from a state Medicaid program for 340B-priced medicines that manufacturers also pay a Medicaid rebate on. *See* 42 U.S.C.§ 256b(a)(5)(A). *Second*, covered entities may not dispense 340B-priced medicines to individuals who are not their patients. *Id.* § 256b(a)(5)(B). These anti-duplication and anti-diversion provisions are critical to ensuring that the 340B program hews to its purpose.

Thus, the 340B statute includes procedures intended to help police unlawful duplication and diversion. Manufacturers may audit a covered entity's records that "directly pertain to the entity's compliance" with those prohibitions. 42 U.S.C. § 256b(a)(5)(C). And to resolve any

[3] The relevant language in Lilly's PPA and PPA addendum match the language included in the form agreements in the administrative record. *See* AR 36–47.

disputed claims, Congress directed the HHS Secretary to create an Administrative Dispute Resolution (ADR) mechanism. 42 U.S.C. § 256b(d)(3)(A). The Secretary has done so, *see* 340B Drug Pricing Program, 89 Fed. Reg. 28,643 (Apr. 19, 2024), but a manufacturer must complete an audit before it can initiate an ADR proceeding, 42 C.F.R. § 10.21(a)(2).

HRSA, however, has locked manufacturers' access to audits behind a requirement not found in the statute. HRSA requires manufacturers to first show "reasonable cause" for initiating an audit. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). To do that, HRSA demands "sufficient facts and evidence in support of the belief" that "a violation of [the prohibitions on duplication or diversion] has occurred." *See id.* So if a manufacturer lacks hard evidence that a covered entity has duplicated discounts or diverted 340B product, HRSA's procedures put it in a catch-22: To get such evidence, the manufacturer must begin an audit, but it cannot begin an audit until it has the evidence.[4]

II. THE PROBLEM: THE PRODUCT-REPLENISHMENT MODEL

In recent years, covered entities have unilaterally imposed an opaque method for effectuating 340B prices, often called the "product-replenishment model." As described in more detail below, covered entities pay the market price for medicine up front, then later "replenish" that product at the 340B price after identifying—through post hoc data mining—prior prescriptions as having been dispensed to 340B patients. *See* ECF No. 1-2 (Pedley Decl.) ¶¶ 3, 5. Those providers and their vendors freely commingle 340B inventory and non-340B inventory, *see id.* ¶ 11, effectively concealing which inventory is subject to the 340B statute's anti-duplication and anti-diversion provisions, and inevitably causing violations of these two statutory prohibitions.

[4] Lilly reserves all rights to challenge this HRSA requirement as arbitrary, capricious, contrary to law, and in excess of statutory authority. But such a challenge is outside the scope of this case.

A. Creation of the Product-Replenishment Model

That has not always been so. At the 340B program's outset, most covered entities used a physical-inventory model. Under that model, covered entities physically segregated 340B-priced medicines from commercial priced medicines, and determined whether a prescription was 340B-eligible *before* it was dispensed. *See* 340B Health, *Key Terms* (defining "Physically Separate Inventory"), *available at* https://tinyurl.com/49fh5prc; HHS Office of Inspector General (OIG), *Contract Pharmacy Arrangements in the 340B Program* 5 (Feb. 4, 2014) (Contract Pharmacy Arrangements), *available at* https://tinyurl.com/2nmdrcey. If a prescription met the criteria to be filled with 340B priced-medicines, the provider dispensed from its 340B-priced inventory; if not, the provider dispensed commercially purchased medicine. That segregated-inventory system offered all parties some confidence that 340B-priced medicine would be dispensed consistent with the 340B statute's prohibitions on diversion and duplicate discounts.

Physically segregating inventory required forethought and attention to each medicine dispensed, however. So the more convenient—and more manipulable—product-replenishment model cropped up in its place. The product-replenishment model rests on an elaborate accounting fiction: (1) a "full package" of medicine is purchased at market price; (2) that medicine is dispensed, often in smaller quantities; (3) sometime later, the covered entity and its revenue-seeking partners assess whether prescriptions were 340B-eligible; (4) after purporting to fill enough eligible prescriptions to equal a full package, a "replenishment" package is purchased at the 340B price; (5) the 340B-priced replenishment package is placed in general inventory; (6) that replenishment medicine is dispensed—regardless of whether the person filling the prescription is a patient of the covered entity; and (7) the cycle begins anew. *See generally* ECF No. 1-2 (Pedley Decl.) ¶¶ 3–11.

A defining characteristic of that accounting fiction is that covered entities neither determine whether medicine is 340B-eligible before dispensing it nor establish which package of medicine

is "340B" for purposes of the covered entity's compliance obligations. Regardless of whether a package of medicine is purchased at a 340B or non-340B price, it is placed in "neutral inventory," where units from that package may be dispensed *regardless* of whether a prescription is 340B-eligible. ECF No. 1-2 (Pedley Decl.) ¶¶ 5, 8, 11. Only after those units are dispensed do covered entities or their vendors "attempt to discern" whether individual prescriptions were actually filled by 340B patients. *Novartis Pharms. Corp.*, 102 F.4th at 457. Thus, one package of medicine may be treated as commercial for dispensing purposes, but as 340B-eligible for pricing purposes.

That system facilitates straightforward violations of the 340B statute's duplication and diversion prohibitions by treating a medicine's 340B status as transferrable and divorced from the price at which is it sold. Medicine starts out the journey as *commercial* (freeing it to be dispensed to anyone), is next retroactively declared *340B* (to generate a replenishment claim), that 340B status is then *transferred* from the dispensed medicine to the replenishment medicine (so that the latter can be purchased at the 340B price), but the covered entity then deems that replenishment medicine *commercial* so that it can be dispensed to anyone. That constant yo-yoing of 340B status nullifies the statute's duplication and diversion prohibitions. Under the product-replenishment regime, covered entities necessarily purchase medicine at a 340B price and then "resell or otherwise transfer the drug" to non-340B-eligible individuals. 42 U.S.C. § 256b(a)(5)(B). And the shifting nature of which packages are "340B" makes tracking the duplication provision virtually impossible. *See* Kalderos, *2022 Annual Report: Conquering the "Great Unknown"* 24–26 (2022), *available at* https://tinyurl.com/45tv6bw6.

Nevertheless, HHS has acceded to the product-replenishment model's widespread adoption, characterizing the model as simple "inventory-accounting." HHS Off. Of the Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* 6 & n.6 (Dec. 30,

2020) (Contract Pharmacies Opinion), *available at* https://perma.cc/L7W2-H597. Notably, HRSA never purported to *preapprove* the product-replenishment model's use, even though it is a system of in-kind rebates. Nor did HRSA study its pitfalls, get input from stakeholders, or formally mandate its use. Covered entities simply created it without agency preapproval—or manufacturer consent, for that matter.

B. Third-Parties' Involvement in the Product-Replenishment Model

Sophisticated software is needed to sustain the accounting fiction that props up the product-replenishment model. When covered entities dispense prescriptions in-house, they use such software themselves. That software collects data about each prescription filled from so-called "neutral" inventory. It then "uses logic based on configurations, chosen by the entity, to separate 340B from non-340B transactions after they occur." Apexus, *340B Split-Billing Software Key Attributes* (Jan. 17, 2023), *available at* https://tinyurl.com/2wb589up. When a covered entity has filled a full package's worth of prescriptions to 340B-eligible patients, the software helps the provider place replenishment orders at 340B prices.

Not all covered entities dispense covered outpatient medicines in-house. HRSA has permitted covered entities to use "contract pharmacies": for-profit commercial pharmacies that "dispens[e] 340B-purchased drugs on behalf of a covered entity" in exchange for a cut of the arbitrage profits. Contract Pharmacy Arrangements at 4. For-profit contract pharmacies administer the product-replenishment model in much the same way as covered entities. Contract pharmacies deploy software that "compares the information about the dispense with eligibility criteria provided from the covered entity, in order to determine if the patient was eligible for 340B product." ECF No. 1-2 (Pedley Decl.) ¶ 6. Then, the software "notifies the covered entity that it may place a replenishment order for the drug in question" using a covered entity's 340B purchasing account with the relevant wholesaler of the pharmaceutical manufacturer. *Id.* ¶ 7.

Some covered entities and pharmacies also bring in for-profit third-party administrators to manage the product-replenishment model. Those administrators, too, are in it for the money. As the D.C. Circuit has explained, third-party administrators "often receive a larger fee for every prescription deemed eligible for the discount." *Novartis Pharms. Corp.*, 102 F.4th at 457. For that reason, covered entities, contract pharmacies, and third-party administrators alike have "a financial incentive to catalog as many prescriptions as possible as eligible." *Id.* at 457–58. Once they have done so, they all "divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457.

The methods by which covered entities, pharmacies, and administrators retrospectively "catalog" those 340B-eligible prescriptions, *id.*, are shrouded in secrecy. Contract pharmacies and third-party administrators use black-box algorithms to determine which prior dispenses may have been 340B-eligible. And third-party administrators market their prowess in identifying as many supposedly 340B-eligible transactions as possible. To "maximize the revenue generated" from 340B prices, third-party administrators review dispense data and harvest 340B claims, often weeks or months after a prescription was filled. *See* Aaron Vandervelde et al., Berkely Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 5 (Oct. 2020), *available at* https://tinyurl.com/mrxxr4rn. The proprietary algorithms used to perform that task run various profitability scenarios to reveal the most desirable, allowing "for-profit pharmacies to influence which prescriptions are classified as 340B." *Id.* at 8; *see also* Neal Masia, Ph.D., Alliance for Integrity & Reform, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019* 2, *available at* https://tinyurl.com/7cc3dw2t; Ellen Gabler, *How a Company Makes Millions off a Hospital Program Meant to Help the Poor*, N.Y. Times (Jan. 16, 2025) (noting that the for-profit middleman

Apexus "show[s] hospitals how to . . . boost[ ] the number of prescriptions that can qualify for discounts"), *available at* https://tinyurl.com/yv7akn6t.

The predictable result: The algorithms sweep in customers who are not in fact "patients" of the covered entity—or who are "patients" of multiple covered entities. *See, e.g.*, Government Accountability Office (GAO), *GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 2011), *available at* https://www.gao.gov/assets/d11836.pdf. The D.C. Circuit has noted a helpful example: "[S]uppose a physician practices at a covered entity and somewhere else. The physician writes a prescription for a patient of his private practice. Yet the contract pharmacy, connecting the physician to the covered entity, classifies the prescription as eligible for the discount." *Novartis Pharms. Corp.*, 102 F.4th at 458. Multiple covered entities and their contract pharmacies also sometimes claim the same patient, creating duplicative product replenishment orders based on the same prescription.[5]

Identifying purported 340B-eligible transactions thus has become big business. A handful of massive for-profit pharmacy chains and pharmacy benefit managers now dominates the contract-pharmacy industry. *Fein*, *supra* n.5. Those entities receive a startling share of the pie: about 16 percent of *all* 340B "revenue" currently goes to for-profit third parties.[6] That share is so significant that some covered entities reported a "net loss" on 340B transactions "as a result of their high external operational costs." *Id.* at 25. And third parties are not shy about their dependence

[5] *See, e.g.*, Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), *available at* https://tinyurl.com/5n6hfmtd.

[6] Minnesota Dep't of Health, *340B Covered Entity Report* 9 (Nov. 25, 2024), *available at* https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

on this largesse. In its 2023 10K, for instance, Walgreens admitted that changes to contract-pharmacy arrangements under the 340B program "could . . . significantly reduce [its] profitability."[7] Likewise, CVS warned investors that "a reduction in the use of the Company's administrative services by Covered Entities . . . could materially and adversely affect the Company."[8]

None of this arbitrage revenue makes it into *patients'* pockets. As covered entities themselves often emphasize, "the 340B program does not require passing 340B discounts on to patients." *See, e.g.*, Amicus Brief of 340B Health, *Genesis Healthcare v. Becerra*, No. 4:19-CV-1531 (D.S.C. Sept. 20, 2023), ECF No. 124-2 at 2 (340B Health Brief). Accordingly, covered entities use the profits they make on 340B sales to fund "a wide range of activities." *Id.* at 3.

The financial incentives created by the product-replenishment model have warped the 340B program beyond recognition. The program's original mission was to support the care of uninsured, low-income patients.[9] But dispensing medicine to *uninsured* patients deprives covered entities and their for-profit partners of any "spread" to divvy up because that "spread" comes from the difference between the 340B price and "reimburs[ments] by insurers . . . at the non-discounted price of the drug." *See* 340B Health Brief at 2. So some covered entities now outright refuse to "offer the 340B price to uninsured patients in any of their contract pharmacy arrangements." Contract Pharmacy Arrangements at 14.

HRSA does not meaningfully police covered entities' use of the product-replenishment model, despite its plain potential for spawning incorrect and duplicate price concessions. GAO

---

[7] Walgreens Boots Alliance, *2023 Annual Report* 33 (Oct. 12, 2023), *available at* https://tinyurl.com/ypnas5zt.

[8] CVS Health, *2023 Annual Report* 26 (Feb. 7, 2024), *available at* https://tinyurl.com/kdkx49t2.

[9] IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* (Aug. 30, 2024), *available at* https://tinyurl.com/45cx3u72.

has long "identified several areas of weakness in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied." GAO, *GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 23 (June 2018) (2018 GAO Report), *available at* https://www.gao.gov/assets/d18480.pdf. For example, "HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries," which fails to create "reasonable assurance" that duplicate discounts can be avoided, leaving drug manufacturers "at risk." *Id.* at 24–25. Worse, HRSA does not even try to "assess for the potential for duplicate discounts in Medicaid managed care," which is "particularly problematic" because that space sees the majority of spending and, likely, the majority of duplicate discounts. *Id.* at 25–26. HRSA recently doubled down on this no-managed-care-audit policy, despite conceding that utilization of Medicaid managed care can result in prohibited discount duplication. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,634, 28,649 (Apr. 19, 2024).

C. 340B Program Abuse Under the Product-Replenishment Model

Unsurprisingly, the combined result of distorted financial incentives and lack of government oversight is a 340B program overrun with abuse. And the Court need not take Lilly's word for it; the federal government has confirmed that finding repeatedly. *E.g.*, 2018 GAO Report at 15–16 (noting that "72 percent of the covered entities audited in fiscal years 2012 through 2017 had one or more findings of noncompliance"); House Energy & Commerce Comm., *Review of the 340B Drug Pricing Program* 36 (Jan. 10, 2018) (340B Review) (describing "discount errors" as "likely" and "duplicate discounts" as "quite common"), *available at* https://tinyurl.com/58rpjkfv; GAO, *GAO-20-212, Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* 25–27 (Jan. 2020) (2020 GAO Report) (explaining that even identified instances of

duplicate 340B-Medicare managed care discounts sometimes go unremedied), *available at* https://www.gao.gov/assets/gao-20-212.pdf; *see also* HHS OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* 10–13 (June 2016) (detailing how Medicaid managed-care claims can "result[ ] in duplicate discounts"), *available at* https://tinyurl.com/ya3ncn23.

The potential for abuse intensified in 2010, when the Affordable Care Act expanded the Medicaid Drug Rebate Program to include Medicaid managed care organizations. *See* Pub. L. No. 111-148, § 2501, 124 Stat. 119, 308 (2010). That expansion substantially increased illegal Medicaid-340B duplicates because Medicaid managed-care accounts for most Medicaid utilization. 2020 GAO Report at 1; *see also* Medicaid & CHIP Payment & Access Comm'n, *MACStats: Medicaid & CHIP Data Book* 68–73 (Dec. 2024), *available at* https://tinyurl.com/3ee9fsvr. And HRSA's lack of attention to duplication in Medicaid managed care means "[t]he volume of duplicate discounts . . . may be far greater than has been previously realized." 340B Review at 37.

Tellingly, expansion of the Medicaid Drug Rebate Program coincided with explosions of both contract-pharmacy arrangements and of Medicaid rebates. Between 2010 and 2019, the number of contract pharmacies increased from about 1,300 to about 23,000. 2020 GAO Report at 2. That growth has continued since, recently reaching about 35,000. Avalere, *Contract Pharmacy Trends May Help Inform 340B Reform Debate* (June 10, 2024), https://tinyurl.com/3umyyrvc. GAO has tied that contract-pharmacy trend to an "increase[ ]" in "the potential for duplicate discounts." 2020 GAO Report at 2. HHS OIG, too, has concluded that the proliferation of these relationships "create[s] complications in preventing duplicate discounts." Contract Pharmacy Arrangements at 2. The data bear out those conclusions. Total Medicaid rebates rocketed from about $15 billion in 2011 to over $36 billion by 2018, and then to about $42.5 billion by 2021. 2020 GAO Report at 2; Medicaid & CHIP Payment & Access Comm'n, *High-Cost Drugs and the*

Medicaid Program: MACPAC Evidence and Recommendations (Feb. 2024) (MACPAC Report), *available at* https://tinyurl.com/34tkverf. But even that steep trajectory pales in comparison to 340B growth: *over 129%* from 2018 to 2023. Rory Martin & Harish Karne, IQVIA, *The 340B Drug Discount Program Grew to $124B in 2023* (May 31, 2024), https://tinyurl.com/3b8zcu5a.

While 340B sales have boomed, government audits—even limited as they are—consistently find systematic violations of the 340B statute's prohibitions on duplication and diversion. *See, e.g.*, HRSA, *Audit Results of Covered Entities*, *available at* https://www.hrsa.gov/opa/program-integrity. From just 2012 to 2019, HHS audits revealed over 1,500 instances of 340B program noncompliance, including 429 instances of duplication with the Medicaid Drug Rebate Program, 546 instances of diversion, and 561 instances of other violations of eligibility requirements. GAO, *GAO-21-107, HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 14 (Dec. 2020), *available at* https://www.gao.gov/assets/gao-21-107.pdf. Given the low volume of government audits in the first instance,[10] those findings suggest huge rates of noncompliance. The available evidence confirms as much: In 2021, "[m]ore than 60 percent of audited covered entities had at least one adverse finding." Lindsay Bealor Greenleaf, *Analysis of FY 2021 HRSA 340B Covered Entity Audits* (Feb. 23, 2023), https://tinyurl.com/yc2aktnh.

Opacity is the root cause of these widespread statutory violations. For example, an HHS audit revealed that a "covered entity and its off-site outpatient facilities did not accurately appear" on HHS's 340B Medicaid Exclusion File, which HHS designed "to prevent duplicate discounts by notifying states and manufacturers which drug claims are not eligible for Medicaid rebates." *See* 340B Review at 36–37. GAO has reached the same conclusion. In discussing covered entities'

[10] HRSA explains that it audits only about 200 covered entities per year, ECF No. 1-2 (Pedley Decl.) ¶ 6, and again, not for duplication in Medicaid managed care, 2018 GAO Report at 25.

self-reported program violations, it explained that "HRSA does not know if covered entities have effectively identified the full extent of noncompliance." GAO, *GAO-23-106095, 340B Drug Discount Program: Information About Hospitals That Received an Eligibility Exception as a Result of COVID-19* 20 n.32 (May 11, 2023), *available at* https://www.gao.gov/assets/gao-23-106095.pdf. Of course, common sense suggests that self-reported violations amount to only a fraction of the true extent of malfeasance.

In fact, some have estimated that three to five percent of *all* Medicaid rebates now duplicate 340B pricing. Ashwin Mundra, *The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark, Drug Channels* (Mar. 18, 2022), *available at* https://tinyurl.com/2ewmceba. In 2020 alone, that amounted to between *$1.3 billion and $2.1 billion* in illegal duplicates. *Id.* The amount of duplication is likely much higher today because 340B purchases nearly doubled between 2020 and 2023, rising from $38 billion to $66 billion. Adam J. Fein, Drug Channels, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Action*s (Oct. 22, 2024), *available at* https://tinyurl.com/mryxdh34.

These trends show no signs of stopping, especially given the "[l]imitations in federal oversight" that "impede CMS's and HRSA's ability to ensure compliance with the prohibition on duplicate discounts." 2020 GAO Report at 27. At bottom, HRSA's oversight failures are so severe as to "compromise[ ] the integrity of the 340B Program." *See id.* So in stemming the tide of abuse, drug manufacturers are on their own.

D. Increased Confusion After the Inflation Reduction Act

Illegal 340B duplication is now poised to worsen, thanks to the recently enacted Inflation Reduction Act (IRA). The IRA created Medicare Part B and Part D inflation-rebate programs, under which manufacturers must pay Medicare rebates on medicines covered under Parts B and D if their prices rise faster than the rate of inflation. Under the applicable Part D statute, 340B-priced

medicines will need to be "exclude[d]" from the inflation rebate calculation starting in 2026. 42 U.S.C. § 1395w-114b(b)(1)(B).

CMS, however, lacks enough information to do so correctly. Although manufacturers will face civil monetary penalties if they fail to timely pay the appropriate inflation rebate, *id.* § 1320f–6(c), CMS openly acknowledges that it has no plan to fulfill its statutory obligation to exclude 340B-priced medicines from its Part D inflation rebate claims. Medicare and Medicaid Programs, 89 Fed. Reg. 97,710, 98,292–93 (Dec. 9, 2024). Nor has CMS provided for any type of dispute-resolution process or other mechanism to help avoid unlawful duplication of price concessions for either Part B or Part D drugs. *See id.* at 98,248–49 (declining to conduct audits); *id.* at 98,306 (declining to provide "additional reporting"). The government has acknowledged that it may not bill inflation rebates to manufacturers on 340B-priced units. But the government currently has no way to identify those prescriptions under Part D—and neither will manufacturers.[11]

III. LILLY'S SOLUTION: THE CASH-REPLENISHMENT MODEL

As these problems worsened with no end in sight, Lilly carefully designed its own solution to the broken 340B program: a cash-replenishment model.[12] As the name suggests, Lilly's cash-replenishment model would substitute direct replenishments of *cash* to covered entities for the

[11] The IRA also raises concerns related to duplication between 340B pricing and price controls the IRA imposes on top-spend Medicare products, which the IRA forbids. *See* 42 U.S.C. §§ 1320f-2(a), (d). Despite the prohibition on such duplication, manufacturers currently lack enough information under the product-replenishment model to avoid it—as CMS has effectively acknowledged. *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Section 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* 230–32 (Oct. 2, 2024), https://tinyurl.com/3dahm5p9. Even so, CMS has left manufacturers alone to devise a solution because the IRA does not remove their "obligation to provide the 340B ceiling price to eligible entities." *Id.* at 232.

[12] Lilly adopted the phrase "cash replenishment" when describing its rebate model to highlight the fact that product replenishment is already a functional rebate.

current replenishments of *product*. Both models would share the essential feature of a rebate: an after-purchase true-up to a price at or below the statutory ceiling price. But the cash-replenishment model would accomplish that goal faster, more directly, and more transparently through data parity, thereby preserving—or even improving—covered entities' cash flow. *See, e.g.*, 3 Axis Advisors LLC, *The 340B Rebate Model: Cash Flow Analysis* 15 (Oct. 2021) (finding that switching to a cash-rebate model proposed by Lilly's vendor would "have positive cash flow implications" for covered entities) (Cash Flow Analysis), *available at* https://tinyurl.com/3zxzwcjk.

Under the cash-replenishment model, Lilly would make 340B prices available to all covered entities, for all its products, through one centralized system. AR 272. To do that, Lilly has contracted with Kalderos, a cutting-edge healthcare technology company. *Id.* Kalderos would use a platform called Truzo to provide cash replenishments to covered entities. *Id.* As they do now, those providers would first purchase medicine at the commercial price. *See id.* After identifying a transaction as eligible for the 340B price, a covered entity would then submit a claim via Truzo and receive a cash replenishment to effectuate the 340B price. AR 273, 278–82. Through Truzo, Lilly can provide those cash replenishments weekly, which may be even sooner than covered entities pay wholesalers the market price for the same unit. AR 272. Covered entities may also file claims for each dispense, meaning they no longer need wait to dispense a whole "package" of 340B-eligible prescriptions before being made whole. AR 296. And 340B status will be assigned only once, after a prescription has been filled and without any transfer to another prescription—re-establishing the critical link between the 340B-priced product and the 340B-eligible patient to ensure statutory compliance.

To get a cash replenishment, covered entities will need to provide only readily available, nonproprietary claims data regarding the dispense and purchase of the eligible Lilly product,

consistent with standard commercial business practices. AR 273. Lilly and Kalderos will then evaluate these claims data to either validate the claim and promptly issue a replenishment, or flag the claim if it falls into one of the narrow circumstances that warrants denial or further action, such as when a covered entity is not registered as a 340B-covered entity on HRSA's website. AR 299. To be clear, Lilly will not deny cash-replenishment claims as part of any effort to stamp out unlawful duplication; instead, it will simply use the data generated by the cash-replenishment model's claims process to dispute duplicate Medicaid and Medicare rebates with the relevant state agencies or with CMS. *Id.* Even when a submitted cash-replenishment claim is flagged, covered entities will have clear visibility into the underlying reason. *See id.* They will also be able to ask questions, raise concerns, and resubmit claims, if necessary, after making corrections. AR 282.

Lilly's cash-replenishment model, in other words, will operate in the open. Lilly and covered entities "will see the exact same data—on a claim-by-claim basis." AR 299. That system would replace the current set of secret algorithms, putting everyone on the same playing field.

Lilly's proposal is not just transparent and efficient; it is supported by longstanding practice within the 340B program. A cash-rebate model has successfully operated for decades for a type of covered entity called AIDS Drug Assistance Programs, or ADAPs. An ADAP is a state- or territory-sponsored payor that "provides . . . medications to low-income people with HIV." HRSA, *Part B: Aids Drug Assistance Program (ADAP)* (last updated Dec. 2024), *available at* https://tinyurl.com/yv2yf9sd. Under that rebate model, manufacturers give ADAPs cash, after an initial market-price purchase, in amounts that "equal or exceed the discount provided by the statutory ceiling price," just as Lilly is now proposing to do for all covered entities. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997) (Rebate Notice).

HRSA has never asserted that the ADAP cash-rebate arrangements required its preapproval. Nor has it ever objected to the lawfulness of those arrangements. Instead, after HRSA noticed the existing prevalence (and, presumably, the desirability) of these arrangements, the agency proposed to formally "recognize[ ]" such a model as a legitimate "method of accessing the 340B program." Rebate Notice, 62 Fed. Reg. at 45,824. Then, after a public-comment period, HRSA "recognize[d] an ADAP rebate option" as "consistent with the section 340B rebate program" without purporting to impose "in-depth implementation strategies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) (Rebate Final Notice). The agency simply recommended that ADAPs receiving cash rebates follow "[s]tandard business practices." *Id.*

By adopting a cash-replenishment model, Lilly hopes to bring the benefits created by ADAPs' cash-rebate arrangements to all 340B transactions. The cash-replenishment model's strengths respond to all the weaknesses of the product-replenishment model that have allowed the fraud, waste, and abuse detailed above to fester: The model would bring faster and more efficient payments. It would enable a process of validating eligibility for the 340B price. It would deliver cash directly to covered entities, rather than their third-party administrators. It would give manufacturers information they need to effectuate several important statutory objectives, including the prevention of duplication—especially in the Medicaid managed care context, where HRSA does not audit—the channeling of disputes into the audit and ADR processes, and the ability to implement IRA pricing correctly. And the model would do all that without costing covered entities anything, causing their valid claims for 340B rebates to be denied, or slowing their cash flow.

In sum, the cash-replenishment model would restore some transparency and integrity to a broken federal program that regulators have been unable—and unwilling—to fix themselves.

IV. HRSA'S RESPONSE: A NUCLEAR THREAT

In August 2024, Lilly notified HRSA of its proposed solution. AR 257. Lilly introduced the cash-replenishment model to the agency as "a highly desirable method of effectuating the 340B ceiling price" and requested a meeting with HRSA to discuss the model in more detail. AR 257–58. Lilly explained that it planned to announce its adoption of the cash-replenishment model by late September 2024. AR 258.

Other manufacturers made similar proposals around the same time. HRSA adopted a uniformly hostile stance towards those attempts. In an August 14, 2024 letter addressing a rebate proposal from Johnson & Johnson, HRSA announced: "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." AR 66.

Lilly and HRSA nevertheless met in early September to discuss Lilly's proposed cash-replenishment model. AR 272. A few days later, Lilly followed up with a letter providing further details and asking the agency to publicly endorse Lilly's efforts to fix the 340B system. *Id.* Lilly explained more about how the Truzo platform works, AR 272–73, pointed out that the 340B statute permits manufacturers to offer 340B prices using rebates, AR 274, and noted that the cash-replenishment model is the only way Lilly can navigate the interlocking maze of federal drug-pricing requirements, AR 274–75, and meaningfully participate in statutory audit and ADR processes, AR 276.

While Lilly's submission was pending before HRSA, the agency sent a second letter to Johnson & Johnson. *See* AR 202. That letter asserted the same purported preapproval power over Johnson & Johnson's plan, but this time, it contained a nuclear threat: If Johnson & Johnson implements a cash-replenishment model without HRSA's preapproval, the agency may terminate

the company's PPA—and with it, the availability of federal funds under Medicaid and Medicare Part B for Johnson & Johnson's products—and assess civil monetary penalties. AR 203. HRSA's preference is extraordinary—it would rather deprive Medicare and Medicaid patients of lifesaving medicines than restore integrity to the 340B program.

The implications for Lilly's proposal were obvious.[13] And like clockwork, HRSA shut down Lilly's cash-replenishment model the next day. In a letter dated September 18, 2024, the agency repeated what it had told Johnson & Johnson: offering 340B prices using cash replenishment would "require [its] approval" in advance. AR 292. The letter went on: "To date, the Secretary has not provided for such rebate as proposed by Lilly. 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 Lilly has proposed." *Id.* And HRSA did not provide any such approval, instead asking Lilly several further questions about the cash-replenishment model without indicating when, whether, or under which criteria the agency would consider purporting to "approve" the model's use. AR 292–94. HRSA did not cite any statutory provisions in support of its questions. *See id.*

Although disappointed by HRSA's decision to reject its cash-replenishment model, Lilly tried to persuade the agency by thoroughly answering its questions. AR 295–304. Lilly further

[13] HRSA's harsh threats came after covered entities urged the agency to "take immediate enforcement action" against manufacturers attempting to implement a cash rebate program. *See, e.g.*, American Hosp. Ass'n, *AHA Urges HRSA to Take Immediate Enforcement Action to Block J&J's Illegal Imposition of 340B Rebate Model* (Aug. 28, 2024), https://tinyurl.com/bdwewpav; *see also generally* AR 564–82 (covered entities' pre-decision communications to HRSA regarding Johnson & Johnson's cash-rebate proposal). The administrative record appears to contain various such letters from covered entities and other third parties, including many that post-date HRSA's decision to reject Lilly's cash-replenishment model. *See* AR 534, 537–57, 561–87, 609–15, 632–47. Given that HRSA afforded Lilly no process and offered no explanation for rejecting Lilly's cash-replenishment model, these letters have (and can have) no role to play in this challenge.

explained why the cash-replenishment model is the only way Lilly can address the problems that have riddled the 340B program and showed that the agency's expressed concerns are not rooted in the facts of Lilly's proposal. AR 295–301. Lilly also objected to HRSA's mistaken claims that the 340B statute requires Lilly to get the agency's preapproval before implementing a cash-replenishment model, and that HRSA has ad hoc authority to reject such a system. AR 295, 301. Lilly asked HRSA to notify Lilly if HRSA changed its mind, and noted that it understood HRSA's September 18 letter to have expressed the agency's final view. AR 301.

HRSA did not change its mind. Instead, it redoubled its efforts to cow manufacturers into obeying its commands. In a *third* letter to Johnson & Johnson, HRSA warned that, if it implements a rebate model, HRSA "*will* begin the process" of terminating its PPA and "*will*" refer Johnson & Johnson to HHS OIG. AR 214 (emphases added).

HRSA's threat applies to all manufacturers, as the agency later made even clearer. After a third manufacturer, Sanofi, told covered entities it would implement a rebate model, HRSA responded exactly as it had before. The agency sent Sanofi a letter asserting purported preapproval authority over Sanofi's rebate model, and it threatened to terminate Sanofi's PPA and impose civil monetary penalties if Sanofi does not comply. AR 424–25. HRSA also "publicly articulate[d]" its "unequivocal position," *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986), by publishing its threats to Johnson & Johnson and Sanofi prominently on its website. *See* HRSA, *Program Integrity* (last updated Jan. 2025), https://www.hrsa.gov/opa/program-integrity. The agency still trumpets its mistaken legal position online: "[I]mplementing a rebate proposal without Secretarial approval would violate Section 340B(a)(1) of the Public Health Service Act." HRSA, *340B Drug Pricing Program* (last updated Jan. 2025), https://www.hrsa.gov/opa; *see also*

Pharmaceutical Rsch. & Mfrs. of Am. v. HHS, 138 F. Supp. 3d 31, 43–44 (D.D.C. 2015) (noting that HRSA had announced supposed "statutory requirements" on its website) (quotation omitted).

Shortly after HRSA announced its position and threatened revocation of manufacturers' PPAs, several manufacturers sued the agency. Johnson & Johnson filed first. *Johnson & Johnson Health Care Sys. Inc. v. Becerra*, No. 24-CV-3188 (D.D.C. filed Nov. 12, 2024). Two days later, Kalderos, Lilly's technology vendor, moved for leave (later granted) to amend an existing complaint before this Court to assert claims against HRSA for stopping manufacturers from implementing rebate models, preventing those manufacturers from using its services. *Kalderos, Inc. v. United States*, No. 21-CV-2608 (D.D.C. filed Nov. 14, 2024), ECF No. 31. Lilly filed this suit the same day. ECF No. 1. Bristol Myers Squibb, Sanofi, and Novartis then filed their own suits, which have been assigned to this Court, and are proceeding on the same briefing schedule for dispositive motions. *See Bristol Myers Squibb Co. v. Johnson*, No. 24-CV-3337 (D.D.C. filed Nov. 26, 2024); *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-CV-3496 (D.D.C. filed Dec. 16, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 25-CV-117 (D.D.C. filed Jan. 15, 2025).

Lilly seeks three forms of relief. *First*, the Court should set aside HRSA's position, expressed in its September 18 letter to Lilly and elsewhere, that Lilly's decision to implement a cash-replenishment model is unlawful without HRSA's preapproval. *Second*, the Court should enjoin HRSA from enforcing its unlawful position regarding Lilly's cash-replenishment model. *Third*, the Court should declare that Lilly's cash-replenishment model is lawful and that Lilly may implement it. Absent that relief, the 340B program will remain broken.

LEGAL STANDARDS

The APA requires a reviewing 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)(A). Agency action must be set aside when it violates a

statute, *Orion Rsrvs. Ltd. P'ship v. Salazar*, 553 F.3d 697, 703 (D.C. Cir. 2009), or the agency's own regulations, *National Env't Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014). Agency action is arbitrary and capricious if it treats similar cases differently without adequate explanation. *See, e.g.*, *Lone Mountain Processing, Inc. v. Secretary of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013). So too if the agency defies logic, or if the agency's decision reflects a lack of reasoned decisionmaking. *See, e.g.*, *Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012).

Judicial review requires a "searching and careful" inquiry into the basis of the agency's decision. *Zotos Int'l, Inc. v. Young*, 830 F.2d 350, 352 (D.C. Cir. 1987). Courts "may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024). A reviewing court may defer to an agency's technical or scientific judgments to the extent they are consistent and reasonable, but courts do "not hear cases merely to rubber stamp agency actions." *Natural Res. Def. Council, Inc. v. Daley*, 209 F.3d 747, 755 (D.C. Cir. 2000). Instead, the APA requires courts to hold agency action unlawful unless they reach the "independent conclusion," *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995), that the action was "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

ARGUMENT

I. HRSA'S PURPORTED "PREAPPROVAL" REQUIREMENT IS UNLAWFUL.

A. The Statute Permits Manufacturers to Choose Between Rebates and Discounts Unless and Until HRSA Amends PPAs.

The 340B statute authorizes both rebates and discounts—and it does not preference one over the other, much less suggest a default (or exclusive) approach. The text simply requires manufacturers to agree with the Secretary to charge no more than the statutory ceiling price. *See* 42 U.S.C. § 256b(a)(1). Under that agreement, "the amount required to be paid" must account for

"any *rebate* or discount, as provided by the Secretary." *Id.* (emphasis added). To state the obvious, the statute's use of the disjunctive "or" matters because it connotes a choice between two valid alternatives. *See, e.g.*, *In re Espy*, 80 F.3d 501, 505 (D.C. Cir. 1996).

The statute continues to reference rebates throughout. The very next paragraph, for example, defines the statutory ceiling price, which is achieved by reducing the "average manufacturer price." *See* 42 U.S.C. § 256b(a)(2). That reduction is called the "rebate percentage." *Id.* Later, in the statute's prohibition on duplication, it again describes "discounts or rebates." *Id.* § 256b(a)(5)(A). And when an amendment to the statute sought to improve its functionality, one of the targeted changes was a "mechanism" for reporting "rebates and other discounts" and ensuring that "such discounts or rebates" resulted in the appropriate ceiling price. *See id.* § 256b(d)(1)(B)(iv). Such persistent textual parity between rebates and other forms of achieving the ceiling price belies any suggestion that the statute disfavors rebates. "Had Congress intended to" mandate the use of point-of-sale discounts, "it presumably would have done so expressly." *See Rusello v. United States*, 464 U.S. 16, 23 (1983). Instead, Congress directed HRSA to select pricing methods, if at all, in "an agreement with each manufacturer." *See* 42 U.S.C. § 256b(a)(1).

Lilly's PPA likewise makes no distinction between rebates and discounts. In fact, it does not mention discounts or rebates at all. It provides only that Lilly "shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." AR 47. Like the statute, Lilly's PPA does not specify a mechanism for doing so. *See id.* That is unsurprising because, in practice, PPAs have "simply incorporate[d] statutory obligations and record[ed] the manufacturers' agreement to abide by them." *Astra USA*, 563 U.S. at 118. Thus, neither operative legal authority establishes how manufacturers must effectuate 340B prices.

Because there is no constraint in either the statute or in Lilly's PPA, manufacturers may choose how to offer 340B prices. The absence of any statutory or contractual command about which method to use "implies that private parties may act freely." *Novartis Pharms. Corp.*, 102 F.4th at 460; *see also Sanofi*, 58 F.4th at 707 ("Legal duties do not spring from silence."). HRSA has nevertheless attempted to deny Lilly the freedom to implement the ceiling price using one of the methods expressly authorized by the statute, without pointing to any basis in Lilly's PPA.

B. HRSA Has No Ad Hoc "Pre-Approval" Authority.

Perhaps recognizing the 340B statute's permissiveness, HRSA has not quite claimed that the statute outright forbids manufacturers to use a cash-replenishment model. Its position instead is that manufacturers cannot do so without HRSA's *preapproval*. *See* AR 202–03, 424–25. HRSA apparently intends to exercise that supposed preapproval authority by ad-hoc and opaque adjudications, using undisclosed standards and weighing unknown factors, on whatever timeline it deems convenient. *See* AR 292–94 (purporting to withhold approval of Lilly's cash-replenishment model indefinitely while considering Lilly's responses to various questions). But the statute gives HRSA no such power—and HRSA accordingly has never exercised such authority over either the ADAP cash-rebate model or the product-replenishment model.

HRSA, for its part, has repeatedly emphasized that the 340B statute mentions a role for the HHS Secretary in choosing between rebates and discounts. *See, e.g.*, AR 202, 292. Yet only by ignoring the context in which that reference occurs can HRSA suggest that the agency may compel that selection by any method it likes. The statute directs the Secretary to "enter into an agreement with each manufacturer"—that is, a PPA—"*under which* the amount required to be paid" to the manufacturer does not exceed the ceiling price. 42 U.S.C. § 256b(a)(1) (emphasis added). Thus, it is the PPA "under which" the ceiling price must account for "any rebate or discount, as provided by the Secretary." *Id.* Put differently, any restrictions on the selection of either rebates or discount

must be contained in the PPA, which is deemed to have the force and effect of law with respect to its signatories. *See Astra USA*, 563 U.S. at 118.[14]

That conclusion also follows from "the broader context of the statute as a whole." *See Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). The phrase "as provided by the Secretary" occurs in the part of the statute devoted solely to establishing "requirements for agreement with Secretary." 42 U.S.C. § 256b(a) (capitalization altered). That statutory heading supplies a further "cue[ ] that Congress did not intend" to give HRSA unfettered discretion to employ case-by-case decisionmaking. *See Yates v. United States*, 574 U.S. 528, 540 (2015).

HRSA thus misconstrues the statute by pointing out that it "has not provided for such rebate [*sic*] as proposed by Lilly." AR 292. That is exactly backwards. Under the statute, any "providing" the Secretary intends to attempt must be done in the PPA. So what matters is that Lilly's PPA contains no limit on how it may charge a rate at or below the ceiling price—or, indeed, any instructions *whatsoever* for effectuating 340B prices. *See* AR 47.

The PPA's silence in this regard is no accident. HRSA could not, of course, amend Lilly's PPA to require any particular mechanism without articulating a reasoned basis for doing so. *See Doe v. Devine*, 703 F.2d 1319, 1326 (D.C. Cir. 1983) (applying the arbitrary-and-capricious standard to an agency's contracting behavior). And HRSA could not articulate any reasonable basis for enshrining the disastrous product-replenishment model as a legal requirement. Any attempt to do so would lay bare the myriad problems with that model and entangle the agency in a doomed attempt to "show that there are good reasons" for eschewing a fast, transparent, and fair solution to those problems. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). But what

[14] The extent to which HRSA *can* change PPAs through notice-and-comment rulemaking is not an issue presented in this case.

HRSA cannot do explicitly for lack of rational justification, it also may not do by silently withholding preapproval, manufacturer by manufacturer and case by case. To do that would be to impermissibly "exercise [a] power[ ] not delegated to it by Congress." *Ball, Ball & Brosamer, Inc. v. Reich*, 24 F.3d 1447, 1450 (D.C. Cir. 1994).

II. HRSA'S POSITION IS ARBITRARY AND CAPRICIOUS.

HRSA's rejection of Lilly's cash-replenishment model is independently unlawful because it is arbitrary and capricious. HRSA's failure to engage in reasoned decisionmaking could hardly be more flagrant—it failed to give Lilly *any* explanation for rejecting its cash-replenishment model. *See* AR 292–94. And the administrative record reveals no deliberation whatsoever. Despite receiving volumes of information explaining the benefits of cash replenishment and the failings of product replenishment, *e.g.*, AR 56–65, 72–200, 207–11, 234–46, 262–91, HRSA failed to consider those factors before rejecting Lilly's model, let alone provide a coherent rationale. This Court need go no further to vacate HRSA's decision. "[A] conclusion accompanied by '*no* explanation' is the epitome of 'arbitrary and capricious' decision-making." *Policy & Rsch., LLC v. HHS*, 313 F. Supp. 3d 62, 72 (D.D.C. 2018) (quoting *Communications & Control, Inc. v. FCC*, 374 F.3d 1329, 1335–36 (D.C. Cir. 2004)).

HRSA's caprice also manifests in at least four ways, each of which independently violates the APA and requires summary judgment for Lilly. *First*, the product-replenishment model and the cash-replenishment model are legally indistinguishable, so HRSA cannot reasonably treat them differently. *Second*, the cash-replenishment model already has succeeded with some covered entities, as HRSA has acknowledged, so the agency cannot prevent its implementation as to other covered entities without irrationally treating like cases differently. *Third*, HRSA's position fails to account for the significant policy reasons for adopting the cash-replenishment model. *Fourth*, HRSA's position frustrates the commonsense benefits the cash-replenishment model offers.

A. HRSA Has Offered No Cogent Reason for Treating Product Replenishment and Cash Replenishment Differently.

An agency's obligation to "treat like cases alike" is a "fundamental principle of administrative law." *Grayscale Invs., LLC v. SEC*, 82 F.4th 1239, 1242 (D.C. Cir. 2023). To reasonably treat two situations differently, an agency must "identify the features of" each situation "that point toward one [decision] or another" and "offer sensible distinctions between" them. *Colorado Interstate Gas Co. v. FERC*, 850 F.2d 769, 775 (D.C. Cir. 1988). Such distinctions must be rooted in "the relevant regulatory factors." *Grayscale Invs.*, 82 F.4th at 1245. Here, HRSA failed even to acknowledge its differing treatment of those models, much less offer any sensible distinctions between them.

Covered entities and their profit-seeking partners implemented the product-replenishment without any HRSA "preapproval" whatsoever.[15] Not only did HRSA never object to the product-replenishment model's emergence; but HRSA also acknowledged the model's prevalence as though the agency were no more than a neutral observer. *See, e.g.*, Contract Pharmacies Opinion at 6–8 & n.6. In claiming for the first time that manufacturers require the agency's blessing before using a method of charging covered entities, HRSA failed to "display awareness" that it had never before asserted such power. *See Encino Motorcars*, 579 U.S. at 221–22 (quotation omitted). That "failure to even acknowledge its past practice[,] . . . let alone to explain its reversal of course" is prototypically "arbitrary and capricious." *American Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017).

---

[15] *See* National Council for Prescription Drug Programs, *340B Information Exchange* 12 (July 2011) (describing the model as an accounting covered entities "may elect to utilize"), *available at* https://tinyurl.com/ycyc4hnd. Tellingly, Lilly's PPA does not instruct it to offer product replenishments to covered entities, AR 47, and HRSA has not pointed to language from the PPA to support its position, AR 295–301.

HRSA also has not attempted to explain why its preapproval is required for one model and not the other. Nor could it. There is no legal distinction between the two models; the 340B statute displays no preference between various possible mechanisms for effectuating the ceiling price. *Supra* at 26–27. The same is true of Lilly's PPA, which references neither mechanism and focuses simply on the outcome: whether the transaction results in the covered entity's paying for medicine "at or below the applicable ceiling price." AR 47.

HRSA has likewise failed to distinguish factually between the product-replenishment model and the cash-replenishment model. The core problem for the agency's position is that both models involve rebates. In the product-replenishment model, a covered entity must first pay the market price for covered outpatient medicines. *See* ECF No. 1-2 (Pedley Decl.) ¶¶ 3, 5 (explaining that entities do not receive "the 340B discount" until "after a drug is dispensed"). Only following the initial purchase at the market price may a covered entity replenish the dispensed product at the 340B-price. *Id.* In fact, covered entities' agents often do not even "*attempt* to discern" whether a particular medicine was eligible for the 340B price until long after dispensing it. *Novartis Pharms. Corp.*, 102 F.4th at 457. And only after many such transactions may a covered entity or its agent place an order for a full package to "replenish its section 340B purchases," effectuating the 340B price. *Id.*; *see also* ECF No. 1-2 (Pedley Decl.) ¶ 8 (noting that most covered outpatient medicines have a "pre-set package size" larger than the amount of a single dispense, and covered entities cannot replenish the product at the 340B price until they have dispensed the product enough times to amount to that package size).

The product-replenishment model thus provides covered entities the 340B price retrospectively, after the initial purchase at the market price. That is the essential feature of a rebate. *See, e.g.*, 42 C.F.R. § 1004.952(h)(4) ("[A] rebate 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*." (emphasis added)); *Elevance Health, Inc. v. Becerra*, 736 F. Supp. 3d 1, 5 (D.D.C. 2024) (noting that the Medicare Advantage statute describes money to be "return[ed]" to a plan "as a 'rebate' ") (quoting 42 U.S.C. § 1395w-23(a)(1)(E)); 42 U.S.C. §§ 1396r-8(b)(1)(A), (2)(A) (establishing a "rebate" to be paid "after the date of receipt" of information about medicine "for which payment *was* made" (emphasis added)); Oxford English Dictionary (defining "rebate" as a "deduction from a sum of money to be paid," especially "one given retrospectively"); Cambridge Dictionary (defining "rebate" as "money that is returned to you after you pay for goods or services"); Merriam-Webster Dictionary (defining "rebate" as "a *return* of part of a payment" (emphasis added)); Britannica Dictionary (defining "rebate" as "an amount of money that is paid *back* to you" (emphasis added)).

Because both the cash-replenishment model and the product-replenishment model rely on rebates, there are no "relevant regulatory factors" that allow HRSA to treat them differently. *See Grayscale Invs.*, 82 F.4th at 1245. The statute hints at only one possible distinction: whether the ceiling price is accomplished by a "rebate or discount." *See* 42 U.S.C. § 256b(a)(1). The two models are "functionally indistinguishable" on that ground, and HRSA has provided no reason to think otherwise, despite its attempt to give the models different legal status.[16] *See Independent Petrol. Ass'n of Am. v. Babbitt*, 92 F.3d 1248, 1260 (D.C. Cir. 1996). Thus, HRSA has flouted "the very meaning of the arbitrary and capricious standard." *Id.*

[16] HRSA cannot dispute that the product-replenishment model is a rebate model without also undermining its legality. As the agency has recognized, the product-replenishment model requires an initial purchase at the market price. *See* ECF No. 1-2 (Pedley Decl.) ¶ 5. It therefore cannot qualify as a "discount" mechanism of providing 340B prices. *See, e.g.*, *United States v. Shaw*, 106 F. Supp. 2d 103, 116 (D. Mass. 2000) ("A rebate is typically given after sale and discounts are effected at the time of sale."). If the product-replenishment model is neither a "rebate" nor a "discount," then it is not authorized by the statute. 42 U.S.C. § 256b(a)(1).

B. HRSA Has Offered No Cogent Reason for Treating ADAPs and Other Covered Entities Differently.

HRSA's attempt to quash Lilly's implementation of a cash-replenishment model also treats like cases differently in another critical way: it allows manufacturers to use cash replenishment for ADAPs, but not for other types of covered entities. That disparity has no rational basis, and HRSA has offered no justification for creating it.

ADAPs' participation in the 340B program via a cash-replenishment model is now a "long-standing practice." 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,313 (Aug. 28, 2015). For decades, ADAPs have been able "to access 340B prices on covered outpatient drugs" by receiving "a rebate after the purchase." *Id.* HRSA has not denounced this practice as unlawful, nor did it insist on its pre-approval; instead, it formally *endorsed* that cash-replenishment model *after the fact*.

Take it from HRSA itself: After considering public comments, the agency concluded that cash rebates for ADAPs are "consistent with the section 340B rebate program." Rebate Final Notice, 63 Fed. Reg. at 35,240. Such a model does not constitute an overcharge, HRSA explained, so long as the rebates "provide at least the minimum statutory discount and do not contain requirements inconsistent with section 340B and published program guidelines." *Id.* Nor do cash rebates offend the statutory text; according to HRSA, "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)." Rebate Notice, 62 Fed. Reg. at 45,824.

Despite HRSA's recognition of a cash-replenishment model for ADAPs, however, it did not purport to *pre*approve that model. HRSA was clear: it "only recognize[d]" that a preexisting "ADAP rebate option" was lawful—it did not create something new. Rebate Final Notice, 63 Fed.

Reg. at 35,240; *see also id.* ("ADAPs may *continue* to provide utilization data according to terms of *existing* agreements if so desired." (emphasis added)). HRSA even described preexisting methods of implementing cash rebates as "models to be emulated," and the agency elected not to "provide in-depth implementation strategies." *Id.* Nor has Lilly's PPA ever contained any instruction or authorization to use a cash-replenishment model for ADAPs.

Those statements directly contradict HRSA's more recent comments on the same subject. In its second letter to Johnson & Johnson, HRSA hinted that a cash-replenishment model could violate the statute because the up-front market price may temporarily exceed the statutory ceiling price. AR 203. That claim cannot be squared with HRSA's longstanding stance that a post-purchase rebate may be paid to ADAPs "as a method" of furnishing "the 340B discount provided by the statutory ceiling price." Final Rebate Notice, 63 Fed. Reg. at 35,242. Likewise, in its recent letters to Lilly and other manufacturers, the agency said nothing of "recognizing" the payment of cash rebates, insisting instead upon its advance "approval of a rebate model." AR 203, 295, 425.

HRSA had it right the first time. Worse, HRSA again failed to acknowledge or explain its about-face. *None* of HRSA's recent letters mentions ADAPs at all, even though Lilly and other manufacturers explained in their submissions to the agency that ADAPs' use of a cash-replenishment model implicates the same legal questions. *See* AR 202–03, 292–94, 424–25. That failure is fatal to HRSA's decision. "[A]n agency's unexplained departure from precedent is arbitrary and capricious," *ABM Onsite Servs. W., Inc. v. NLRB*, 849 F.3d 1137, 1142 (D.C. Cir. 2017), and the circuit has "never approved an agency's decision to completely ignore relevant precedent," *Jicarilla Apache Nation v. U.S. Dep't of the Interior*, 613 F.3d 1112, 1120 (D.C. Cir. 2010).

Given HRSA's silence, it goes without saying that the agency has not tried to justify its disparate treatment of ADAPs and other covered entities by identifying special features of ADAPs

that warrant a cash-replenishment model. At most, HRSA once alluded to that possibility by stating that it agreed with a commenter's assertion that ADAPs have "unique needs" that justify a rebate model. Rebate Final Notice, 63 Fed. Reg. at 35,241. But neither the commenter nor HRSA explained what those supposed unique needs *are*, much less how any such needs justify foreclosing an admittedly lawful model as to other covered entities. HRSA should not be heard to attempt such distinctions now, because "*post hoc* rationalization . . . cannot support [agency] action." *Republic Airline Inc. v. DOT*, 669 F.3d 296, 302 (D.C. Cir. 2012).

In any event, ADAPs are not meaningfully different from other covered entities. HRSA's most recent guidance manual to ADAPs recognizes as much. As the manual explains, ADAPs "submit claims to drug manufacturers for rebates on medications that were purchased through a retail pharmacy network at a price higher than the 340B price." HIV/AIDS Bureau, *AIDS Drug Assistance Program (ADAP) Manual* 42 (June 2023) (ADAP Manual), *available at* https://tinyurl.com/2pcx49t4. But that is exactly how other entities use the *product*-replenishment model: They purchase drugs at the market price and later reconcile that purchase with the 340B ceiling price. ECF No. 1-2 (Pedley Decl.) ¶¶ 3, 5. Similarly, HRSA noted that ADAPs implement the cash-replenishment model through "formal agreements with a network of retail pharmacies." ADAP Manual at 42. Again, that system mimics the contract-pharmacy and third-party-administrator arrangements utilized by covered entities under the product-replenishment model. *See* ECF No. 1-2 (Pedley Decl.) ¶ 4.

Perhaps HRSA's most significant concession regarding ADAPs' use of the cash-replenishment model is that the model works. HRSA has recommended to ADAPs that they pursue 340B rebates using "standard business practices"—conditions inherent in rebate models that HRSA thereby implicitly has recognized as lawful. *See* Rebate Final Notice, 63 Fed. Reg. at 35,239–41.

HRSA has encouraged ADAPs to provide "detailed and accurate . . . initial claim data," *id.* at 35,241, and to "engage in a thorough cash flow analysis," ADAP Manual at 43. By doing so, the agency explained, ADAPs can use rebates to "ensure a continuous cash flow" and "prevent the potential for cash shortages and program service delivery disruption." *Id.* That guidance dispels HRSA's purported concern, expressed to Johnson & Johnson, that a cash-replenishment model may cause covered entities to struggle with "higher up-front costs" for covered drugs. AR 203. HRSA did not attempt to explain why covered entities could not simply follow the same standard business practices that have worked for ADAPs and myriad other entities in the healthcare system—that is what makes them "standard."

That reasoning gap is attributable to HRSA's utter neglect to compare ADAPs and other covered entities, despite the obvious precedent ADAPs provide for the questions before the agency. That failure caused HRSA to impose different rules on indistinguishable situations. That was unlawful. *Dillmon v. National Transp. Safety Bd.*, 588 F.3d 1085, 1091 (D.C. Cir. 2009).

C. HRSA Neither Acknowledged nor Addressed the Benefits of the Cash-Replenishment Model.

Of the several ways the cash-replenishment model would help restore integrity to the 340B program, two merit particular consideration: (1) the cash-replenishment model would help prevent duplicate discounts and rebates—facilitating compliance with important statutory prohibitions the product-replenishment model has thwarted; and (2) the cash-replenishment model would enable Lilly to meaningfully participate in the statutory audit and ADR processes. HRSA's caprice is heightened by its disregard of both factors.

An agency acts unlawfully if it "entirely fail[s] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An aspect of the problem is important "by definition" if Congress mandated its

consideration by including it in the statute. *See Public Citizen v. Federal Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004). And an agency may not simply purport to have considered all important aspects of the problem; it must "provide more than 'conclusory statements' to prove [it] 'considered the relevant priorities.' " *Stewart v. Azar*, 313 F. Supp. 3d 237, 259 (D.D.C. 2018) (quoting *Getty v. Federal Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986)) (alterations adopted).

1. The Cash-Replenishment Model Would Curb Unlawful Duplication.

One of the 340B program's basic objectives is to prevent duplicate price concessions. The statute's first "requirement[ ] for covered entities" is to "prohibit[ ]" them from requesting "duplicate discounts or rebates" through the Medicaid Drug Rebate Program. 42 U.S.C. § 256b(a)(5) (capitalization altered). Congress also prohibited duplication with respect to the IRA's Medicare inflation rebates, *see id.* §§ 1395w-3a(*i*)(3)(B)(ii)(I), 1395w-114b(b)(1)(B), and price controls, *id.* § 1320f-2(d).

The product-replenishment model places that objective behind an insurmountable obstacle. Its critical defect is that a prescription cannot be identified as 340B-eligible until long after medicine has been dispensed, and then its status as 340B-eligible may be transferred to other packages, further obfuscating the audit trail. *See* ECF No. 1-2 (Pedley Decl.) ¶¶ 5–11. Thus, a manufacturer cannot know that a sale poses a risk of duplication until it is too late to prevent it, assuming the daisy chain can even be followed through to the end.

Lilly's cash-replenishment model would surmount that obstacle with swift transparency. The model would align covered entities' incentives with Lilly's incentives because each would have good reason to identify a single prescription as 340B-eligible as quickly as possible—providers to receive the 340B price, and Lilly to prevent duplication. The model would also give Lilly the tools needed to achieve the statutory scheme's anti-duplication objective. The providers'

readily available claims data will enable Lilly to match those data with claims for rebates under the Medicaid Drug Rebate Program and with claims subject to inflation rebates. Lilly can then help ensure that all stakeholders receive the price they are supposed to receive, when they are supposed to receive it.

The agency's failure to consider those benefits is especially frustrating given HHS's documented failure to solve 340B duplication problems itself. *See supra* at 14–17. And for Medicare Part D inflation rebates, manufacturers have only CMS's hollow assurance that it "plan[s] to explore" a solution to duplication problems someday. Medicare and Medicaid Programs, 89 Fed. Reg. at 98,292–93.

Thus, HHS has effectively thrown up its hands, leaving manufacturers to come up with some way to realize the statutory prohibitions on duplicative price concessions. But now that Lilly has done so, HRSA has tried to foreclose that solution, without even acknowledging the impossible bind in which HHS agencies' abdications have put manufacturers.

2. The Cash-Replenishment Model Would Make Statutory Guardrails Meaningful.

The story is similar as to the 340B statute's audit and ADR procedures. Here, though, the problem is apparent on the face of the applicable statute and regulations. The product-replenishment model denies Lilly access to information, locking Lilly out of the statute's mechanisms for addressing the very problems HHS has refused to help solve.

If Lilly suspects a covered entity has unlawfully duplicated price concessions or diverted 340B-priced medicines, the first step under HRSA regulations is to establish "reasonable cause" for an audit. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). In other words, Lilly needs some evidence that a covered entity caused a suspected violation. Under the product-replenishment model, however, Lilly often lacks enough

information to do so because covered entities (conveniently) need not ever provide enough information for Lilly to get that far.

As a result, Lilly's efforts to ensure compliance often fail to launch. Without "sufficient facts and evidence in support" of "reasonable cause," there can be no audit. 61 Fed. Reg. at 65,410. Without an audit, there can be no ADR claim against a covered entity. 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.21(a)(2). Without the ability to initiate audits or, if necessary, to bring ADR claims, the 340B statute's "provision of remedies and enforcement" for its anti-duplication and anti-diversion requirements becomes a dead letter. *Contra* 42 U.S.C. § 256b(d)(3)(A).

As if that consequence were not enough, the product-replenishment model's opacity also prevents Lilly from full participation in ADR proceedings initiated by others. When a covered entity brings a claim that it has been overcharged, HRSA regulations allow it to request documents or other information from a manufacturer. 42 C.F.R. § 10.22(a). A manufacturer has only 20 business days to respond, *id.* § 10.22(b), and it "is responsible for obtaining relevant information or documents" from third parties, which may be outside its control, *id.* § 10.22(c). Thus, manufacturers operate from a doubly disadvantaged position regarding the ADR process. They are denied information they need to pursue their own claims, and they are saddled with an obligation to get information that is not necessarily within their grasp.

Again, the cash-replenishment model's transparency would bridge those gaps. By timely centralizing claims data and confirming the bases for covered entities' requests for the 340B price, the cash-replenishment model enables all parties to vindicate their rights by using the statute's audit and ADR processes effectively. That result would not only be fairer by virtue of ensuring that price concessions are correctly paid; it would also accomplish Congress's design by

effectuating its repeated prohibitions against duplication and making the statutory dispute-resolution mechanisms meaningful.[17]

As the statutes' repeated emphases on anti-duplication and dispute resolution make clear, *see* 42 U.S.C. § 256b(a)(5); *id.* § 256b(d)(3)(A); *id.* § 1395w-114b(b)(1)(B), the proper functioning of those processes is a statutorily mandated "salient factor" that HRSA had to consider. *See Humane Soc'y of the U.S. v. Zinke*, 865 F.3d 585, 607 (D.C. Cir. 2017). Yet HRSA, again, made no mention of this in its letters purporting to stop manufacturers from implementing programs that would have furthered those statutory objectives. *See* AR 202–03, 292–94, 424–25. Because HRSA has refused to acknowledge these issues, it has fallen far short of "prov[ing]" that it has "considered the relevant priorities." *Stewart*, 313 F. Supp. 3d at 259 (quotation omitted). Likewise, HRSA has failed to "respond meaningfully" to Lilly's legitimate objections on these grounds. *See PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (quotation omitted); *see also* AR 295, 298 (Lilly's raising to HRSA the anti-duplication, audit, and ADR rationales for the cash-replenishment model). For both reasons, HRSA's decision is arbitrary and capricious.

D. HRSA's Position Defies Common Sense.

Finally, HRSA's position simply runs counter to common sense. The agency has attempted to thwart a system with undeniable policy benefits—a system that would fix several of the 340B

[17] The cash-replenishment model would also eliminate the current practice of commingling 340B and non-340B inventory. The accounting fiction in which units purchased at a 340B price are treated as "neutral inventory" that can "be dispensed to any subsequent patient," *see* ECF No. 1-2 (Pedley Decl.) ¶ 11; *see also* AR 300, flagrantly violates the 340B statute's direction not to "resell or otherwise transfer [a] drug" purchased at the 340B price "to a person who is not a [340B] patient." *See* 42 U.S.C. § 256b(a)(5)(B). The cash-replenishment model would end that shell game because medicine would clearly and permanently be identified as either subject to 340B compliance obligations, or not. That transparency will enable all parties—including HRSA—to fulfill their statutory responsibilities.

program's most serious shortcomings, benefiting all stakeholders. The APA does not permit an agency to spurn good governance, particularly without an explanation.

Agencies may not act "in defiance of common sense to reach an illogical result." *Evergreen Shipping Agency (Am.) Corp. v. Federal Mar. Comm'n*, 106 F.4th 1113, 1117–18 (D.C. Cir. 2024). Agencies' decisionmaking processes must therefore be rational and discernable, *Tripoli Rocketry Ass'n v. ATF*, 437 F.3d 75, 77 (D.C. Cir. 2006), and an agency cannot "ignore an obvious fact," *Grayscale Invs.*, 82 F.4th at 1248 (quotation omitted and alteration adopted). Nor should an agency act for "reasons not mentioned in the regulations." *See Menkes v. DHS*, 486 F.3d 1307, 1313 (D.C. Cir. 2007).

HRSA violated those principles by closing its eyes to the various programmatic benefits the cash-replenishment model offers over the product-replenishment model—including for covered entities. The cash-replenishment model will help all stakeholders by using state-of-the art technology to generate and share data that will enable informed decision-making. It will streamline the cash flow by delivering money directly to covered entities, rather than third-party administrators and contract pharmacies. And Lilly expects to be able to pay rebates to covered entities weekly. AR 296. That means covered entities will often receive rebates *before* they must pay wholesalers for a purchase, likely improving their cash flow compared to the current full-package requirement. AR 297; *see also* Cash Flow Analysis, *supra*, at 15–16 (identifying benefits to covered entities including faster receipt of revenue, "lower inventory carrying costs," and pricing advantages). In short, the cash-replenishment model is more compliant, more efficient, more transparent, and faster than the product-replenishment model.

HRSA did not identify any harms that could offset those benefits. Once again, it simply did not evaluate those benefits at all. *See* AR 202–03, 292–94, 424–25. Instead, HRSA has offered

a non sequitur: It complained to Johnson & Johnson that the cash-replenishment model is supposedly unlawful because it is "not voluntary for covered entities," in contrast to the product-replenishment model, which covered entities created on their own authority. AR 203. But neither the statute nor HRSA's regulations says anything about covered entities getting to choose exactly how they receive the 340B ceiling price. *See* 42 U.S.C. § 256b(a)(1) (providing for either "rebate[s] or discount[s]"). And by that logic, HRSA should not permit use of the product-replenishment model, which is "not voluntary" for manufacturers. HRSA may not privilege that biased, made-up justification over the many statute- and regulation-based justifications for the cash-replenishment model—especially without bothering to address the latter. *See Menkes*, 486 F.3d at 1313; *Grayscale Invs.*, 82 F.4th at 1248.

Nor would the cash-replenishment model create offsetting harms that HRSA neglected to mention. Critically, Lilly would not use the cash-replenishment model to deny any covered entities access to 340B prices. AR 299. Lilly would instead use the claims data generated by the cash-replenishment model to work with state Medicaid programs to resolve duplicate Medicaid Drug Rebate Program rebates, *id.*; to participate in CMS's process for correcting erroneous IRA inflation-rebate calculations, *see* Medicare and Medicaid Programs, 89 Fed. Reg. at 98,598; and, as needed, to initiate audits and ADR proceedings as provided by the 340B statute, *see id.* § 256b(d)(3)(A). Put differently, the cash-replenishment model would strengthen existing legal processes without posing new risks to covered entities or imposing further costs on them. It is hard to imagine a more illogical result than rejecting those improvements in favor of a status quo that is slow, bloated, opaque, unfair, and honeycombed with fraud, waste and abuse. HRSA's decision—and its lack of explanation for that decision—thus violate the APA and should be vacated. *See, e.g.*, *Evergreen Shipping Agency*, 106 F.4th at 1118.

CONCLUSION

For the foregoing reasons, Lilly's motion for summary judgment should be granted.

Dated: February 3, 2025

Respectfully submitted,

/s/ Catherine E. Stetson
John C. O'Quinn
Matthew S. Owen
Megan McGlynn
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, D.C. 20004
(202) 389-5000
john.oquinn@kirkland.com
matt.owen@kirkland.com
megan.mcglynn@kirkland.com

Catherine E. Stetson (D.C. Bar No. 453221)
Jacob T. Young (D.C. Bar No. 90014334)
HOGAN LOVELLS US LLP
555 Thirteenth Street N.W.
Washington, D.C. 20004
(202) 637-5600
cate.stetson@hoganlovells.com
jake.young@hoganlovells.com

Attorneys for Plaintiffs