IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Plaintiff,

v.

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

and

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

Defendants.

Civil Action No. 1:24-cv-3188

MOTION OF
NATIONAL ALLIANCE FOR HEALTHCARE PURCHASER COALITIONS
FOR LEAVE TO FILE AMICUS CURIAE BRIEF

Under Local Civil Rule 7(o)(2), National Alliance for Healthcare Purchaser Coalitions ("National Alliance") moves for leave to file a brief as amicus curiae supporting Johnson and Johnson Health Care System Inc.'s ("J&J") motion for summary judgment.

National Alliance is the only nonprofit, purchaser-led coalition with a national and regional reach. It is the voice for more than 40 regional and local employer/purchaser coalitions, which together represent more than 12,000 employers with more than 40 million covered lives, spending over $400 billion annually on healthcare in the commercial market. The Alliance has been an outspoken proponent for much needed transparency and reform of the 340B Program, including in testimony before the United States House of Representatives. National Alliance is a proven 340B subject matter expert and has unique and valuable insight about the questions posed by this case.

When Congress enacted the 340B Drug Pricing Program as part of the Veterans Health Care Act of 1992, it had laudable aims: to provide prescription drugs at discount prices to a select set of health care providers, known as "covered entities," which generally serve low-income, uninsured, and rural patients, with the understanding that those discounts would be passed on to patients and/or used to expand services to the poor and underserved. But third-party involvement has significantly expanded the 340B Program, which is now dominated by large, for-profit pharmacies, pharmacy benefit managers, and their affiliates, creating perverse economic incentives, and precipitating widespread abuse. Although audits conducted by the Health Resources and Services Administration (HRSA) have uncovered unlawful practices by covered entities, the agency has failed to adequately police noncompliance and has engaged in extra-statutory attempts to block permissible policies designed to effectuate the aims of section 340B and redirect savings to vulnerable patients.

The proposed amicus brief provides the Court additional important information about the original purposes behind the 340B Program, the reasons for its steady growth in size the past 15 years, and efforts to bring the 340B Program back within the confines of its original—narrow but

laudable—aims. Further, the National Alliance will describe how the 340B Program increases commercial health care costs for employers and employees alike through incentives for health system consolidation; the prescribing of more expensive covered medications; and the loss of drug discounts from other sources.

Courts have discretion to determine "the fact, extent, and manner of participation by the amicus" in a pending action. *United States v. Microsoft Corp.*, No. 98-cv-1232, 2002 WL 319366, at *2 (D.D.C. Feb. 28, 2002); *see* LCvR 7(o).

It is not uncommon for this District to grant leave for amicus participation. *See, e.g.*, *Virginia v. Ferriero*, 525 F. Supp. 3d 36, 44 (D.D.C. 2021) (Contreras, J.) ("In addition, numerous amici have asked the Court to consider their perspectives on the important issues at stake in this case. The Court grants their motions to file amicus briefs and appreciates their input."); *Washington All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 518 F. Supp. 3d 448, 453 n. 2 (D.D.C. 2021) (granting leave to file amicus briefs where the brief offered "ideas, arguments, theories, insights, facts, or data that are not found in the parties' briefs") (cleaned up).

The Alliance does not have a direct financial interest in the outcome of this litigation and thus its "unique information or perspective . . . can help the [C]ourt beyond the help that the lawyers for the parties are able to provide." *Hard Drive Prods., Inc. v. Does 1–1,*495, 892 F. Supp. 2d 334, 337 (D.C. Cir. 2012) (quoting *Jin*, 557 F.Supp.2d at 137).

Plaintiff Johnson & Johnson Health Care Systems Inc. consents to the filing of this brief. Defendant U.S. Department of Health and Human Services takes no position.

National Alliance respectfully asks that this Court grant the motion for leave to file the attached amicus brief supporting J&J's motion for summary judgment.

Dated: February 12, 2025

Respectfully submitted,

/s/ Michael E. Blumenfeld

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC., *Plaintiff,* v. XAVIER BECERRA, in his official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al. *Defendants.*	Civil Case No. 1:24-cv-3188

[PROPOSED] ORDER

Upon consideration of the Motion of National Alliance for Healthcare Purchaser Coalitions for Leave to File an Amicus Brief, it is hereby ORDERED:

That the Motion is GRANTED;

That the Clerk shall cause the Proposed Amicus Brief attached to the Motion for Leave to File an Amicus Brief to be filed and entered on the docket in the above-captioned proceeding.

IT IS SO ORDERED.

Dated: _____

_____
HON. RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

cc: All Counsel of Record

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.,
1000 US Highway 202 South
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Plaintiff,

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200 Independence Avenue, S.W.
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Civil Action No. 1:24-cv-3188

BRIEF OF AMICUS CURIAE NATIONAL ALLIANCE OF HEALTHCARE PURCHASER COALITIONS IN SUPPORT OF PLAINTIFF JOHNSON & JOHNSON HEALTH CARE SYSTEMS INC.

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CORPORATE DISCLOSURE STATEMENT

The National Alliance of Healthcare Purchaser Coalitions is a non-profit 501(c)(6) organization. It has no corporate parent and is not owned in whole or in part by any publicly held corporation.

INTEREST OF AMICUS CURIAE[1]

National Alliance of Healthcare Purchaser Coalitions is the only nonprofit, purchaser-led coalition with a national and regional reach. It is the voice for more than 40 regional and local employer/purchaser coalitions, which together represent more than 12,000 employers with more than 40 million covered lives, spending over $400 billion annually on healthcare in the commercial market. The Alliance has been an outspoken proponent for much needed transparency and reform of the 340B Program, including in testimony before the United States House of Representatives Committee on Energy and Commerce.

INTRODUCTION AND SUMMARY OF ARGUMENT

Lowering health care costs, including by reducing the cost of prescription drugs for uninsured, low-income, and vulnerable patients, is a commendable goal. To pursue this policy objective, Congress enacted the 340B Drug Pricing Program as part of the Veterans Health Care Act of 1992, later amending the statute in 2010 as part of the Affordable Care Act (ACA). Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967; Pub. L. No. 111-148, tit. VII.B, §§ 7101–02, 124 Stat. 119, 821–27 (both codified at 42 U.S.C. § 256b). "As a condition of participating in Medicare Part B and Medicaid, section 340B requires drug manufacturers to sell certain drugs" at discounted prices to health care providers, known as "covered entities," which generally serve low-income, uninsured, and rural patients. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455 (D.C. Cir.

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

2024); *see also* 42 U.S.C. § 256b(a)(4). These covered entities then benefit by receiving insurance reimbursements for the full price of drugs that they purchased at the 340B discount, a "ceiling price" set by a statutory formula. *See id.* §§ 256b(a)(1), (2). The 340B Program is administered by the Health Resources and Services Administration (HRSA), an operating division of the U.S. Department of Health and Human Services (HHS). *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

The landscape of the 340B Program has evolved markedly in the three decades since its enactment. It now ranks as the "second-largest federal prescription drug program, surpassing the Medicaid Drug Rebate Program" and second only to Medicare Part D. Ellie Blalock et al., *The Pharmaceutical Supply Chain, 2013–2023*, Berkeley Rsch. Grp., 4 (Jan. 2025), https://media.thinkbrg.com/wp-content/uploads/2025/01/06161850/PhRMA_Supply-Chain-2013-2023_White-Paper.pdf. From the beginning, HRSA recognized that covered entities "may set the price [for covered drugs] slightly higher than the actual acquisition cost plus a reasonable dispensing fee" and concluded "that a modest section 340B price markup . . . does not appear to be inconsistent with the drug pricing program." 61 Fed. Reg. 43,551 (Aug. 23, 1996). But (perhaps in a fit of wishful thinking) HRSA anticipated that covered entities would either "pass all or a significant part of the discount to their patients," or "us[e] the savings to reach more eligible patients and provide more comprehensive services." *Id.*

Unfortunately, as this case demonstrates, the 340B Program has since strayed from its beneficent aims, given expanded opportunities for covered entities and third-party pharmacies to pursue profit through price markups and unlawful duplicate discounts—all at the expense of the patients that the Program purports to benefit. And this despite one of the Program's professed aims: allowing "covered entities to stretch scarce federal resources as far as possible, reaching more

eligible patients and providing more comprehensive services," *340B Drug Pricing Program*, Health Res. & Servs. Admin., https://www.hrsa.gov/opa. HRSA has latched onto this rationale as a justification for the unprecedented growth in the 340B Program, notwithstanding the fact that the Program does not stretch federal resources but instead operates primarily as a government-sponsored price arbitrage program.

As a result of HRSA's regulatory reversals, expansions in the eligibility criteria for covered entities, and endemic issues in the Program's framework, the 340B Program is now dominated by large, for-profit enterprises, including publicly traded pharmacy benefit managers (PBMs), large disproportionate share hospitals (DSHs), and their web of affiliates. The unconstrained growth of 340B has been aided by supercharged consolidation throughout the health care system, which is induced and incentivized by the generous discounts the 340B Program affords covered entities in seeking insurance reimbursement for the dispense of eligible pharmaceuticals. The 340B Program has thus been transmogrified from a commendable patient-assistance program, confined to discrete acute care providers, to a distended, profit-generating juggernaut dominated by DSHs, for-profit pharmacies, and PBMs. Worse still, although HRSA's own audits have uncovered pervasive Program abuse, the agency has failed to adequately police covered entity noncompliance.

The financial burdens imposed by the growth of the 340B Program are not solely shouldered by drug manufacturers. On the contrary, the *primary* victim of 340B's excesses are the employers, purchasers, and working families that are forced to pay billions of dollars more in prescription drugs and other health care services, while large DSHs, PBM middlemen, and contract pharmacies engage in arbitrage under 340B, marking up drug prices by as much as 72%, while declining to pass their savings (and their rebates) on to their patients in low-income, marginalized, and underserved communities.

Through its reports and advocacy, including in Congressional testimony, the National Alliance has identified three primary ways the expansion of the 340B Program increases commercial health care costs for employers, purchasers, and employees alike: First, "340B is a strong incentive for health system consolidation"; second, "[c]overed entities tend to prescribe more expensive medications than non-covered entities"; and third, "[e]mployers and purchasers lose access to drug discounts (rebates) when dispensed through 340B." Shawn F. Gremminger, *Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. On Energy and Commerce*, 6–7 (June 4, 2024), https://acrobat.adobe.com/id/urn:aaid:sc:va6c2:54524ccd-9d63-4cef-8920-df991a37fa62?viewer%21megaVerb=group-discover.

To be sure, legislative oversight and reform are necessary to ameliorate Program dysfunction, effectuate the aims of section 340B, and embolden transparency. However, recent court decisions construing the 340B statute have also operated to either expand the scope of the Program or uphold state intermeddling in its operation, thereby facilitating further arbitrage, abuse, and unaccountability. In the instant case, the National Alliance urges this Court to reject HRSA's extra-textual interpretation of 42 U.S.C. § 256b(a)(1), which will only serve to further compromise Program integrity and impose unnecessary costs on employers, purchasers, and working families.

ARGUMENT

I. The unconstrained growth of the 340B Program has frustrated its original aims, owing to an increase in the number of covered entities, a pervasion of third-party involvement, and supercharged consolidation throughout the health care system.

During the first decade of 340B, it remained a relatively small Program, focused on the provision of charity care by only a handful of covered entities. Indeed, in 2005, pharmaceutical

sales at 340B prices totaled "only" $2.4 billion.[2] After 2010, however, the 340B program has grown exponentially, owing to the proliferation of covered entities and contract pharmacies. When the 340B statute was enacted, exceedingly few covered entities had in-house pharmacies. However, the 340B statute does not contemplate the existence of 340B discounts for pharmacies not owned and operated by covered entities. So, after urging by small community health centers which lacked their own in-house pharmacy—and thus were unable to take advantage of the 340B Program—in 1996, HRSA issued a guidance document providing "that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Novartis*, 102 F.4th at 457 (citing 61 Fed. Reg. 43,550, 43,555) (Aug. 23, 1996)). In 2010, however, HRSA changed course, issuing a new guidance permitting covered entities to "contract with an *unlimited number* of outside pharmacies . . . regardless of whether the entities have in-house pharmacies." *Id.* (citing 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010)) (emphasis added).

The 2010 guidance led to a rapid increase in the use of third-party contract pharmacies and thus "prompted a significant expansion in the section 340B [P]rogram." *Id.* at 457. The Government Accountability Office ("GAO") has found that, from 2010 to 2019, the number of contract pharmacies used by covered entities increased from 1,300 to 23,000. U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, 2 (Jan. 27, 2020) [hereinafter 2020 GAO Report], https://www.gao.gov/assets/gao-20-212.pdf. As of 2023, there were 33,000 340B contract pharmacies, which maintained over 194,000 *unique* contractual relationships with nearly 9,600 340B covered entities. Adam Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and*

[2] Karen Mulligan, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, USC-Brookings, 5 (2021), https://healthpolicy.usc.edu/wp-content/uploads/2022/07/USC_Schaeffer_340BDrugPricingProgram_WhitePaper.pdf.

PBMs Dominate an Evolving 340B Contract Pharmacy Market, Drug Channels (July 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html. Indeed, "[t]he number of contractual relationships has grown more quickly than has the number of contract pharmacy locations," with such relationships increasing by about 25,000, or 15 percent, since 2022. *Id.*

As a result, the 340B Program is now dominated by large, for-profit enterprises, including publicly traded pharmacy chains. *Id.* Because of the discounts the 340B Program offers—an average of about 57 percent off list price and, in some cases, requiring drugs be offered to covered entities for as little as a penny—many covered entities and contract pharmacies appear to rely upon manufacturers' supply of 340B-discounted drugs as an added revenue stream by selling those drugs at steep profit margins, often as high as 72 percent. *See* Ellie Blalock et al., *The Pharmaceutical Supply Chain, 2013–2023, supra*, at 4 ("[o]utside of 340B, pharmacy margins on brand drugs are typically in the single digits" (citations omitted)). In so doing, many covered entities engage in arbitrage, declining to pass savings on to their patients in underserved communities.[3] Today, five multi-billion-dollar, publicly traded pharmacy chains and PBMs account for 75% of all 340B contract pharmacy relationships with covered entities. Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, *supra*. The volume of 340B purchases has skyrocketed during the past decade or so. *See Novartis*, 102 F.4th at 457 (noting that, according to one analyst's estimates, 340B purchases "jumped from roughly $6.9 billion in 2012 to $24.3 billion by 2018" (citing Adam Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—as Hospitals' Charity Care*

[3] *See* Neal Masia, *Comparing the Financial Health and Charitable Care of 340B and Non-340B Hospitals*, Health Cap. Grp. 3, 12, 13 (2023), https://www.healthcapitalgroup.com/340b-hospitals-and-charity-care-2023.

Flatlines, Drug Channels (May 14, 2019)). In 2023, "discounted purchases under the 340B program reached a record $66.3 billion—an astounding $12.6 billion," or 23.4 percent, increase over 2022. Adam Fein, *The 340B Program Reached $66 Billion in 2023, supra*. Purchases by DSHs now constitute nearly $52 billion (or 78 percent) of total 340B purchases by covered entities. *Id.*

There are several reasons for the rapid expansion of the Program which account for the profound costs imposed on employers, purchasers, and working families. *First*, owing to the expansion of Medicaid, far more acute care hospitals now qualify as covered entities under 340B. To put things in perspective, in 1991, a year before 340B's enactment, approximately 11 percent of the U.S. population was covered by Medicaid. *See* Assistant Secretary for Planning and Evaluation, Dep't of Health and Hum. Servs., *March 1992 Current Population Survey Shows Health Insurance Coverage Up in 1991*, 1 (Feb. 1993) https://aspe.hhs.gov/sites/default/files/private/pdf/74066/rn04.pdf. However, owing to expansions over the last three decades in the scope of Medicaid coverage—including through the ACA—the share of the U.S. adult population covered by the assistance program has increased to 18.9 percent. Katherine Keisler-Starkey & Lisa N. Bunch, *Health Insurance Coverage in the United States: 2023*, U.S. Census Bureau, 3 (Sept. 2024), https://www2.census.gov/library/publications/2024/demo/p60-284.pdf. Nevertheless, the 340B Program has not been adequately reformed to reflect the broadened scope of public health insurance coverage.

For example, a statutorily prescribed adjustment calculation determines which hospitals that serve a "significantly disproportionate number of low-income patients," 42 U.S.C. § 1395ww(d)(5)(F)(i)(l), qualify as a DSH for increased reimbursements under Medicaid (and

Medicare); the size of any adjustments they receive; and thus whether they likewise qualify for the 340B Program, *see id.* § 1395ww(d)(5)(F)(v). This calculation is based upon a hospital's "disproportionate patient percentage," *see id.* § 1395ww(d)(5)(F)(v), the product of a formula accounting for the percentage of hospital patient days for Medicaid patients and low-income Medicare patients. *See id.* The threshold for 340B qualification—a DSH adjustment of 11.75%--has remained unaltered since 1992, despite Medicaid's sizable growth over the years (making it far easier for a hospital to reach the 11.75% adjustment, given that significantly more patients are covered by Medicaid now than when the Program began). *See* Gov't Accountability Off., *Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program*, (June 18, 2018), https://www.gao.gov/assets/gao-18-521r.pdf (noting that "[g]eneral acute care hospitals that have a DSH adjustment percentage greater than 11.75 percent have been eligible for the program since its inception in 1992"). As a result, a Program originally intended for fewer than 100 DSH covered entities—a subset of health care providers constituting the largest, most financially robust hospitals in the country—now permits participation by more than half of *all* U.S. hospitals. Moreover, although DSHs account for less than 10% of all covered entities today (which include non-hospital clinics, treatment centers, and grantees), as noted above, by 2023, the share of 340B purchases made by DHSs has skyrocketed to nearly 78 percent. Fein, *The 340B Program Reached $66 Billion in 2023*, *supra*.

For context, since the 340B Program's creation in 1992, Congress has created new types of qualifying covered entities, extending the 340B Program to family planning clinics, freestanding children's hospitals, sole community hospitals, rural referral centers, and freestanding cancer centers. *See* Cong. Resch. Serv., *Overview of the 340B Drug Discount Program*, 1 (Oct. 14, 2022) https://crsreports.congress.gov/product/pdf/IF/IF12232 (noting that "Congress . . . made

substantial changes to the 340B Program in 2010 via the [ACA] . . . and that "[h]ospital participation in the 340B Program has tripled from the time before the ACA's enactment"). While these expansions in the scope of the Program have contributed to skyrocketing 340B purchases, the six newer categories of covered entities accounted for only $4.7 billion in 2022, or less than 10 percent of total sales. *Id.* In short, along with for-profit PBMs and contract pharmacies, DSHs now dominate 340B.

A. The expansion of the 340B Program increases commercial health care costs for employers and employees by incentivizing health system consolidation, inducing markups in pharmaceutical pricing, and preventing employers and purchasers from benefitting from discounts and Medicaid rebates for 340B drugs.

Other issues even more intrinsic to the 340B Program have imposed substantial costs on employers, purchasers, working families, and other stakeholders. The National Alliance has identified three primary ways the expansion of the 340B Program increases commercial health care costs for employers and employees alike: *First*, "340B is a strong incentive for health system consolidation";[4] *second*, "[c]overed entities tend to prescribe more expensive medications than non-covered entities"; and *third*, "[e]mployers and purchasers lose access to drug discounts (rebates) when dispensed through 340B." Gremminger, *Oversight of the 340B Drug Pricing Program*, *supra*, at 6–7. Each trend is addressed in turn.

[4] As just one example, the New York Times published an article detailing how Bon Secours purchased Richmond Community Hospital, which primarily serves poor Black patients who were either uninsured or covered through Medicaid, to take advantage of its status as a 340B covered entity. *See* Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 24, 2022), https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html. Bon Secours then purchased and opened nine "satellite" clinics of Richmond Community Hospital in wealthier areas of Richmond, entitling the clinics to 340B price discounts. *Id.* Bon Secours would then profit by charging the private insurers a higher rate for the discounted drugs. *Id.* Meanwhile, Richmond Community was hollowed-out, with few services beyond an emergency room and psychiatric ward. *Id.*

Various studies indicate that the 340B Program has induced consolidation—both horizontal and vertical—throughout the health care industry. *See, e.g.*, Sunita Desai and J. Michael Williams, *Consequences of the 340B Drug Pricing Program*, New Eng. J. of Med. (Jan. 24, 2018), https://www.nejm.org/doi/full/10.1056/nejmsa1706475 (finding that [t]he 340B Program has been associated with hospital–physician consolidation in hematology–oncology"). Through these acquisitions, health care systems and providers seek to broaden their participation in the Program, and thus obtain Program discounts, by merging with or acquiring other practices or hospitals.[5] In fact, one study published in the *New England Journal of Medicine* found that "the 340B Program was associated with 2.3 more hematologist–oncologists practicing in facilities owned by the hospital, or 230% more hematologist–oncologists[,] than expected in the absence of the [P]rogram." Desai & Williams, *supra*.

Moreover, according to an article published in *Health Services Research*, "the 340B program [has] shifted the place of cancer drug administration" from physician's offices to hospital outpatient departments (HOPDs)" such that "the probability of a patient receiving cancer drug administration in HOPDs versus [physician's o]ffices increased 7.8 percentage points more in markets that newly gained a 340B hospital than in markets with no 340B hospitals." Jeah Jung et al., *Impact of the 340B Drug Pricing Program on Cancer Care Site and Spending in Medicare*, Health Serv Res. (Oct. 2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6153182/. These shifts in the delivery of care further suggest hospital-physician consolidation, and evidence indicates that

[5] *See* Zachary Levinson, et al. *Ten Things to Know About Consolidation in Health Care Provider Markets*, KFF (Apr. 19. 2024), https://www.kff.org/health-costs/issue-brief/ten-things-to-know-about-consolidation-in-health-care-provider-markets/. There were 428 hospital and health system mergers announced between 2018 to 2023 alone, while "[t]he share of community hospitals that are part of a larger health system . . . increased from 53% in 2005 to 68% in 2022"; and "the share of physicians working for a hospital or in a practice owned at least partially by a hospital or health system increased from 29% in 2012 to 41% in 2022." *Id.*

such vertical integration alters hospital referral practices and increases prices for patients—without necessarily enhancing the quality of care. *Cf.* Levinson, et al., *Ten Things to Know About Consolidation in Health Care Provider Markets*, *supra* note 5. For example, hospital prices for the top 37 infused cancer drugs averaged 86.2% higher per unit than in physician offices. Fronstin P. Roebuck et al., *Location, Location, Location: Cost Differences for Oncology Medications Based on Site of Treatment*, Emp. Benefit Rsch. Inst., 1 (Jan. 16, 2022) https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_498_chemocosts-16jan20.pdf?sfvrsn=9d073d2f_8.

There is also evidence that such consolidation impedes access to care. Studies have found that "rural hospitals that merged with other hospitals or health systems were more likely to eliminate certain service lines, such as obstetrics care," and "that independent hospitals (urban and rural) that joined a health system were more likely to stop offering inpatient pediatric services." Levinson, et al., *Ten Things to Know About Consolidation in Health Care Provider Markets*, *supra* note 5. These closures—wrought by covered entity-driven consolidation—ultimately redound to the detriment of the marginalized communities that the 340B Program was designed to serve. The upshot is that large, covered entities are thus able to realize substantial profits by buying physician practices, converting them to outpatient clinics, and then harnessing the 340B Program as a vehicle for pricing arbitrage.

Hospital consolidation has also led to a proliferation of hospital-affiliated outpatient facilities, known as "child sites." As a result of robust consolidation in the health care industry, in 2021, there were over 33,000 hospital-affiliated child sites, an approximately tenfold increase over 2009. Mulligan, *The 340B Drug Pricing Program*, *supra* note 2, at 4. These sites are able to use 340B discount pricing, even though studies have shown that they are frequently located in higher income and less diverse areas than their "parent" covered entity. *See id.* at 1 (explaining that

"340B-participating hospitals with offsite outpatient clinics ('child sites') can register those sites for 340B if they are listed as reimbursable on the hospital's most recently filed Medicare Cost Report"); *see also* Kolton Gustafson & Milena Sullivan, *340B Hospital Child Sites and Contract Pharmacy Demographics*, Avalere Health (Apr. 18, 2022), https://avalere.com/insights/340b-hospital-child-sites-and-contract-pharmacy-demographics. In fact, one report found that 61% of child sites are located in a different ZIP code than the main 340B DSH hospital"; that "of these, 60% are in areas with at least 10% higher median income than their main 340B DSH hospital"; and that nearly half "have median incomes at least 30% higher than their parent sites." *Id.* These outpatient facilities only further enable DSH covered entities to use 340B rebates and discounts as a profit maximizer, while failing to expand access to care in low-income communities.

Finally, with respect to drug price markups, several academic studies have found that covered entities are more likely to prescribe higher cost therapies and use more expensive sites to deliver care than non-340B health care providers. According to a report published in the *New England Journal of Medicine*, price markups at hospitals eligible for 340B discounts were over 6.5 times higher than in independent physician practices. James Robertson, et al., *Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance*, New Eng. J. of Med. (Jan. 24, 2024), https://www.nejm.org/doi/full/10.1056/NEJMsa2306609. And a 2022 study from the Community Oncology Alliance, which analyzed self-reporting drug pricing data for 49 of the top 340B Program-participating acute care DSHs, found that the entities "price the top oncology drugs at 4.9 times their 340B acquisition costs, assuming a 34.7 percent discount," with discounts ranging from factors of 3.2 to 11.3. Community Oncology Alliance, *Examining 340B Hospital Price Transparency, Drug Profits, and Incentives*, 2, 3 (Sept. 2022), https://communityoncology.org/wp-

content/uploads/2022/09/COA_340B_hospital_transparency_report_2_final.pdf. Furthermore, according to one analysis, "340B margins account for 77 percent of all revenue from the sale of brand medicines received by US pharmacies and providers (both 340B and non-340B entities)—up from just 14 percent in 2013." *See* Blalock et al., *The Pharmaceutical Supply Chain, 2013–2023*, *supra*, at 4 ("Pharmacies and 340B providers—including eligible clinics and hospitals (and often hospitals' off-campus outpatient departments)—are increasingly leveraging the 340B program to raise profits on the sale and administration of brand medicines."). These price markups line the pockets of large PBMs and their affiliates at the expense of employers, their employees, and patients in low-income communities. *See infra.*

II. The price-distorting effects of the 340B Program increase costs for employers, which miss out on rebates from 340B purchases.

While extant Medicare and Medicaid rebate-driven prescription drug pricing models pose challenges for employers and purchasers, at least a portion of the rebates negotiated by PBMs under those programs are passed onto employers. Within the 340B Program, however, any discounts inure to the benefit of the *covered entity*, not to the purchasers of a drug. As a result, the price-distorting effects of the 340B Program increase costs for self-insured employers, which miss out on rebates from 340B purchases. *See* Chuan Sun, et al., *The Cost of the 340B Program Part 1: Self-Insured Employers*, IQVIA, 9 (2024), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/iqvia-cost-of-340b-part-1-white-paper-2024.pdf (finding that the 340B Program "increases drug costs for self-insured employers and their workers by 4.2% due to the manufacturer rebates that are lost when drugs are purchased at the 340B discount price," a figure which translates "to a $5.2 billion increase in healthcare costs for self-insured employers" and their 103.4 million workers). Similarly, the costs of the 340B Program to employer-sponsored health plans is substantial, although there is wide variation across states, owing to disparate 340B utilization rates

and a diverse patchwork of contract pharmacy laws. Chuan Sun, et al., *The Cost of the 340B Program to the States*, IQVIA, 10 (2025), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2025/iqvia-cost-of-340b-to-states-whitepaper-2025.pdf. As a result, contrary to the Program's stated objective of lowering health care costs, "in some states, employers and workers are being asked to pay a disproportionate share of the cost of the 340B program." *Id.* And yet, owing to "a lack of transparency regarding how the [P]rogram raises costs, employers and workers" are often unaware of the extent of its adverse economic impact. *Id.* In sum, it is clear that pervasive 340B Program abuse only exacerbates these financial strains on employers, purchasers, and working families. Meanwhile, large corporate hospitals, contract pharmacies, and PBMs profit through consolidation, pricing markups, and insurance reimbursements, all without necessarily improving access to care or passing savings along to underserved communities.

III. While legislative reform is necessary to ameliorate Program dysfunction, effectuate the aims of section 340B, and embolden transparency, courts have a vital role in constraining the Program's excesses by faithfully interpreting the 340B statute.

As the foregoing data demonstrates, employers and purchasers—and the nearly 180 million[6] individuals who receive their health coverage through their employers—are spending billions of dollars more in health care costs due to the expansion of the 340B Program. Thus, the National Alliance has called on Congress to enact comprehensive reform to the 340B Program to ameliorate dysfunction and abuse, and render it a more effective and transparent patient-assistance

[6] *See* Thom Bales & Ruchita Kewalramani, *Employer Benefits Perspective Survey*, PwC, https://www.pwc.com/us/en/industries/health-industries/library/employer-benefits-perspective-survey.html#about (noting estimate that "nearly 180 million working Americans receive health insurance coverage through their employer").

mechanism directed at core safety net providers—thereby better safeguarding the interests of employers, purchasers, and working families.

As this case demonstrates, the dominance of the 340B Program by large hospital covered entities, PBMs, and their affiliates has been facilitated and enabled by HRSA's failure to adequately police covered entity noncompliance and eliminate unlawful duplicate discounting and diversion—even though these unlawful practices have been uncovered by the agency's own audits. *See* U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, 13 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf (reporting a total of 1,536 findings of covered entity noncompliance between 2012 and 2019, including 546 instances of diversion and 429 instances of duplicate discounts).[7] While recent efforts at emboldening transparency have permitted stakeholders to identify the extent of 340B revenues *system-wide*, discrete hospital systems are still not required to disclose their revenue from pricing arbitrage, nor the percentage of those funds that they expend on charity care. As noted *supra*, when the 340B Program was enacted, HRSA anticipated that covered entities would either "pass all or a significant part of the discount to their patients," or "us[e] the savings to reach more eligible patients and provide more comprehensive services." 61 Fed. Reg. 43,551 (Aug. 23, 1996). But existing research has indicated a concerning lack of investment in charity care, even by 340B hospitals. *See* Masia, *Comparing the Financial Health and Charitable Care of 340B and Non-340B Hospitals*, *supra* note 3, at 3, 12, 13 (finding

[7] In fact, the degree of Program abuse is likely far worse than the limited data suggest: for example, HRSA's audits of covered entities cannot reveal the full extent of potential duplicate discounts because they focus solely upon Medicaid fee-for-service arrangements and do not review Medicaid managed care claims. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, 39 (June 2018), https://www.gao.gov/assets/d18480.pdf.

that "340B participation is not associated with any increase in charity care for 340B hospitals, on average"; on the contrary, "340B hospitals with the highest operating margins in 2021 provided significantly less charity care than the non-340B hospitals with the highest operating margins"; and "the top quintile of 340B hospitals based on operating margins earn $9.92 in profit for every dollar they spend on charity care compared to $7.51 for the top quintile of non-340B hospitals"). Even so, much of the existing data on price markups is sourced from covered entity self-reporting. *Cf.* Community Oncology Alliance, *Examining 340B Hospital Price Transparency, Drug Profits, and Incentives*, *supra*, at 2, 3 (analyzing markups in 340B cancer drug prices based on covered entities' self-reported data).[8] Absent a mandatory public disclosure regime, the 340B Program will remain opaque, effective legislative oversight will be frustrated, and employers, purchasers, and working families will continue to have difficulty ascertaining the extent to which they are ultimately footing the bill for the Program—all while DSHs, PBMs and their affiliates benefit from substantial markups in covered drug sales. *Cf.* Chuan Sun, et al., *The Cost of the 340B Program to the States*, *supra*, at 10 (noting that owing to "a lack of transparency regarding how the [P]rogram raises costs, employers and workers" are often unaware of the extent of its adverse economic impact). And yet, while legislative reform is necessary to ameliorate Program dysfunction, effectuate the aims of section 340B, and embolden transparency, courts have a vital role in constraining the Program's current excesses by faithfully interpreting the 340B statute.

* * *

[8] A prudent and straightforward reporting requirement would mandate, at a minimum: (1) reporting by hospitals on the aggregate revenue derived from 340B price arbitrage at the system, hospital, and child-site levels; (2) reporting by contract pharmacies on their revenue derived from 340B sales; and (3) an accounting of how (if at all) hospital systems have re-invested their 340B revenues into underserved, rural, and low-income communities. *See* Gremminger, *Oversight of the 340B Drug Pricing Program*, *supra*, at 9.

Of course, this tribunal is not the proper forum for advocating legislative reform; however, the endemic issues in the 340B Program and the need for exigent policy changes are worthy of consideration in the instant case, given the difficult interpretive task courts often confront in construing 42 U.S.C. § 256b. Indeed, several recent court decisions construing the 340B statute have either (a) operated to expand the scope of the Program by broadly interpreting undefined statutory terms, or (b) upheld state legislative intermeddling in the face of preemption challenges. *See, e.g.*, *Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 324–26 (D.S.C. 2023) (rejecting HRSA's interpretation of "patient of the entity" under 42 U.S.C. § 256b(a)(5)(B)); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1139–40 (8th Cir. 2024) (rejecting a preemption challenge to Ark. Code Ann. § 23-92-604(c), which prohibits manufacturers from limiting covered entities' ability to contract with outside pharmacies), *cert. denied*, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024). Either way, these rulings will have the unintended effect of enabling further arbitrage, abuse, and unaccountability, as third-party involvement continues to mount.

The *Genesis* decision is particularly instructive. There, the District of South Carolina interpreted the phrase "patient of the entity" as used in the 340B statute: "[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a *patient of the entity*." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). As the court explained, although "the [340B] statute defines other terms, [it] does not define 'patient,' nor does it contain a requirement that a prescription originate from a 'covered entity' in order for an individual to be consider[ed] an eligible 340B patient." *Id.* at 324. And so, in 1996, attempting to arrive at a reasonable definition, HRSA promulgated a guidance document purporting to define the term "patient of a covered entity" under the 340B

statute. *Id.* at 318–19 (citing 61 Fed. Reg. 55,156)). The guidance provided, in relevant part, that an individual would be considered a patient of a covered entity only if:

> 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare; and
>
> 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity . . . .

Id. (quoting 61 Fed. Reg. 55,158). In light of the above, in *Genesis*, "HRSA maintain[ed] that in order for an individual to qualify as a 'patient' of a 'covered entity' under the 340B Program, the prescription for the 340B drug must originate from a health care encounter with [a covered entity,] or one of its contract health care providers." *Id.* at 321. On the other hand, Genesis (the covered entity) urged that, "pursuant to the plain wording of the 340B statute, the only requirement for an individual to be 340B eligible is for that individual to be a 'patient' of a 'covered entity.'" *Id.* at 321–22 (citing 42 U.S.C. § 256b(a)(5)(B) ("[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is *not a patient of the entity*") (emphasis added)).

Invoking the ordinary meaning of "patient," the court held that HRSA's interpretation of the term "was contrary to the plain language of the 340B Statute." *Id.* at 324–25. Embracing a comparatively broad reading of the term, the court reasoned that "[n]othing in the statute conditions an individual's eligibility as a 340B patient on whether the health care service resulting in the prescription was initiated by the 'covered entity." *Id.* In so doing, the court rejected HRSA's purportedly "restrictive interpretation of the statutory term 'patient'" as "unpersuasive." *Id.* Although the "[c]ourt agree[d] that the statute does require an ongoing patient relationship between the individual and the 'covered entity,'" it "disagree[d] with [Genesis's] position that the 340B

drug prescription must originate from the ongoing relationship between the individual and the 'covered entity.'" *Id.* at 326. Finally, consulting the structure of the statute and Congressional intent, the court concluded that HRSA's narrow construction "limits the scope of the 340B Program, limits the profitability of 'covered entities,' and frustrates the goal of the 340B statute," which, the court explained, "is to make 'covered entities' profitable in the face of the prescription drug price increases that followed the Medicaid Drug Rebate Program and that continue to this day." *Id.* at 330. Accordingly, the court enjoined HRSA from enforcing its more restrictive interpretation of "patient" against Genesis. *Id.* at 331–32.

Although the *Genesis* ruling is being construed to only apply to one, discrete covered entity, the decision has engendered uncertainty as to the definition of "patient" under the 340B statute, the import of the holding to HRSA's prospective enforcement actions, and how the court's analysis will affect covered entity and manufacturer compliance *writ large*. Moreover, the lack of a coherent limiting factor on who is a "patient" of a covered entity for the purposes of 340B could lead to an even more rapid expansion in the size of the Program in the future—and a continued proliferation of contract pharmacy relationships—further harming employers, purchasers, and working families.

While any prospective statutory reform is, of course, in Congress's sole preserve, the instant case raises similar questions of statutory interpretation with respect to the meaning of the term "price" under the 340B statute. *See* 42 U.S.C. § 256b(a)(1) (providing that each agreement, known as a Pharmaceutical Pricing Agreement (PPA), "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling *price* if such drug is made available to any other purchaser at any price (emphasis added)). The National Alliance urges this Court to reject HRSA's extra-textual interpretation of § 256b(a)(1) in this case.

If allowed to stand, HRSA's reading of § 256b(a)(1) will only serve to impede lawful attempts to enhance transparency under the existing statutory regime, further compromise Program integrity, increase the leverage that PBMs and contract pharmacies exert, encourage duplicate discounting and diversion by covered entities, and thus impose additional, unnecessary costs on employers, purchasers, and working families.

CONCLUSION

For the foregoing reasons, the National Alliance respectfully requests that this Court grant summary judgment in Johnson & Johnson Health Care System Inc.'s favor.

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Respectfully submitted,

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COMBINED CERTIFICATIONS

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

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

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

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

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

Dated: February 12, 2025 */s/ Michael E. Blumenfeld*