EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC.,

Plaintiff,

v.

DOROTHY FINK, *et al.*,

Defendants.

Case No. 1:24-cv-03188-RC

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTERESTS OF *AMICI CURIAE*[1]

Amicus curiae Pharmaceutical Research and Manufacturers of America ("PhRMA") is an association that represents the country's leading innovative biopharmaceutical research companies and manufacturers. PhRMA devotes its resources to developing medicines that enable patients to live longer and healthier lives. PhRMA's members participate in the 340B Drug Pricing Program ("340B"), and face direct harm from duplicate discounting (where a manufacturer is forced to provide 340B pricing and additional rebates under Medicaid), as well as the improper transfer and sale of 340B drugs.

Amicus curiae Biotechnology Innovation Organization ("BIO") is the world's largest biotechnology trade organization, representing more than 1,000 member companies and research organizations who research and develop biotechnological products, including lifesaving medicines. BIO's members participate in 340B and, like PhRMA's members, suffer harm when the boundaries Congress placed on 340B are ignored.

Amici's members share a commitment to innovation and the development of new drugs and products, which often requires a decade or more of research as well millions or even billions of dollars in investment. *Amici*'s members also share a commitment to the long-term sustainability of 340B. They believe that honoring the limits Congress chose to impose on 340B ensures fidelity to Congress's vision for the Program, while also safeguarding the delicate balance essential to promote further innovation and research.

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[1] No party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the preparation or submission of this brief; and no person other than *amici curiae*, their members, and their counsel contributed money intended to fund the preparation or submission of this brief. Johnson & Johnson is a member of PhRMA and BIO but did not directly contribute financially to the preparation or submission of this brief.

INTRODUCTION

Congress intended the 340B Drug Pricing Program to be limited in scope, but 340B has now ballooned into the second largest federal drug program. In 2023, for example, the commercial value of 340B drugs purchased reached $124 *billion*, representing a 23.4% growth in a single year.[2] Unfortunately, much of this growth is the product of covered healthcare entities that receive discounted drugs failing to follow the limits established by Congress: Specifically, although Congress prohibited covered healthcare entities from seeking rebates under Medicaid for drugs already subject to 340B pricing (called "duplicate discounting") or selling or transferring 340B drugs to anyone other than their patients (known as "diversion"), 42 U.S.C. § 256b(a)(5), those statutory violations now occur regularly. In an effort to curb duplicate discounting, plaintiff Johnson & Johnson Health Care Systems Inc. ("J&J") sought to implement a manufacturer rebate model as its mechanism for providing the 340B price. That model, which requires submission of commercially standard claims data, is a common sense and straightforward mechanism designed to help J&J determine which prescriptions are genuinely 340B-eligible. And it will ensure that covered healthcare entities receive 340B benefits while allowing J&J to detect instances of fraud, abuse, and mistake.

The U.S. Health Resources and Services Administration's ("HRSA") rejection of that model impermissibly ignores the well-documented and pervasive 340B abuses that are occurring, and the significant ongoing and illegal harm to manufacturers. To start, the D.C. Circuit has already made clear that manufacturers may require healthcare entities covered by the federal Program ("covered entities") to provide "claims data" related to 340B prescriptions. *See Novartis*

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

Pharms. Corp. v. Johnson, 102 F.4th 452, 458, 463 (D.C. Cir. 2024) (holding that claims data requirement was permissible where manufacturer sought to impose it to "police diversion and duplicate discounts" and that the requirement aligned with agency guidance); *see also Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *8 (D.D.C. Nov. 5, 2021) ("For its part, United Therapeutics convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and [administrative dispute resolution] procedures that Congress established for manufacturers in Section 340B."), *aff'd*, *Novartis*, 102 F.4th 452. And J&J's rebate model is entirely consistent with the D.C. Circuit's interpretation of manufacturers' obligations under 340B. Such rebate models are common in the industry generally, including in federal drug programs, and provide an efficient means to deliver benefits through a complex distribution system.

HRSA rejected the rebate model with no substantive discussion on 340B abuses. The 340B statute itself provides that preventing "duplicate discounts" and other statutory violations are critical aspects of the 340B Program. *See* 42 U.S.C. § 256b(a)(5)(A), (B); *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, No. 2:24-cv-00298, 2024 WL 5147643, at *6 (S.D. W. Va. Dec. 17, 2024) (noting 340B's "twin federal purposes—providing discounts to covered entities only *and* prohibiting fraud through duplicate discounts"). Multiple government audits have confirmed the problems that J&J's model addresses. *See infra* at 15-16. Indeed, HRSA cannot deny that the Program is rife with duplicate discounting and other statutory violations: It correctly recognized in 2015, in proposed but since-withdrawn guidance, that the "[r]isk of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements" and that "not all covered entities have sufficient mechanisms in place to ensure their contract pharmacies' compliance with all 340B Program requirements." 80 Fed. Reg.

52,300, 52,309, 52,311 (Aug. 28, 2015). HRSA has reached this conclusion over and over in the years since in its covered entity audit reports. *See infra* at 16 (providing links to findings for limited audits of covered entities conducted).

J&J's efforts to remedy these unaddressed problems, via the rebate model, directly further the statute's aims by allowing J&J to detect duplicate discounting and other statutory violations in a timely fashion when claims are submitted. And they further facilitate J&J's access to the federal enforcement mechanisms explicitly provided in the statute.

As set forth below, HRSA's summary rejection of the rebate model violates the law in multiple respects. An agency cannot just wish significant problems away—it must grapple with them. *See infra* at 10. *Amici* respectfully urge the Court to grant J&J's motion for summary judgment.

ARGUMENT

As PhRMA and BIO have previously explained to HRSA in letters on this very issue, manufacturer rebate models, of which J&J's rebate model is one example, ensure that covered entities receive expedient access to 340B benefits while simultaneously safeguarding Program integrity.

The rebate model complies fully with 340B. The D.C. Circuit has already held that a manufacturer complies with the 340B statute so long as its offer to provide 340B pricing under 42 U.S.C. § 256b(a)(1) is "*bona fide.*" In making that determination, the Court emphasized that normal commercial conditions, including manufacturer requirements for covered entities to submit claims data, are permissible and that 340B expressly preserved manufacturers' ability to impose them. *See infra* at 5-7. Neither aspect of J&J's rebate model—the claims data requirement already blessed in *Novartis* or the use of rebates to provide a discount—renders a manufacturer's offer not *bona fide*. Indeed, rebate models are used across a broad swath of federal healthcare programs,

including 340B itself. The rebate model also buttresses Program integrity, by addressing instances of fraud and mistake. HRSA forthrightly acknowledged in 2015, in a (since-withdrawn) proposed omnibus guidance document that duplicate discounting, as well as other statutory violations by covered entities, plagued the Program. 80 Fed. Reg. at 52,309, 52,311. And multiple federal audits have identified the types of 340B violations that J&J's model will address. *See infra* at 15-16; *see also Novartis*, 102 F.4th at 457-58 (noting incentive for covered entities and their contract pharmacies "to catalog as many prescriptions as possible as eligible for the discount").

But rather than address what it "confesse[d]" is a problem, HRSA "plant[ed] its head right in the sand." *Snohomish Cnty. v. Surface Transp. Bd.*, 954 F.3d 290, 306 (D.C. Cir. 2020) (Millett, J., concurring) ("Reasoned decisionmaking under the Administrative Procedure Act requires more than just wishing serious problems away."). The adoption of a manufacturer rebate model, which is designed to address the issues recognized by HRSA, furthers the purposes of the statute: It provides the Program's circumscribed benefit to enumerated entities while ensuring the Program's limits are maintained.

I. A REBATE MODEL IS PERMISSIBLE UNDER *NOVARTIS* AND CONSISTENT WITH INDUSTRY PRACTICE AND OTHER HEALTHCARE PROGRAMS

HRSA's rejection of the rebate model is surprising given the D.C. Circuit's decision in *Novartis*, the leading appellate case addressing manufacturers' obligations under the 340B Program and a decision that HRSA elected not to further appeal. The Court interpreted the key statutory provision at 42 U.S.C. § 256b(a)(1), which simply "requires manufacturers to 'offer each covered entity covered outpatient drugs for purchase' at or below a specified ceiling 'price.'" *Novartis*, 102 F.4th at 460 (citation omitted). Applying the plain language of the statute and looking to "background contract principles" inherent in that language, the Court concluded that a permissible 340B "offer" will "contain both price and non-price terms." *Id.* The only term of that

offer mandated by Congress was the "price" term. *Id.* at 460-61. Congress's silence on non-price terms expressly "preserve[d]—rather than abrogate[d]—the ability" of manufacturers to impose other terms. *Id.* at 460; *see also Arizona v. United States*, 567 U.S. 387, 403-07 (2012); *TelTech Systems, Inc. v. Bryant*, 702 F.3d 232, 238 (5th Cir. 2012). Because "statutory silence" about other terms "implies that private parties may act freely," manufacturers *may* impose other conditions, so long as their offers remain "bona fide." *Novartis*, 102 F.4th at 460, 462.

Importantly, the D.C. Circuit specifically addressed whether a manufacturer's policy requiring the submission of claims data to provide drugs at the 340B price was permissible under the federal statute. *Id.* at 463-64. It concluded that such a restriction was lawful. *Id.* at 463. As it noted, prior guidance from HRSA had stated that "drug manufacturers may require 'standard information' from covered entities" and that "covered entities must 'maintain auditable records sufficient to demonstrate continued compliance with 340B requirements." *Id.* And "nobody would say that this policy undermines the bona fides of any 'offer'" under the "shall offer" requirement. *Id.* The Court thus concluded that a claims data requirement complied with the statute. *Id.* That policy, as this Court recognized, also helped manufacturers access 340B's enforcement mechanisms where violations had occurred. *See Novartis*, 2021 WL 5161783, at *8 ("For its part, United Therapeutics convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and [administrative dispute resolution] procedures that Congress established for manufacturers in Section 340B."). In short, the D.C. Circuit has already blessed a key component of the rebate model.

The only remaining question, then, is whether J&J can implement its obligation to offer the 340B price through a rebate, as opposed to a prospective discount. As J&J shows, ECF No. 18-1 at 26-31, nothing in the statute forecloses it from doing so. In fact, the statute expressly

contemplates J&J's chosen path. *Id.*at 26-27, 36-39. And it follows from *Novartis* itself that a rebate model is entirely appropriate. Like the conditions at issue in *Novartis*, 102 F.4th at 463-64, a cash rebate mechanism does not affect the ultimate price paid by the covered entity for a 340B drug and is expressly permitted under 340B. That condition, as *Novartis* made clear, is thus valid so long as J&J's 340B offer remains "bona fide." *Id.* at 460, 462. Indeed, so long as manufacturers satisfy that obligation, 340B "preserves" their ability to impose other conditions, including conditions designed to effectuate the Program's limitations. *Id.*

Here, as J&J explained in its summary judgment brief, ECF No. 18-1 at 36-39, 42-45, the bona fide offer requirement is met: Covered entities remain free to purchase the same amount of 340B drugs as under the product replenishment model currently in use and will receive cash payment directly for those drugs. And like in *Novartis*, HRSA provided no analysis—much less evidence—that the rebate condition renders the 340B offer illusory, as it would be required to in order to forbid rebates.

HRSA did not do so for good reason, given that retrospective payments using rebates and refunds are a common mechanism of providing discounted pricing, including across a broad number of federal healthcare programs and 340B itself. *Cf. Novartis*, 102 F.4th at 462 ("[A]ssessing the bona fides of an offer perhaps can take into account the historical context of section 340B[.]"). In the general commercial context, manufacturers routinely provide discounted pricing via post-sale rebates.[3] Manufacturer rebate mechanisms are ubiquitous where there are

[3] *See, e.g.*, House Comm. on Oversight & Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 51, available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf (noting that pharmacy benefit managers, for example, often require high rebates post-sales from drug manufacturers).

eligibility requirements for a discount to apply, as with rebates to payors that have reimbursed pharmacies for products dispensed to their insured populations.

In the 340B context as well, for almost 30 years, HRSA has permitted the use of the rebate model for AIDS Drug Assistance Programs ("ADAP") covered entities. 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997) (stating that "Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)"). Under that model, ADAP covered entities purchase drugs and manufacturers then provide retrospective rebates in amounts that "equal or exceed the discount provided by the statutory ceiling price." *Id.* As HRSA recognized as to ADAP covered entities, rebate models are "consistent with the section 340B rebate program." 63 Fed. Reg. 35,239, 35,240 (June 29, 1998). That permission accords with the legislative history, which states the 340B statute "*does not specify* whether 'covered entities' would receive these favorable prices through a point-of-purchase discount, *through a manufacturer rebate*, or through some other mechanism." H.R. Rep. No. 102-384, pt. 2, at 16 (1992) (emphases added).

That the 340B statute contemplates rebates is no surprise: Rebates and refunds are used in numerous other federal drug programs, too. For example, under the TRICARE Retail Refund Program, manufacturers issue retrospective refunds for drugs dispensed to "eligible covered beneficiaries" of military members. 10 U.S.C. § 1074g(f). Implementing regulations for that program state that procedures for manufacturer refunds "shall provide the manufacturer at least *70 days* from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due." 32 C.F.R. § 199.21(q)(3)(ii) (emphasis added).

Similarly, under the Coverage Gap Discount Program (Medicare Part D) and the program replacing it, the Manufacturer Discount Program (Medicare Part D), manufacturers pay retrospective rebates "within 38 calendar days of receipt of invoice" for qualifying prescriptions. 42 U.S.C. §§ 1395w-114a, 1395w-114c; 42 C.F.R. § 423.2315; Centers for Medicare and Medicaid Services, Revised Medicare Part D Manufacturer Discount Program Final Guidance (Dec. 20, 2024) ("Medicare Discount Final Guidance")[4]. In particular, the Centers for Medicare and Medicaid Services ("CMS") has recognized the value of providing claims level data in the context of the Manufacturer Discount Program. In response to comments by manufacturers, CMS stated that it "will provide additional detail on manufacturer invoices . . . including new data elements and certain data elements that are currently available only on audit under the Coverage Gap Discount Program." Medicare Discount Final Guidance at 39. CMS stated this additional information would "increase transparency and help manufacturers better understand the basis and accuracy of the reported discounts." *Id.* Upon receiving invoices with that claims data information, manufacturers then provide retrospective payments within 38 calendar days from receipt of the invoice. *Id.* at 40.

Numerous other examples include the following:

- Medicare Part D voluntary manufacturer rebates. 42 U.S.C. § 1395w-102(d)(1)(B).
- Medicare Part B and Part D inflation rebates. *Id.* §§ 1395w-3a(i)(1)(B), 1395w-114b(a)(2).
- Medicare Part B discarded drug refunds. *Id.* § 1395w-3a(h)(2).
- Medicare Drug Negotiation Program. *Id.* § 1320f-2(a)(3); 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

[4] Available at https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf.

Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (Oct. 2, 2024)[5].

- Medicaid Drug Rebate Program. 42 U.S.C. § 1396r-8.

The rebate model at issue here accords with the widespread use of rebate and refund models in federal programs. And, like the rebate mechanisms in those other programs, the rebate model equally facilitates use of the 340B Program while allowing for "transparency." Medicare Discount Final Guidance at 39.

II. A REBATE MODEL FURTHERS CONGRESS'S PURPOSES IN ENACTING 340B AND RESPONDS TO FRAUD AND ABUSE

The rebate model also furthers 340B's statutory purposes of preventing duplicate discounts and other statutory violations. The 340B statute itself provides that avoiding duplicate discounts and other statutory violations are central aims of the Program. *See* 42 U.S.C. § 256b(a)(5)(A), (B); *Morrisey*, 2024 WL 5147643, at *6 (noting 340B's "twin federal purposes—providing discounts to covered entities only *and* prohibiting fraud through duplicate discounts"); *Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 343-44 (D.C. Cir. 2019) ("statutory objectives and factors" setting bounds for an agency program are an important aspect of the regulatory problem).

But HRSA has unlawfully failed to consider how the rebate model furthers 340B's objectives. That runs contrary to the fundamental maxim that "[a]gencies cannot disregard important aspects of a problem before them." *Ky. Mun. Energy Agency v. Fed. Energy Regul. Comm'n*, 45 F. 4th 162, 177 (D.C. Cir. 2022) (vacating agency decision for failing to consider the effect on customer rates and noting agency's "'ostrich-like approach' will not do" (citation omitted)); *see also Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*,

[5] Available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

463 U.S. 29, 43 (1983) (agency decision contravenes the Administrative Procedure Act where it fails to consider "important aspect[s] of the [regulatory] problem").

A. Congress Imposed Duplicate Discount And Other Statutory Restrictions To Maintain The Program's Balance

Under 340B, participating manufacturers must "enter into an agreement" with the "Secretary" (the "Pharmaceutical Pricing Agreement" ("PPA")). 42 U.S.C. § 256b(a)(1). The statute provides that such an agreement "shall require that the manufacturer offer each covered entity [certain enumerated healthcare providers] covered outpatient drugs for purchase" at a ceiling price set by a formula. *Id.*; *Novartis*, 102 F.4th at 460-62. The ceiling price set for drugs in 340B is "strikingly generous" and "can be as low as a penny per unit." *Novartis*, 102 F.4th at 456. At 340B's inception, Congress thought the Program would be small. H.R. Rep. No. 102-384, pt. 2, at 13 (anticipating that only 90 hospitals, and a range of clinics and health centers would participate). In return for providing this circumscribed benefit to a limited number of entities, manufacturers are eligible for their drugs to receive reimbursement under Medicare Part B and the federal share of Medicaid. 42 U.S.C. § 1396r-8(a)(1), (5).

From the outset, Congress embedded prohibitions within the 340B Program's statutory framework intended to limit the Program's scope. Congress defined, with specificity, the types of healthcare providers eligible to participate in 340B. *See id.* § 256b(a)(4). Congress then barred covered entities from reselling or transferring 340B drugs to anyone other than their patients, a practice known as "diversion." *Id.* § 256b(a)(5)(B). It also prohibited covered entities from exploiting "duplicate discounts or rebates." *Id.* § 256b(a)(5)(A)(i). A "duplicate discount" occurs where a covered entity obtains and prescribes a 340B discounted drug, a claim for payment is submitted to Medicaid for the drug, and the state Medicaid agency then seeks a rebate from the manufacturer for the same, already-discounted drug. The ceiling price set for drugs in 340B can

be "as low as a penny per unit." *Novartis*, 102 F.4th at 456. So, when a manufacturer is erroneously subject to *both* the 340B price and the Medicaid rebate it can be financially crushing. U.S. Gov't Accountability Off. ("GAO"), GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement 1 (Jan. 2020) ("2020 GAO Medicaid Rep.").[6] To prevent this, covered entities are statutorily directed to not allow duplicate discounting to occur, 42 U.S.C. § 256b(a)(5)(A)(i), and Congress directed the U.S. Department of Health and Human Services ("HHS") to "establish a mechanism" to defeat the possibility of duplicate discounts, *id.* § 256b(a)(5)(A)(ii).[7]

In recent years, the Program has grown exponentially, due in part to the introduction of outside pharmacies into the Program. Although HRSA issued guidance in 1996 allowing certain covered entities (those without their own in-house pharmacy) to identify one "contract pharmacy" to receive 340B drugs, its guidance set strict limits on the nature of the relationship and the pharmacy's conduct. *See Novartis*, 102 F.4th at 456-57 (noting that HRSA imposed one-contract pharmacy limit); 61 Fed. Reg. 43,549, 43,550, 43,555 (Aug. 23, 1996). Under the guidance, the pharmacy was to act as the covered entity's agent, and the limit of one pharmacy practically ensured that the pharmacy would act like an in-house pharmacy. *Novartis*, 102 F.4th at 457; 61

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[6] Available at https://www.gao.gov/assets/gao-20-212.pdf.

[7] These limitations are intentional. The Federal Government cannot mandate transfers of private property for private parties' benefit. *Kelo v. City of New London*, 545 U.S. 469, 477 (2005); *Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015). In an effort to circumvent this core constitutional concern, Congress tied 340B to manufacturers' right to receive reimbursement under other federal programs, portraying 340B as a condition for receiving federal benefits. Congress thus included "carefully calibrated" limitations, circumscribing manufacturers' obligations. 42 U.S.C. § 256b(a)(5); *see also Novartis*, 102 F.4th at 456. But to even come close to passing constitutional muster, any such "condition" *must* have an "essential nexus" to the government benefit justifying that condition and a "rough proportionality" to the purported impact on governmental interests created by the party's receipt of the benefit. *See Sheetz v. Cnty. of El Dorado*, 601 U.S. 267, 275 (2024). A condition that does not meet those requirements cannot even arguably qualify as constitutional.

Fed. Reg. at 43,551-53. In 2010, HRSA "swerved," purporting to expand the "one contract pharmacy policy" to permit an unlimited number of contract pharmacies. *Novartis*, 102 F.4th at 457 (citing 75 Fed. Reg. 10,272, 10,272-74 (Mar. 5, 2010)). As the GAO and the HHS Inspector General ("OIG") have explained, this move opened the floodgates. *See* GAO, GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement 20, 26-28 (June 2018) ("2018 GAO Rep.");[8] HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program 9-10, 16 (Feb. 2014) ("2014 OIG Rep.").[9]

Predictably, contract pharmacy usage exploded. Sophisticated for-profit pharmacies, including the Nation's largest pharmacy chains, recognized that if they could insert themselves into the 340B Program supply chain, they could sell 340B drugs at or near full price and pocket a portion of the difference as profit, by receiving either a percentage of the sales price or a flat fee per prescription. *See* 2018 GAO Rep. at 26-28.[10] In the intervening years, covered entities and contract pharmacies have maximized their arbitrage profits, while often failing to deliver on the patient benefits Congress intended.[11]

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[8] Available at https://www.gao.gov/assets/gao-18-480.pdf.

[9] Available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[10] CVS and Walgreens, two of the largest for-profit pharmacy retailers, have publicly disclosed, for example, that 340B profits are material to their finances. CVS Health Corp., Annual Report (SEC Form 10-K) at 22 (Feb. 8, 2023), available at https://bit.ly/3Sh3Dl1; Walgreens Boots Alliance, Inc., Annual Report (SEC Form 10-K) at 28 (Oct. 13, 2022), available at http://bit.ly/3kflVXh ("Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce our profitability.").

[11] While Congress had the noble aim of benefiting patients through discounted drugs or increased charity care, the reality is that commercial entities such as for-profit pharmacies and third-party administrators are now reaping sizeable profits without any concurrent benefit to patients. A recent study conducted by the Minnesota Department of Health found that $1 out of $6 dollars of Minnesota covered entity revenue from 340B went to contract pharmacies and third-party

B. HRSA Has Failed To Prevent Duplicate Discounting

Despite the deleterious effects of duplicate discounting, HRSA has failed to ensure that it does not occur. 340B's statutory prohibition on duplicate discounting bars covered entities from purchasing a covered outpatient drug at the 340B price if that drug also generates a Medicaid rebate. Preventing duplicate discounting has long been a recurring issue. But it sharply increased in 2010 with the expansion of Medicaid rebates to Medicaid managed care organizations, through which 50% of Medicaid beneficiaries now receive their pharmacy benefits.[12] A 2021 study estimated that about *one-quarter* of 340B drugs are potentially subject to illegal duplicate discounts. Luke Greenwalt, *Uncover the Invisible Impacts of 340B Discounts*, IQVIA (Dec. 20, 2021), available at https://tinyurl.com/yyxusxum (emphasis added).

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administrators. Minn. Dep't of Health, *340B Covered Entity Report* 4, 7-8 (Nov. 25, 2024) ("MDH Rep."), available at https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

Even where funds make it to covered entities, many fail to use that revenue for charity care. As the White House recognized: "An unintended consequence of the 340B program has been that covered entities receive guaranteed profits while low-income patients who are the purported target of the program may receive little to no benefit." White House Council of Economic Advisers, *Reforming the Biopharmaceutical Pricing at Home and Abroad* 15 (Feb. 2018), available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf. One California covered entity foundation, for example, reported earning $1.9 billion from its pharmacy network—the bulk of its $2.2 billion revenue. Liam Dillon et al., *Inside the World's Largest AIDS Charity's Troubled Move Into Homeless Housing*, L.A. Times (Nov. 16, 2023), available at https://www.latimes.com/homeless-housing/story/2023-11-16/aids-healthcare-foundation-low-income-housing-landlords. That same foundation in 2018 and 2020 spent a combined $64 million to push ballot measures to expand rent control and another $178 million to purchase rental properties. *Id.* The entity's alleged use of funds was so concerning that a California state senator asked for an investigation into whether it was misusing Program funds. Carla Marinucci & Victoria Colliver, *Powerhouse AIDS Organization Faces Scrutiny For Use of Federal Money*, Politico (Aug. 19, 2019), available at https://www.politico.com/states/california/story/2019/08/19/powerhouse-aids-organization-faces-scrutiny-for-use-of-federal-money-1147976.

[12] *See* Kathy Gifford et al., *State Approaches to Managing the Medicaid Pharmacy Benefit* (Aug. 20, 2024), available at https://www.healthmanagement.com/wp-content/uploads/2024-Medicaid-Rx-Survey-Rpt_FINAL.pdf.

Notwithstanding those issues, HRSA has failed to adequately police or curtail duplicate discounting. GAO has found that neither HRSA nor CMS has taken effective steps to prevent duplicate discount violations. *See generally* 2020 GAO Medicaid Rep. On the Medicaid side, CMS "conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts[]" and "does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests." *Id.* at GAO Highlights. As for 340B, HRSA "audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply" with the duplicate discount prohibition. *Id.*

The increasing size of the Program has added to these duplicate discounting concerns. As the web of players in the 340B Program has grown, so too has the risk of duplicate discounting. With profits on the line, covered entities and contract pharmacies have clear incentive to "catalog as many prescriptions as possible." *Novartis*, 102 F.4th at 457-58. And, even where there is no intention to game the system, covered entities may inadvertently seek duplicate discounts given the difficulty of policing compliance when drugs are not dispensed by the covered entity and records are kept, in part, by third parties. 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."). Indeed, GAO has noted the difficulty of auditing and obtaining reliable data for covered entities with "complex" networks. *Id.* at 45.

Even where violations are discovered, these violations typically do not result in sanctions that meaningfully deter and penalize covered entities. A common finding in the limited number of audits HRSA undertakes is that covered entities have not met the requirements to prevent

duplicate discounting in the fee-for-service Medicaid context. Where such a violation is found, typically the covered entity is only required to make a repayment to manufacturers without monetary penalty. *See* HRSA, Program Integrity: FY22 Audit Results;[13] HRSA, Program Integrity: FY23 Audit Results.[14] And in many instances, manufacturers report that HRSA does not enforce repayment, even when there is no dispute that the covered entity owes such a repayment. *See* 2020 GAO Medicaid Rep. at 26 ("HRSA officials told us they would not require a covered entity to develop corrective action plan or make offers of repayment to a manufacturer if a drug manufacturer's audit of that covered entity identified a duplicate discount in managed care."). Given that 340B pricing alone can be as low as "as a penny per unit," *Novartis*, 102 F.4th at 456, these unrecoverable losses can be staggering. And, all the while, manufacturers continue to receive demands for duplicate discounts from covered entities.

Nor has HRSA issued the guidance on duplicate discounting that Congress explicitly required. In 2010, when Congress extended manufacturer Medicaid rebate liability to Medicaid managed care organizations utilization, it sought to curtail duplicate discounting by requiring HRSA to issue guidance on preventing such discounts. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 308, 821 (2010). Among these required actions was to "develop[] . . . more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts." 42 U.S.C. § 256b(d)(2)(B)(iii), (d)(2)(B) (providing that the improvements mandated by subparagraph (A) "*shall* include" the items in subparagraph (B) (emphasis added)). HRSA has failed to issue the required "duplicate discount" guidance, failed to implement any

[13] Available at https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results.

[14] Available at https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results

systematic scheme of genuine auditing, and failed to take any meaningful enforcement efforts to prevent these abuses. J&J is entitled to know when 340B pricing is and is not genuinely required, and its rebate model is designed to achieve that end. Indeed, without this claims data, J&J cannot fully avail itself of the explicit remedies Congress provided for manufacturers in the statute. *Id.* § 256b(a)(5)(C), (d)(2).

Given the concerns discussed above, *see supra* at 15, in every year since 2018, GAO has urged HRSA to remedy its failure to provide guidance on avoiding duplicate discounting, particularly in the managed care context.[15] In 2019, GAO sent a letter to HHS, admonishing it to "issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care" and assess "covered entities' compliance with the prohibition on duplicate discounts" as part of its audit process. 2019 GAO Priority Recommendations at 7. GAO went on to warn that "[w]ithout addressing [these] recommendations . . . , HHS does not have assurance that covered entities are complying with program requirements, which puts manufacturers at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions." *Id.* As GAO recognized, the resulting state of affairs is that "manufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries." 2020 GAO Medicaid Rep. at 32.

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[15] GAO, GAO-19-364SP, HHS Priority Recommendations (2019) ("2019 GAO Priority Recommendations"), available at https://www.gao.gov/assets/gao-19-364sp.pdf; GAO, GAO-20-552PR, HHS Priority Recommendations (2020), available at https://www.gao.gov/assets/gao-20-552pr.pdf; GAO, GAO-21-527PR, HHS Priority Recommendations (2021), available at https://www.gao.gov/assets/gao-21-527pr.pdf; GAO, GAO-22-105646, HHS Priority Recommendations (2022), available at https://www.gao.gov/assets/gao-22-105646.pdf; GAO, GAO-23-106467, HHS Priority Recommendations (2023), available at https://www.gao.gov/assets/gao-23-106467.pdf; GAO, GAO-24-107257, HHS Priority Recommendations (2024) ("2024 GAO Recommendations"), available at https://www.gao.gov/assets/gao-24-107257.pdf.

Ensuring the prevention of duplicate discounts has become an increasingly pertinent concern following the recent passage of the Inflation Reduction Act ("IRA"). The IRA establishes the Medicare Drug Price Negotiation Program, under which HHS "negotiate[s]" with manufacturers "maximum fair price[s]" for selected drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must offer those drugs under these so-called maximum fair prices, except when the 340B price is lower than the maximum fair price. *Id*. § 1320f-2(d). That is, manufacturers are statutorily protected and need not offer duplicate 340B and "maximum fair price" discounts on the same drug. *Id*. To avoid duplicate discounting, this scheme necessarily requires identifying when a drug subject to the "maximum fair price" is dispensed as a 340B drug.

CMS issued final IRA guidance that discusses duplicate discounting but failed to create a mechanism to address the issue. Under the guidance, a *manufacturer* bears the burden of determining and verifying whether a "claim for the selected drug is a 340B-eligible claim." CMS, Medicare Drug Pricing Negotiation: Final Guidance 60 (Oct 2, 2024) ("Final Guidance");[16] *see also* CMS, Medicare Drug Price Negotiation Program: Draft Guidance 48 (May 3, 2024) ("Draft Guidance") (A manufacturer must "indicate[] that the claim for [a] selected drug is a 340B-eligible claim.").[17] To facilitate identification of 340B drugs, dispensing entities are merely "encouraged" to use claims codes indicating which drugs are dispensed under 340B and to provide prescriber identification information to help manufacturers identify "whether a prescription was written by a prescriber with a high percentage of claims originating from a 340B covered entity." Draft Guidance at 41; Final Guidance at 45, 57. But CMS refused to require such identifying information

[16] Available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[17] Available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

while simultaneously reaffirming that it was placing the burden on manufacturers. Final Guidance at 57-58.

As a result, manufacturers with drugs subject to "maximum fair prices" under the IRA and 340B discounts face an impossible task.[18] Absent the cash rebate model, manufacturers have no clear way to identify units subject to the 340B discount when forced to provide the "maximum fair price" rebate, because that information is held by covered entities—not manufacturers. And without that information, manufacturers have no way to avoid providing duplicative IRA and 340B discounts for a given unit. HHS, through CMS, had notice of these concerns, "acknowledge[d]" them, and then stated it "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and [the 'maximum fair price']." Final Guidance at 55. Now, through HRSA, HHS is simultaneously forbidding manufacturers from taking action that would allow them to receive the non-duplication protection Congress explicitly afforded without explaining why it can do so.

To date, HRSA has refused to take an active role to ensure that Congress's duplicate discount prohibitions are followed, including in the IRA context. This failure to manage covered entity conduct has exposed manufacturers to repeated instances of duplicate discounting. 2020 GAO Medicaid Rep. at 32.

C. HRSA Has Failed To Police Statutory Violations

HRSA has also failed to take an active role in ensuring Program compliance. Only a limited number of covered entities are audited each year by HRSA. For example, as of February 2025, there were 198 completed covered entity audits for the 2022 fiscal year and 164 completed

[18] Each year, the number of drugs subject to the IRA's "maximum fair price" will grow. Currently, 25 drugs have been selected, with up to an additional 15 drugs to be selected for the third round and 20 drugs each cycle after that. 42 U.S.C. § 1320f-1(a).

for the 2023 fiscal year. *See* Program Integrity: FY22 Audit Results; HRSA, Program Integrity: FY23 Audit Results. To put that in context, there are over 50,000 covered entity sites operating in the United States. Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021).[19]

Notwithstanding that it exercises very limited oversight, HRSA has identified hundreds of instances of statutory violations. *See* 2018 GAO Rep. at 37, 44; *see also* GAO, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement 28 (Sept. 2011).[20] Congress has recognized that the number of audits finding violations is "staggering"—with over 80 percent of audited covered entities showing non-compliance in certain audit years. *See Examining HRSA's Oversight of the 340B Drug Pricing Program, Hearing Before the H. Subcomm. on Oversight & Investigations of the Comm. on Energy & Commerce*, 115 Cong. 69 (July 18, 2017) ("July 18, 2017, H. Subcomm. Hr'g").

HRSA, however, has failed to remedy those statutory violations. *See* 2018 GAO Rep. at GAO Highlights (setting forth findings as to ineffective HRSA oversight). Indeed, HRSA does not appear to police the detailed contractual relationships between covered entities and contract pharmacies to ensure that statutory violations, including duplicate discounting and diversion, do not occur. Decl. of Krista M. Pedley ¶ 3, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 (conceding that "contract-pharmacy arrangements vary, and [HRSA] cannot speak to the exact details of every existing relationship"); *see* July 18, 2017, H. Subcomm. Hr'g at 79 (testimony of Krista M. Pedley, then

[19] Available at https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments.

[20] Available at https://www.gao.gov/assets/gao-11-836.pdf.

Director of HRSA's Office of Pharmacy Affairs, that contract pharmacy arrangements are "a business matter between the parties and their contract").[21]

Even where HRSA does audit covered entities to ensure compliance and discover violations, HRSA does "not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit." *Opportunities to Improve the 340B Drug Pricing Program*, *Hearing Before the H. Subcomm. on Health*, 115th Cong. 54 (July 11, 2018) ("July 11, 2018, H. Subcomm. Hr'g") (testimony of Rep. H. Morgan Griffith). In the very limited cases where HRSA conducted re-audits of covered entities that had compliance issues, it found repeated instances of similar noncompliance. *See id.* at 55 (GAO witness testifying that HRSA should require "more rigorous information . . . from the covered entities as to what they've done"). HRSA also almost never terminates a covered entity's ability to participate in the 340B Program for non-compliance. *See* July 18, 2017, H. Subcomm. Hr'g at 63 (HRSA witness indicating that the agency had "terminated one covered entity" as of 2017); *see also Genesis Health Care, Inc. v. Azar*, No. 4:19-cv-1531, 2019 WL 6909572, at *2 (D.S.C. Dec. 19, 2019) (HRSA "vacated its decision to remove [covered entity] from the 340B Program and promptly reinstated [covered entity] into the 340B Program" after the covered entity initiated litigation.). As a result, violations remain rife within the Program.

D. The Rebate Model Is Designed To Address These Shortcomings

With HRSA idle, J&J and other manufacturers were left without recourse. The rebate approach adopted by J&J will alleviate some of these challenges by providing manufacturers with

[21] HRSA has explained that it does not issue audit findings against covered entities "for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance[.]" GAO, GAO-21-107, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements 15-16 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf.

claims data to keep statutory violations from recurring. This model will help prevent not only fraud and abuse, *see supra* at 14-21, but also instances of duplicate discounting due to mistake. For example, state Medicaid duplicate discount policies may be unclear, ineffective, or non-existent. As a result, covered entities may inadvertently end up seeking impermissible duplicate discounts. The *ex ante* approach of the rebate model allows manufacturers to detect these issues in their infancy.

This ability is significant given that the *ex post* remedies of audits and administrative dispute resolution ("ADR") have proven to be exceedingly difficult to invoke under HRSA's current regime. While manufacturer audits of covered entities could help manufacturers detect 340B violations, HRSA has established significant barriers to manufacturers' ability to audit covered entities. Under HRSA's manufacturer audit guidelines, issued in 1996, HRSA permits manufacturers to conduct an audit only where they "ha[ve] documentation which indicates there is reasonable cause" to believe a covered entity violated 340B's prohibitions. 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996); 89 Fed. Reg. 28,643, 28,644 (Apr. 19, 2024) (stating "manufacturers are required to audit a covered entity prior to filing an ADR claim"); *see also Novartis*, 2021 WL 5161783, at *7. "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibition on duplicate discounting or transfer or sale. 61 Fed. Reg. at 65,409-10 (requiring "clear description of why [manufacturer] has reasonable cause . . . , along with sufficient facts and evidence in support of the belief"). Because manufacturers do not have access to data regarding prescriptions, manufacturers are routinely unable to gather documentation that establishes reasonable cause. As a result, very few manufacturers have managed to audit covered entities. *See* 89 Fed. Reg. at 28,646 (stating that,

"[i]n the last 5 years, six [manufacturers] have followed the guidelines to request audits of covered entities").

In the rare cases where manufacturers have been able to obtain the right to audit a covered entity, covered entities have fiercely resisted those efforts.[22] For example, a manufacturer recently sought to audit several covered entities due to concerns regarding statutory violations, including duplicate discounting. *See* [Proposed] Br. of Johnson & Johnson Health Care Sys., Inc. as *Amicus Curiae* in Supp. of Defs.' Mot. to Dismiss at 9-10, *Univ. of Rochester v. Johnson*, No. 1:24-cv-02268 (D.D.C. Dec. 18, 2024), ECF No. 20-1 ("J&J Consol. Br."). In one such case, the manufacturer was concerned by "the fact that [the covered entity's] purchases of [the manufacturer's] 340B products had grown by 159% over a six-month period, almost all of which was driven by purchases of one product." *Id.* at 19-20 (also identifying growth of 99% over a six-month period by another covered entity); *see also* [Proposed] Br. of Johnson & Johnson Health Care Sys., Inc. as *Amicus Curiae* in Supp. of Defs.' Mot. to Dismiss at 11, *Oregon Health & Sci. Univ. v. Johnson*, No. 1:24-cv-02184 (D.D.C. Dec. 12, 2024), ECF No. 20-1 (detecting an over 70% growth in a mere six months in another entity's 340B utilization). As to yet another entity, the manufacturer "identified hundreds of instances of potential duplicate discounts." J&J Consol. Br. at 20.

In response, even before the audits began, at least five covered entities filed suit against HRSA, seeking to prevent the manufacturer from exercising its statutorily provided audit rights.[23]

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[22] While covered entities should audit their contract pharmacies, HHS's OIG has stated that "most covered entities [it studied] do not" effectively do so. 2014 OIG Rep. at 16; *see also* July 11, 2018, H. Subcomm. Hr'g at 54 (Rep. H. Morgan Griffith).

[23] *Oregon Health & Sci. Univ. v. Johnson*, No. 1:24-cv-02184 (D.D.C. filed July 24, 2024); *MaineGeneral Med. Ctr. v. Johnson*, No. 1:24-cv-02187 (D.D.C. filed July 24, 2024); *Univ. of Rochester v. Johnson*, No. 1:24-cv-02268 (D.D.C. filed Aug. 1, 2024); *Child.'s Nat'l Med. Ctr. v.*

As HRSA put it when defending against the suits: "Rather than attempt to reach a compromise with [the manufacturer], or simply produce records to [the manufacturer] demonstrating that [the manufacturer's] suspicion about diversion and duplication is unfounded, [the covered entity plaintiff] filed a lawsuit to stop the audit, and for the last six months has focused its attention on the lawsuit." Fed. Gov't Reply in Further Supp. of Mot. to Dismiss at 6-7, *Univ. of Rochester*, No. 1:24-cv-02268 (D.D.C. Jan. 21, 2025), ECF No. 25.

These limitations on audits by manufacturers, imposed by HRSA and through covered entities' conduct in the rare cases where manufacturers are able to audit, also materially limit manufacturers' ability to access the ADR process provided by Congress. Prior to bringing an ADR claim, manufacturers are required to first audit a covered entity. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3). Given the onerous limitations on manufacturers' audit rights that make it incredibly difficult to audit a covered entity, manufacturers are effectively foreclosed from relief under ADR because they cannot bring a claim without first conducting an audit. That runs directly counter to Congress's provision of the ADR mechanism to ensure, in part, that manufacturers can obtain redress. *Id.* Against that backdrop, the necessity of J&J's rebate model is clear.

CONCLUSION

For the reasons discussed, J&J's effort to combat Program abuses via the rebate model is permissible and furthers the purposes of 340B. HRSA's rejection of a rebate model, without consideration of these pervasive abuses, cannot stand. Accordingly, *Amici* respectfully urge the Court to grant J&J's motion for summary judgment.

Johnson, No. 1:24-cv-02563 (D.D.C. filed Sept. 6, 2024); *Univ. of Wash. Med. Ctr. v. Johnson*, No. 1:24-cv-02998 (D.D.C. filed Oct. 22, 2024).

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