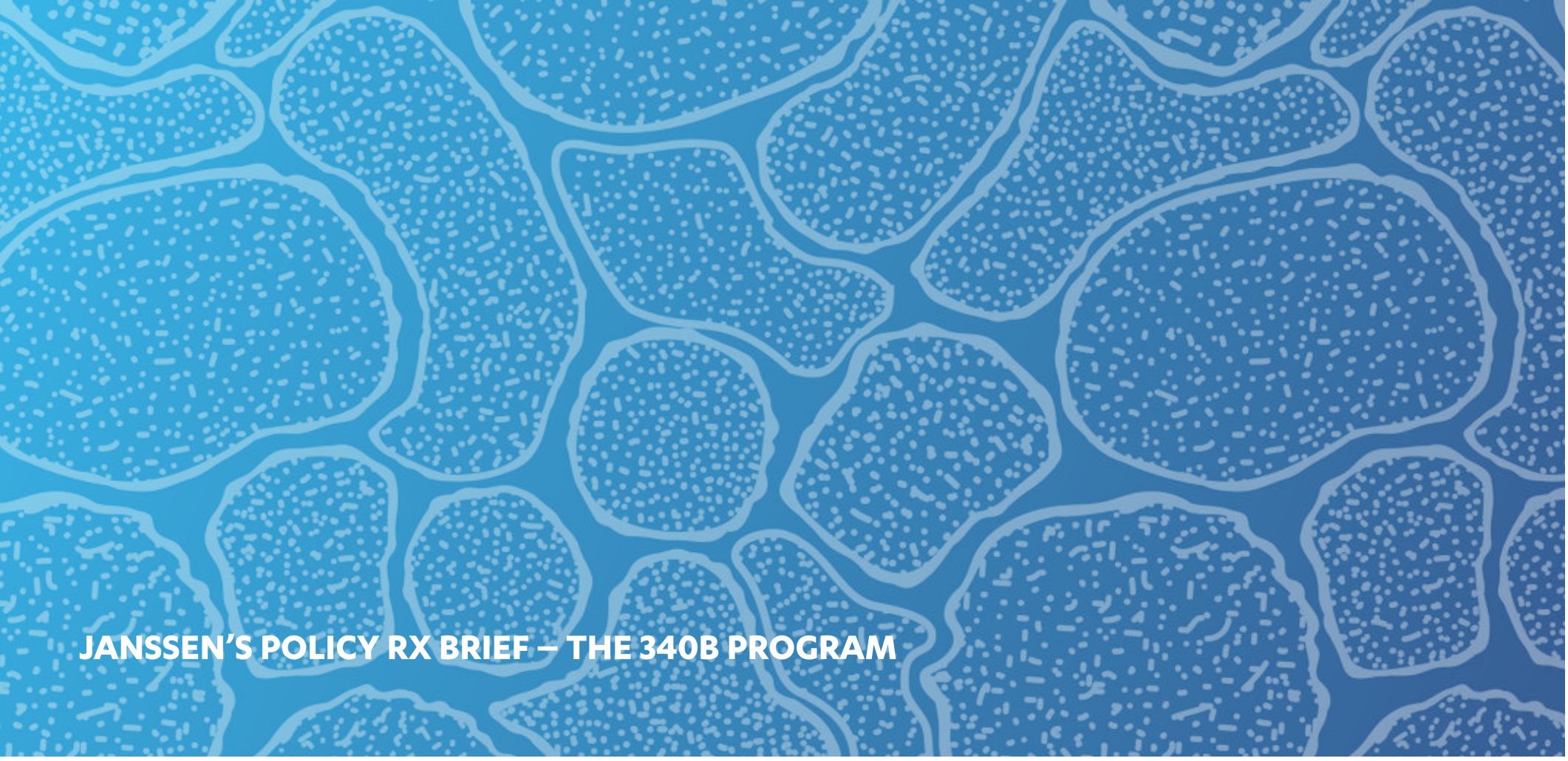


JANSSEN'S POLICY RX BRIEF – THE 340B PROGRAM

How Arbitrage, Opportunism and Opacity Undermine the Program's Original Purpose

Image Info: Microscopic photograph of virus cells and microbes.

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

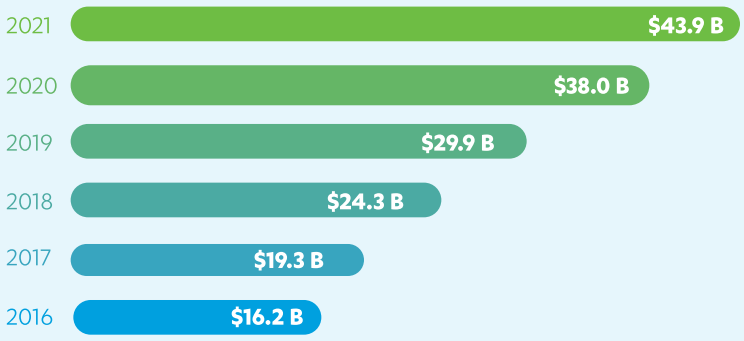
Executive Summary

Over the last 30-plus years, biopharmaceutical advances have transformed how we prevent, treat and cure disease. But many parts of our healthcare system still operate on decades-old programs which undermine the significant progress for patients made through medical innovation. A prime example is the 340B Drug Discount Program, which is rife with arbitrage, opportunism and opacity that benefits large for-profit entities at patients' expense.

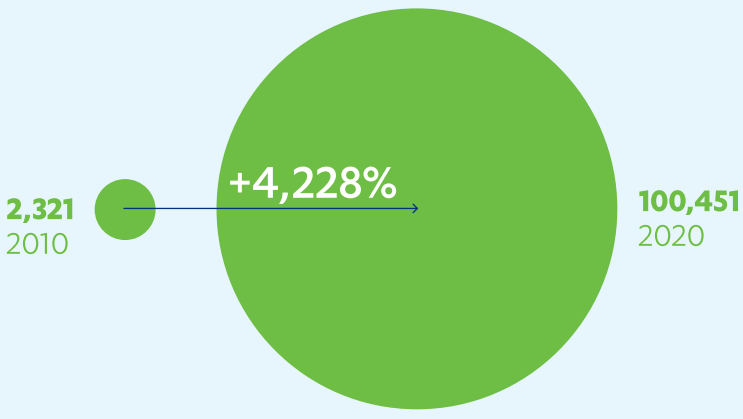
The 340B Drug Discount Program is fundamentally broken – and it is not serving patients in the way that was intended. Significant incentives for financial gamesmanship and lack of transparency throughout the program have moved the program far beyond its original intent and structure.

The 340B Program

Purchases at discounted 340B prices (billions)[1]



At **$43.9 billion** per year (and growing), the 340B Program is now the **second largest** federal prescription drug program after Medicare.[1, 2]



Contract pharmacy arrangements shot up +4,228%, leading to more drugs bought at 340B discounts and the outsized program we have today.[3]

Arbitrage

340B covered entities, including many hospitals, purchase drugs at significant discounts but bill patients and insurers at higher prices. Increasingly many use contracted pharmacies and split the financial windfall with these for-profit entities.[4]

The *New York Times* noted in an investigative report on the 340B program that:

↑7x One healthcare system charged as much as seven times the amount it paid for a particular cancer drug – per patient.[5]

Opportunism

The 340B Program was never intended to subsidize retail pharmacy chains such as CVS and Walgreens. Yet that's what is happening.

As of July 2022, nearly 32,000 pharmacy locations were contract pharmacies – more than 50% of the entire U.S. pharmacy industry.[6, 7]

Opacity

1 out of every 5 dollars

The 340B program now represents nearly 1 out of every 5 dollars of the total manufacturer rebates and discounts provided each year.[8] But independent research was unable to find a link between hospitals' 340B participation and expanded support in vulnerable communities.[9]

Final Rx: Where We Stand

Janssen supports the original intent of the 340B program, but with more transparency, we believe two important developments are possible: **patients could more directly benefit from discounts and there will be more resources available to support innovation.**

Introduction

The Diagnosis: The 340B Drug Discount Program is fundamentally broken – and it is not serving patients in the way that was intended. Significant incentives for financial gamesmanship and lack of transparency throughout the program have moved the program far beyond its original intent and structure.[10] While we support the original intent of the 340B program, a reevaluation of the program is necessary to ensure discounts provided through the program benefit patients in need efficiently, transparently and effectively. This reevaluation should help put the program on a sustainable path to ensure the neediest patients are benefitting the most from it.

Over the last 30-plus years, biopharmaceutical advances have transformed how we prevent, treat and cure disease. While this transformative progress has been embraced in certain parts of our healthcare system, many parts still operate on decades-old models and programs which undermine the significant progress for patients made through medical innovation. A prime example is the 340B Drug Discount Program.

Established in 1992, the 340B Drug Discount Program was designed to fix an unintended problem created by the Medicaid Drug Rebate Program ("MDRP") enacted two years earlier.[10] (See MDRP Call Out Box)

From this narrow, limited purpose, 340B has grown to be a major part of our health system – impacting and conflicting with other systems and processes in ways Congress never intended. The 340B program requires drug manufacturers to provide steep discounts on outpatient drugs to certain, specified safety net providers (known as "covered entities," and specifically enumerated in the statute).[10] Since the program launched in 1992, the U.S. healthcare system has changed significantly, and the 340B program has ballooned into the second largest federal prescription drug program.[2] It is expected to become the largest by 2026.[11]

Explosive Growth with Questionable Benefit to Patients

The explosive growth has been driven largely by factors that were not intended in 1992 and are not supported by the statute today – including how for-profit chain pharmacies and vertically integrated pharmacy benefit managers (PBMs) have inserted themselves to capture a larger and larger share of 340B discounts. These financial arrangements leverage low 340B prices to generate high profits for large for-profit entities with no reporting of whether or how this funding benefits patients in any way. The lack of transparency into these arrangements and the accompanying financial windfall to commercial, for-profit entities underscore a simple fact: this was never the program's original intent. 340B was designed to restore discounts for a targeted set of safety-net providers serving their own patients (see callout).[12] **Its massive and uncontrolled expansion now threatens that important, limited purpose.**

Origins of the 340B Drug Discount Program

In 1990, the MDRP established a requirement for manufacturers to extend their "best price" to Medicaid programs. Prior to MDRP, manufacturers had voluntarily and regularly offered discounts to hospitals and other safety-net providers without impact to Medicaid rebates.[13] But starting in 1990, those steep, voluntary safety-net discounts triggered increased Medicaid rebates. This unintended Medicaid consequence impeded manufacturers from continuing to make voluntary discounts available to safety net providers. Thus, the 340B program's limited purpose was to restore outpatient drug discounts to certain, specified safety net providers that directly purchased and dispensed drugs to their own patients, without having those discounts affect the best price calculation.[13]

Safety Net Providers

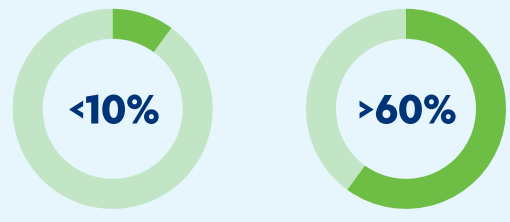
Providers organizing and delivering a significant level of healthcare and other related services to uninsured, Medicaid and other vulnerable patients.[14]

Disproportionate Share Hospitals (DSH)

Hospitals serving a significantly disproportionate number of low-income patients and receiving payments from the Centers for Medicare and Medicaid Services to cover the costs of providing care to uninsured patients.[15]

Hospital Covered Entity Sites

Including Child Sites[12]



Prior to 2004, hospitals represented less than 10% of covered entity sites (including child sites); by 2020 they made up just over 60% of covered entity sites.

How 340B Got So Big

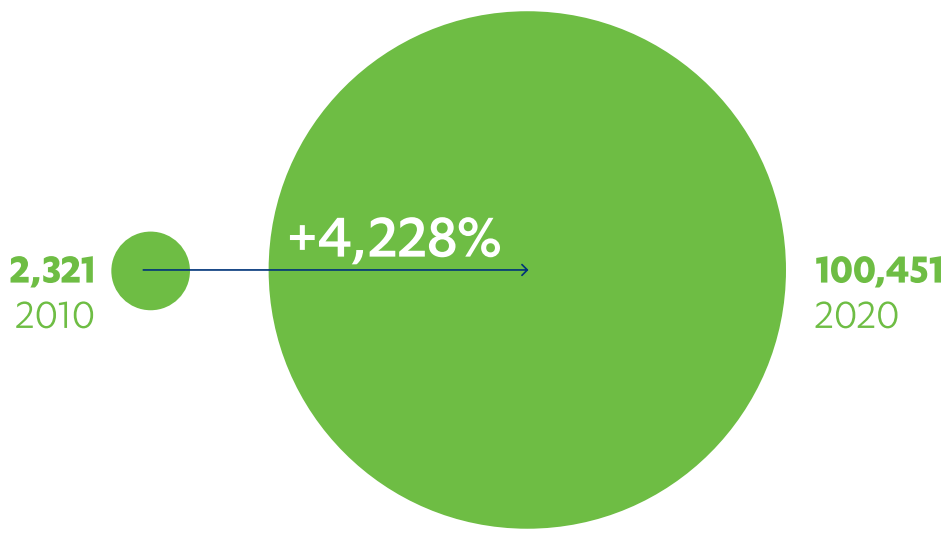
At $43.9 billion per year (and growing), the 340B Drug Discount Program is now the second largest federal prescription drug program after Medicare.[2]
The 340B program, meant to be an incidental "fix" to a Medicaid rebate issue, now is larger than the entire Medicaid rebate program.[2] 340B will likely be the largest federal drug program by 2026.[11]

Most of this growth came after Health Resources and Services Administration (HRSA) issued non-binding, or "sub-regulatory," guidance in 2010, which purported to allow covered entities to expand 340B into an unlimited number of contract pharmacy arrangements.[12] (Contract pharmacy arrangements are not mentioned in or required by the statute). When HRSA took this step–without statutory authority–covered entities, pharmacy chains and PBMs gained power through consolidation and vertical integration.[3, 16, 17] They then used this power to distort the 340B program and seized financial gains for themselves.[18]

As a result, contract pharmacy arrangements shot up, leading to more drugs bought at 340B discounts and the outsized program we have today.[1, 6]

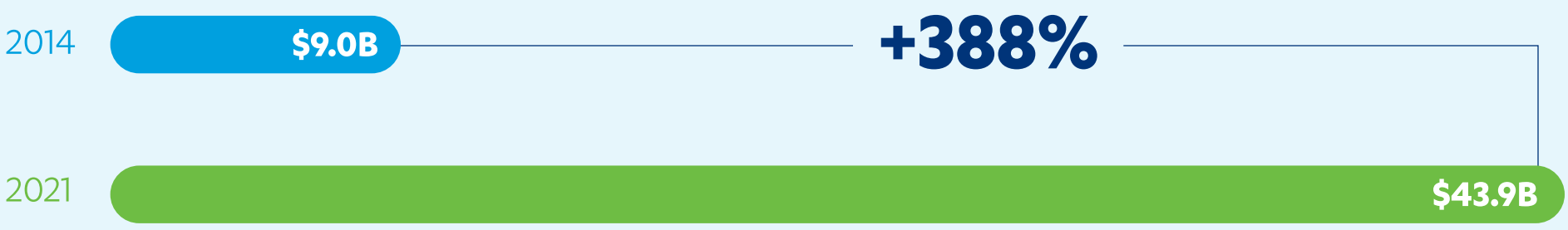
Contract Pharmacy Arrangement

Between April 1, 2010, and April 1, 2020, the number of contract pharmacy arrangements increased from 2,321 to 100,451 – a 4,228% increase.[3]



340B Drug Pricing Program

Purchases by covered entities at discounted 340B prices[1, 8]



Final Rx: For patients, the growth in these contract pharmacy arrangements seems to have limited benefit.[19, 20, 21] In fact, it creates perverse incentives within the program can lead to higher profits for hospital systems, contract pharmacies and PBMS, and has been associated with higher out-of-pocket costs for patients.[22, 23]

Arbitrage, Opportunism, Opacity

The 340B program, which was created with a limited, but important purpose – to restore significant discounts on prescription drugs to certain safety net providers – **is ballooning out of control as major hospital systems and large, commercial companies capitalize on:**

Arbitrage | **Opportunism** | **Opacity**

Covered entities are currently using the program to reap significant financial windfalls using a complex web of large for-profit pharmacies and PBMs. This happens through a "buy low, sell high" arbitrage-like scheme among these companies leveraging "contract pharmacy" relationships. Critically, this windfall from 340B discounts does not reach those patients who continue to pay full price for those drugs.[24]

The New York Times Investigation Highlights Hospitals 340B "Arbitrage"[5]

The New York Times investigated how one healthcare system in Richmond, Virginia uses the 340B Drug Discount Program to financially benefit itself at the expense of vulnerable patients. The *Times* investigation found that:

"Starting in the mid-2000s, big hospital chains figured out how to supercharge the program. The basic idea: Build clinics in wealthier neighborhoods, where patients with generous private insurance could receive expensive drugs, but on paper make the clinics extensions of poor hospitals to take advantage of 340B."

Under "contract pharmacy" arrangements with large hospital chains or PBMs, 340B covered entities, including many hospitals, purchase drugs at significant discounts; a contracted pharmacy dispenses the drugs and bills insurers at a higher price; and they split the financial windfall – almost invariably leaving the patient without any benefit at the pharmacy counter.[24, 25] The 340B program does not require covered entities to pass the 340B discount along to patients, even uninsured and indigent patients.[24] Patients typically pay the co-insurance or co-pay set by their insurance or the full market price if they don't have insurance.[24] Through these contract pharmacy arrangements, which have increased more than 42x (4,228%) since 2010, nearly half of the country's retail, mail and specialty pharmacies, capture profits exceeding $10 billion annually.[3, 6]

Patients, policymakers and other healthcare stakeholders have no visibility into how hospitals, for-profit contract pharmacies and PBMs are using the 340B financial windfall. "Most 340B-eligible patients appear to have no direct benefit – a recent analysis found substantial evidence of patient discount sharing in only 1.4% of eligible pharmacy claims."[24]

Arbitrage, opportunism and opacity have supercharged the financial windfall benefiting certain companies and unsustainable expansion of 340B.

Arbitrage

Hospital systems are using "arbitrage" for financial gain by acquiring outpatient clinics that provide drug-intensive healthcare services, like cancer treatment, and converting to 340B.

This financial-growth strategy gives them access to low 340B pricing on medicines, even as government and private insurers reimburse these covered entities for those medicines at different rates.[12] Exploiting this arbitrage by marking up drug costs, hospitals (and hospital-owned clinics) pocket the resulting financial windfall, with little transparency into how these gains are used.

The *New York Times* noted in an investigative report on the 340B program that:

> one healthcare system charged as much as **seven times** the amount it paid for a particular cancer drug – per patient.[5]

Another recent report from the Community Oncology Alliance noted:

> "340B hospitals' own self-reported pricing data reveals that they price the top oncology drugs at **4.9 times** their 340B acquisition costs..."[26]

Large pharmacy chains, some owned by big PBMs, also profit from 340B, exploiting the arbitrage currently available in the system. In these arrangements, covered entities buy a drug at a 340B price, the commercial pharmacy charges a higher price to the patient or insurer and the financial windfall is split with the large commercial pharmacy that dispenses the prescription.

Another perverse financial incentive that has developed is that 340B-covered facilities access – and profit from – 340B pricing on outpatient drugs for all their patients, regardless of the patient's need.[19] This means 340B covered entities access 340B pricing even on wealthy patients with comprehensive, well-paying insurance.

A recent study in the *Journal of the American Medical Association (JAMA) Internal Medicine* concluded that, in 340B, "[h]ospitals may earn greater revenue per unit from cancer therapies than the pharmaceutical companies that manufactured them."[27] Again, in many cases, the discounts benefit large, commercial contract pharmacies.

A recent analysis investigated how 340B hospitals purchased 59 oncology treatments covered by Medicare Part B at the 340B discounted price. The hospitals then substantially marked up the drugs' prices before billing patients – even uninsured patients – at this higher price.[28] Because of this markup, the study also found, uninsured cancer patients had to pay for life-saving medicines at a median price up to 3.8 times the hospitals' cost to acquire them, and up to 15 times the reimbursement that Medicare would provide.[28]

While this arbitrage has driven clear financial gain for many large healthcare systems, hospitals and large commercial pharmacies, the lack of transparency of how and whether these profits are being used for health care delivery is problematic. In fact, a study in the *New England Journal of Medicine* found "no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients or enhance care for low-income groups in ways that would reduce mortality."[16]

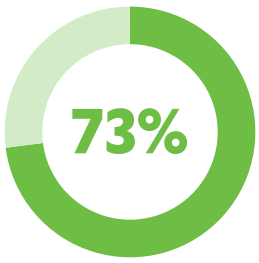
Similarly, a recent study in the *American Journal of Managed Care* noted "because hospital participants have a greater potential to profit from 340B, it is reasonable to assume that they may be more likely to pursue contracts in counties that target their higher-income and well-insured patients."[20]

Two experts came to similar conclusions, noting in a study in *Health Affairs* **"...our findings support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics."**[29]

Opportunism

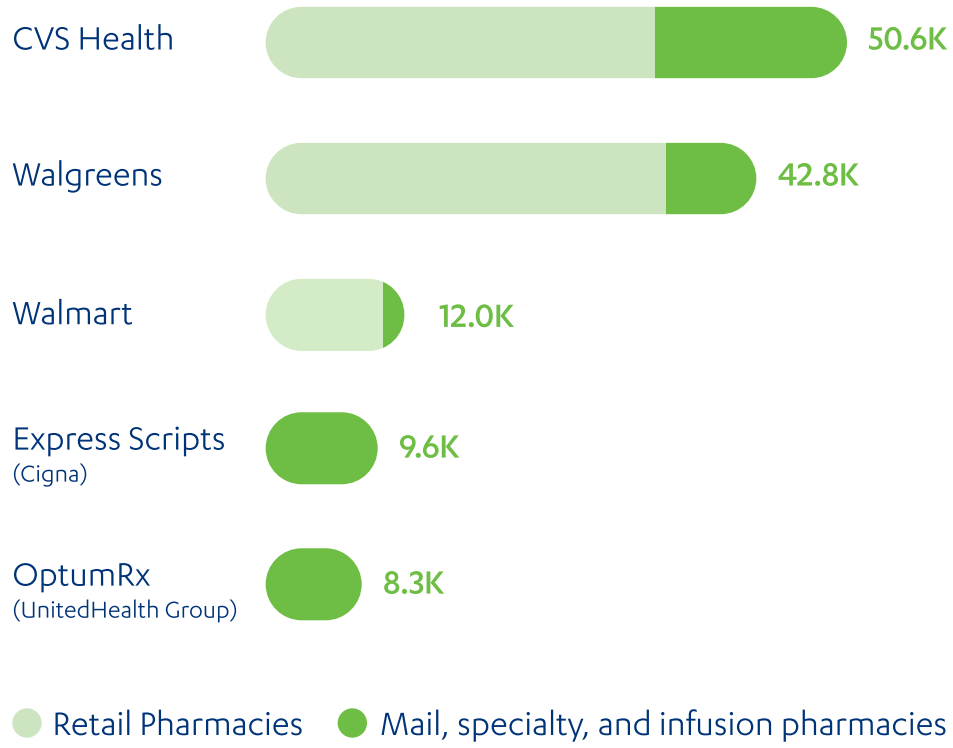
The 340B Program was never intended to subsidize retail pharmacy chains such as CVS and Walgreens. Yet that's what is happening.

As of July 2022, nearly 32,000 pharmacy locations were contract pharmacies–more than 50% of the entire U.S. pharmacy industry.[6, 7]



Five of the largest retail pharmacies and PBMs (all of which are part of the Fortune 25)–including Walgreens, Cigna, CVS Health, UnitedHealth Group and Walmart–represent 73% of all contract pharmacy relationships with covered entities.[6, 30]

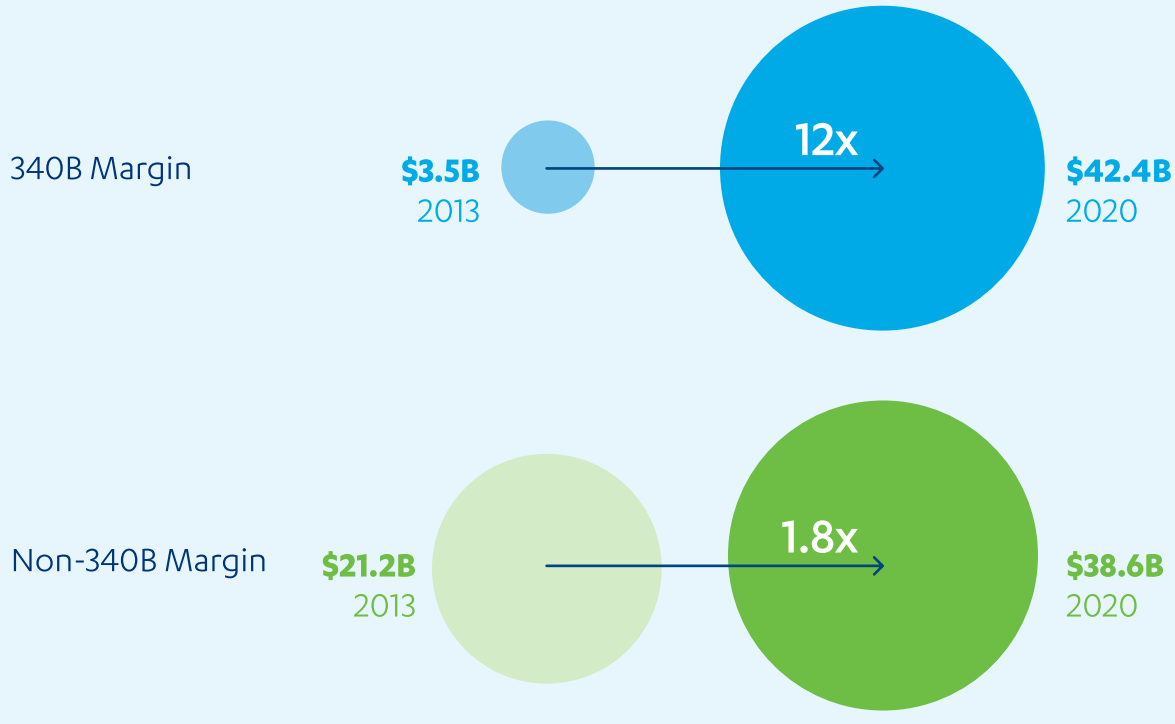
340B Contract Pharmacy Relationships, 2022[6]



PBMs' and retail pharmacy chains' size and power accelerated program growth, extracted the benefit of 340B discounts from the health system and enabled them to pocket funds meant to help support certain safety-net hospitals and covered entities.[3] In fact, 340B profits for providers and their contract pharmacies have increased twelvefold since 2013.[31] And the margins made through the program account for more than half of the revenue that all pharmacies and providers (340B and non-340B alike) make from the sale of branded medicines.[31]

Total U.S. Pharmacy and Provider Gross Margin[31]

Sales of Brand Medicines ($B)



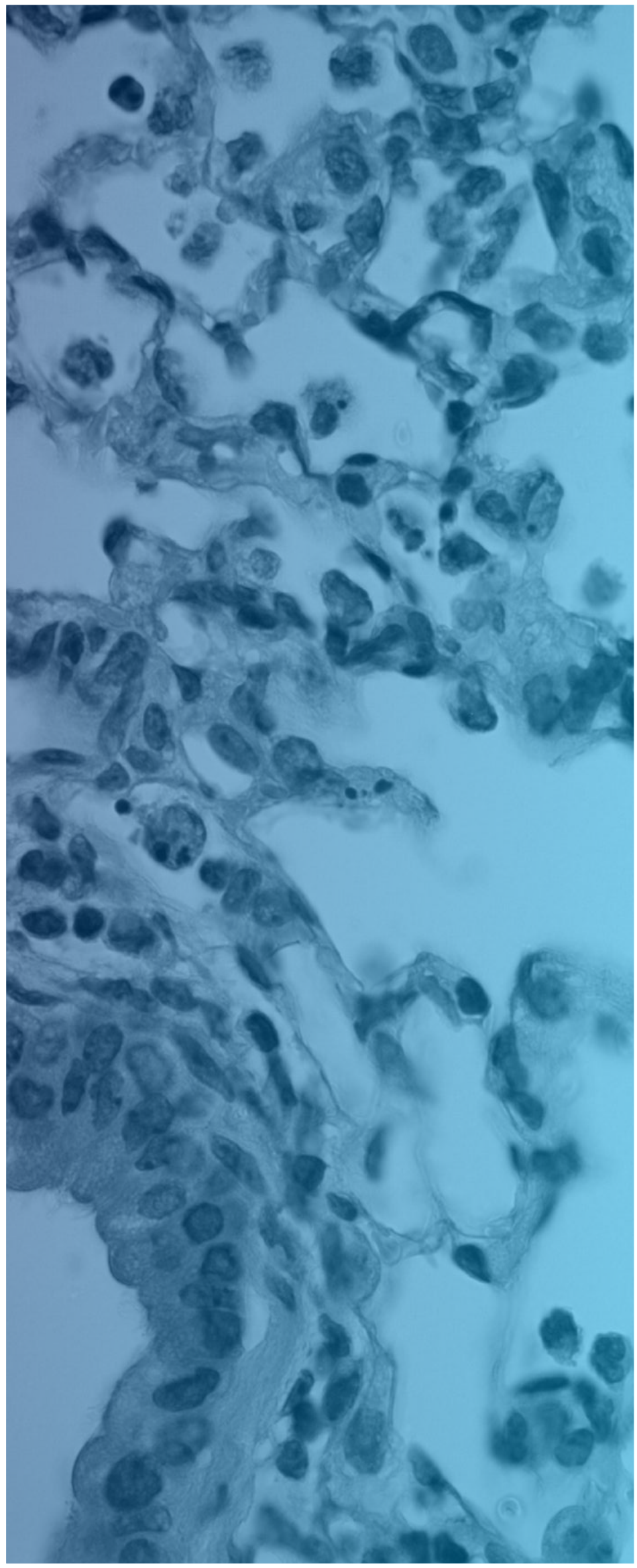
While 340B expansion has been a *bottom-line boon* for hospitals, for-profit pharmacy chains and big PBMs, **there is growing evidence the program is not serving those the program is meant to help.** Today, just 38% of 340B hospitals designated as "disproportionate share hospitals" are in medically underserved areas (defined by HRSA as areas or populations designated as having too few primary care providers, high infant mortality, high poverty or a high elderly population).[32] At the same time, contract pharmacies proliferate in affluent neighborhoods, while the share of 340B pharmacies has declined in low-income areas.[19]

340B Profits Meant to Support Safety Net Facilities and Their Underserved Patients Are Benefiting For-Profit, Fortune 25 Companies

According to an analysis "Contract pharmacies earn **25% to 35% of total 340B discounts**. For the top five contract pharmacy players, that translated into **$3.2 billion in 2021** and a projected **$2.9 billion in 2022**."[33]

These five companies include the following:
Fortune ranking based on annual revenues[30]

- #1 Walmart
- #4 CVSHealth
- #5 UnitedHealth Group
- #12 Cigna
- #18 Walgreens



Pictured: Hematoxylin and eosin stainedmouse lung treated with PolyI:C.

Opacity

Because 340B was designed and intended as a limited program to restore discounts to certain safety net providers, the program does not include transparency reporting typically seen in other, even much smaller, programs. **Hospitals and covered entities are under no obligation to disclose how their financial gains from 340B discounts are being used and whether patients are benefiting from the discounts.**

Right now, $44 billion in healthcare resources are funneled into what's essentially a black box of financial gamesmanship and a windfall for large hospitals, for-profit retail pharmacy chains and PBMs.[1]

1 out of every 5 dollars

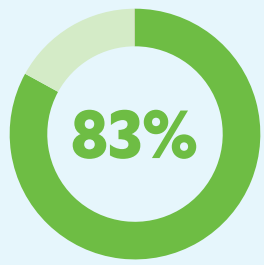
In fact, the **340B program now represents nearly 1 out of every 5 dollars of the total manufacturer rebates and discounts** provided each year.[8]

But there is no real data that demonstrates how this is benefiting patients. The unchecked growth also, as one recent report put it, "...has had unintended consequences and may contribute to shifts in the site of care, which can increase costs to both payers and patients."[2]

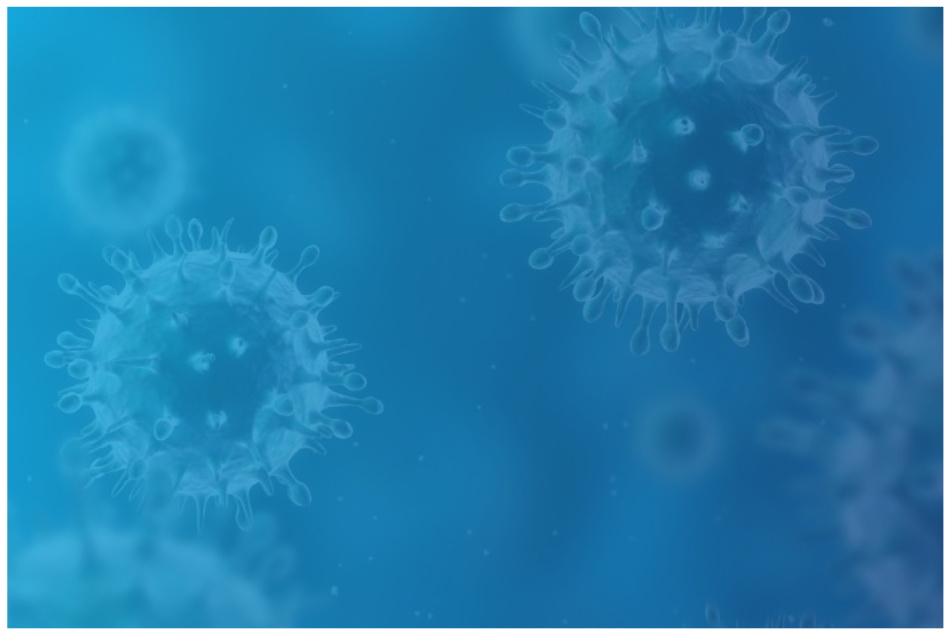
Lack of transparency also results in duplicate discounts and diversion, which are specifically prohibited by the 340B statute.[34]

Diversion is where a 340B drug is provided to an individual who is not a patient of the covered entity.[24] Duplicate discounts happen when manufacturers provide multiple discounts on the same prescription. The statute specifically prohibits 340B duplicate discounts under Medicaid and many commercial duplicate discounts are prohibited by contract.[34]

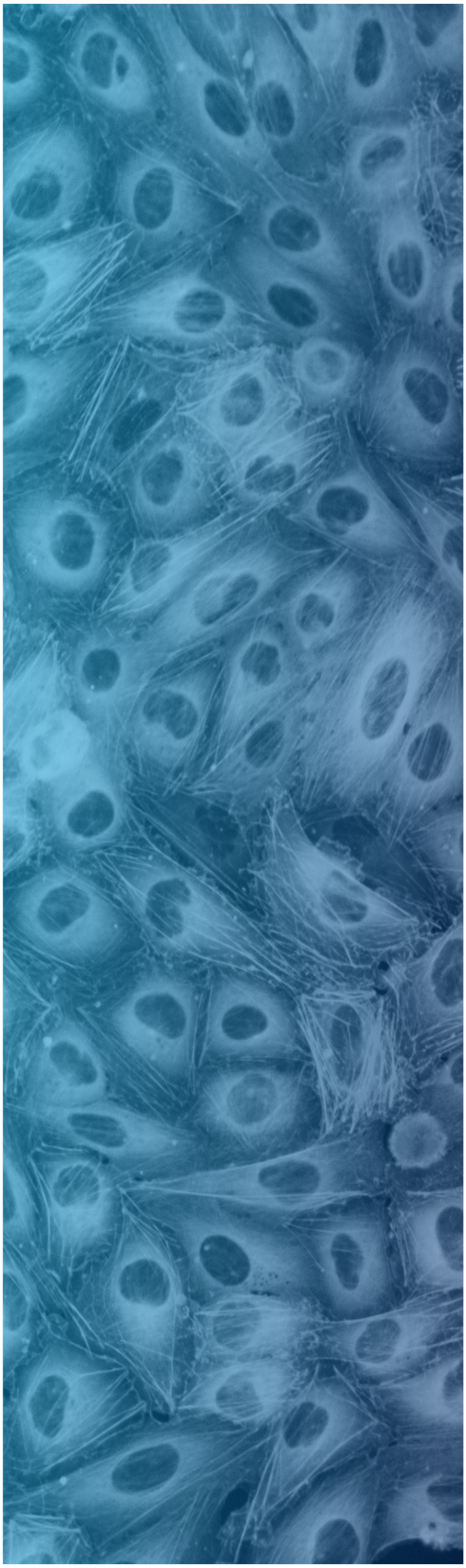
Some 340B hospitals receive more in tax breaks than they provide in charity care, strongly questioning the proper use of 340B profits. A recent evaluation of 275 non-profit private hospital systems (representing over 1,800 individual hospitals) found that 83% of the systems spent less on charity care and community investment than they received in tax breaks in the same year.[35] Of the 10 hospitals with the greatest share deficit, all are 340B entities.[36]



83% of private nonprofit hospitals spent less on charity care and community investment than they received in tax breaks in the same year.[35]



Pictured: Influenza Virus.



Pictured: U2OS Osteosarcoma Cells.

Final Rx – Where We Stand

Janssen supports the original intent of the 340B program. Congress created a balanced program designed to allow manufacturers to restore the discounts that they had traditionally provided to safety net providers, before enactment of the Medicaid Drug Rebate Program, while protecting against duplicate discounts and diversion.

As the program has grown exponentially in recent years, we believe steps must be taken to ensure that duplicate discounts and diversion are limited. More broadly, we think that reform of the program should require that the benefit of discounts be made directly available to patients at the pharmacy counter. We will continue to advocate for a 340B program that truly benefits patients and prevents for-profit intermediaries from seizing discounts meant for patients and that reduces resources available for investments into future innovation.

A lack of transparency in the program limits stakeholders' ability to monitor the program for diversion and duplicate discounts, which are illegal. We believe that this greater transparency will make the program more sustainable.

With more transparency in the 340B program, we believe two important developments are possible:

Patients Could More Directly Benefit from Discounts:

Without reform and more transparency, it is not clear that patients directly benefit from 340B discounts. This is critical to ensure patients do not pay more than they should to access life-saving treatments.

More Resources Available to Support Innovation:

While hospitals and healthcare systems continue to use the opacity of the program to their benefit, this comes at a significant cost to future innovation. As the 340B program discounts grow each year, those increased discounts reduce the resources available for future investments into tomorrow's treatments and cures. Without reform this will undermine our nation's innovation ecosystem.

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