PhRMA

Solutions for a Healthier America

Policies to Preserve and Strengthen American Leadership in Biopharmaceutical Innovation

Index

Overview

We believe in the opportunity for a healthier future

We develop innovative medicines that transform lives and create a **healthier** world, and we fight for **solutions** to ensure patients can access and afford the medicines that prevent, treat and cure disease.

Scientific advances are transforming how we fight disease

- 8,000 medicines in development
- An average of 74% of drugs in the clinical pipeline are potential first-in-class medicines

Medicines and vaccines prevent disease and more expensive health care

- 35% of the improvements in life expectancy from 1990 to 2015 are attributable to medicines
- Government savings from hepatitis C drugs are soon expected to reach $43 billion, even after accounting for the cost of the medicines

Our unique system balances innovation and affordability

- The U.S. saved $445 billion in 2023 from using generics and biosimilars

Americans have more medicine choices than people living anywhere else in the world

- Americans have access to 85% of new medicines, compared to less than 40% for Europeans

Source: PhRMA Analysis of Adis R&D Insight Database. Accessed May 2019 ; Analysis Group. (2017). The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development. https://www.analysisgroup.com/globalassets/content/insights/publishing/the_ biopharmaceutical_pipeline_report_2017.pdf ; Association for Accessible Medicines. (2024). 2024 U.S. Generic & Biosimilar Medicines Savings Report. https://accessiblemeds.org/reSource/reports/2024-savings-report/ ; Buxbaum, J. D., Chernew, M. E., Fendrick, A. M., & Cutler, D. M. (2020). Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015. Health Affairs, 39(9), 1546-1556. https://doi.org/10.1377/hlthaff.2020.00284 ; Roebuck, M. C. (2022). Impact of Direct-Acting Antiviral Use for Chronic Hepatitis C on Health Care Costs in Medicaid: Economic Model Update. American Journal of Managed Care, 28(12). https://doi.org/10.37765/ajmc.2022.89273 ; PhRMA. (2023). Global Access to New Medicines Report. https://cdn.aglty.io/phrma/global/resources/import/pdfs/2023-04-20%20PhRMA%20Global%20Access%20to%20New%20Medicines%20Report%20FINAL-1.pdf

America’s challenge

The U.S. leads the world in biopharmaceutical innovation, but our inefficient system is costing Americans more than it should and limiting our ability to focus on keeping people healthy. Price setting creates more bureaucracy and threatens future cures without helping most patients. We need to defend American leadership – preserving jobs, access to cures and future innovation.

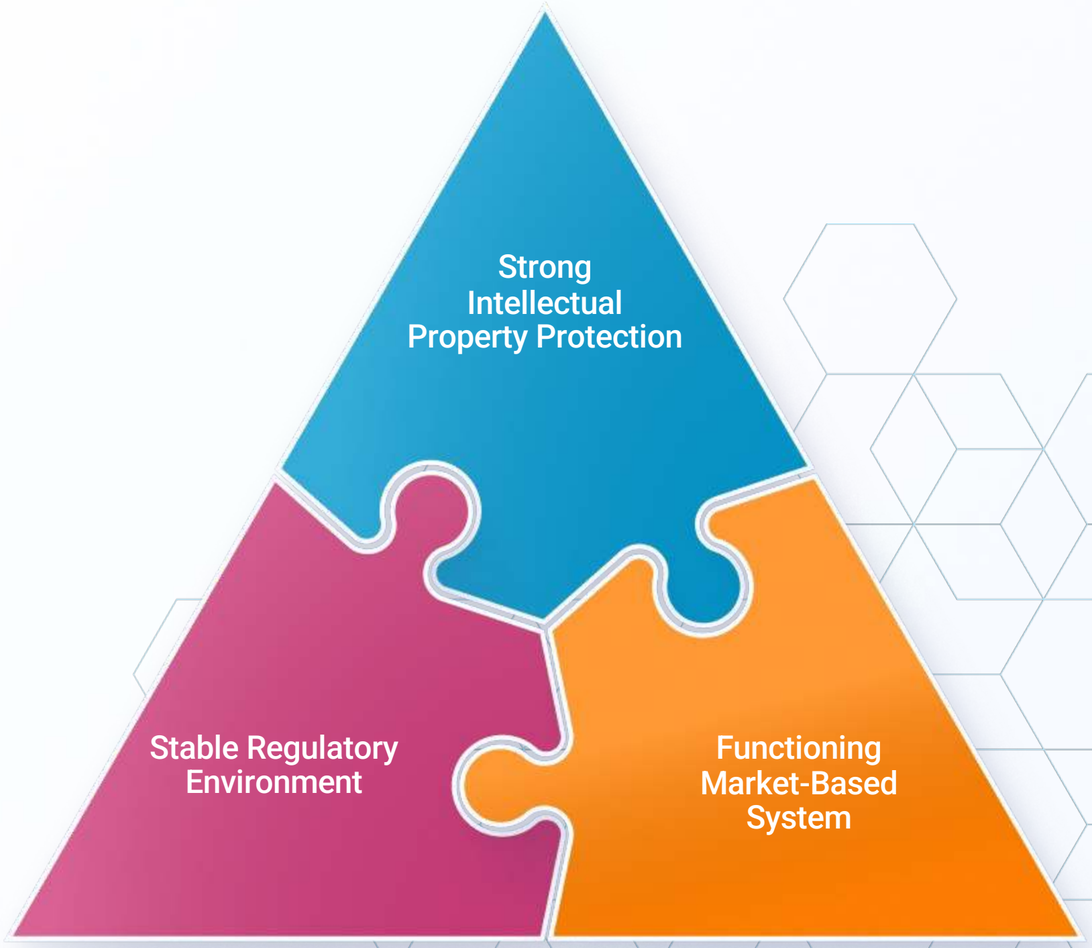
A HEALTHIER AMERICA REQUIRES A COMMITMENT TO:

1. **Protect and strengthen the American R&D and innovation ecosystem**

2. **Reduce costs for Americans by taking on the middlemen and unnecessary bureaucracy**

America leads the world in biopharmaceutical innovation

- **Economic contributions.** The pharmaceutical sector supports 5 million jobs in the U.S., contributing to $1.65 trillion in economic output
- **Regulatory excellence.** 3 out of 4 medicines are approved in the U.S. first by the FDA
- **Low-cost competition.** 90% of prescriptions in the U.S. are filled with generic medicines, which are 33% cheaper on average than in other OECD countries
- **Small and stable spending.** Prescription medicines account for just 14% of total U.S. health care spending



Source: TEConomy Partners & PhRMA. (2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf; PhRMA analysis of FDA. Novel Drugs Approvals at FDA. Accessed in 2024 from: https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda ; RAND. (2024). International Prescription Drug Price Comparisons: Estimates Using 2022 Data. https://www.rand.org/pubs/research_reports/RRA788-3.html; IQVIA. (2021). Drug Expenditure Dynamics 1995-2020: Understanding Medicine Spending in Context. https://www.iqvia.com/Insights/The-IQVIA-Institute/reports-and-publications/reports/Drug-Expenditure-Dynamics

50% of brand medicine spending goes to someone who did not make the medicine

Broken incentives allow middlemen, hospitals and other supply chain entities to enrich themselves at the expense of patients

Breakdown of Spending on Brand Medicines in 2023

Source: BRG. (2025). The Pharmaceutical Supply Chain, 2013–2023. https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf

Solutions for a Healthier America

Protect the Innovation Ecosystem

Adopt a pro-innovation regulatory and trade agenda

- Protect intellectual property at home and abroad
- Modernize the FDA to keep pace with scientific innovation
- Defend American workers and limit free-riding on American innovation through strong trade agreements

Protect the U.S. from the harms of price setting

- Fix the IRA's pill penalty to allow medicines to compete for 13 years before eligibility for government price setting
- Reverse bureaucratic overreach under the IRA to preserve innovation and market competition
- Ensure patient access to Part D medicines at pharmacies and restore appropriate provider payment in Medicare Part B
- Prevent further expansion of government price setting and maintain patient choice of medicines

Take on Middlemen and Costly Bureaucracy

Stop the abuse in the 340B hospital markup program

- Do not stand in the way of private market solutions that would ensure program compliance and limit illegal activity
- Pursue comprehensive reform to reduce the hidden tax on medicines and ensure low-income patients benefit from the program

Rein in the middlemen to put patients over PBM profits

- Share negotiated savings with patients at the pharmacy counter
- Delink PBM compensation from the price of medicines
- Stop middlemen and insurers from diverting manufacturer assistance programs and foundation support to avoid paying for care
- Hold health plans accountable through increased oversight and transparency of utilization management

01

Adopt a pro-innovation regulatory and trade agenda

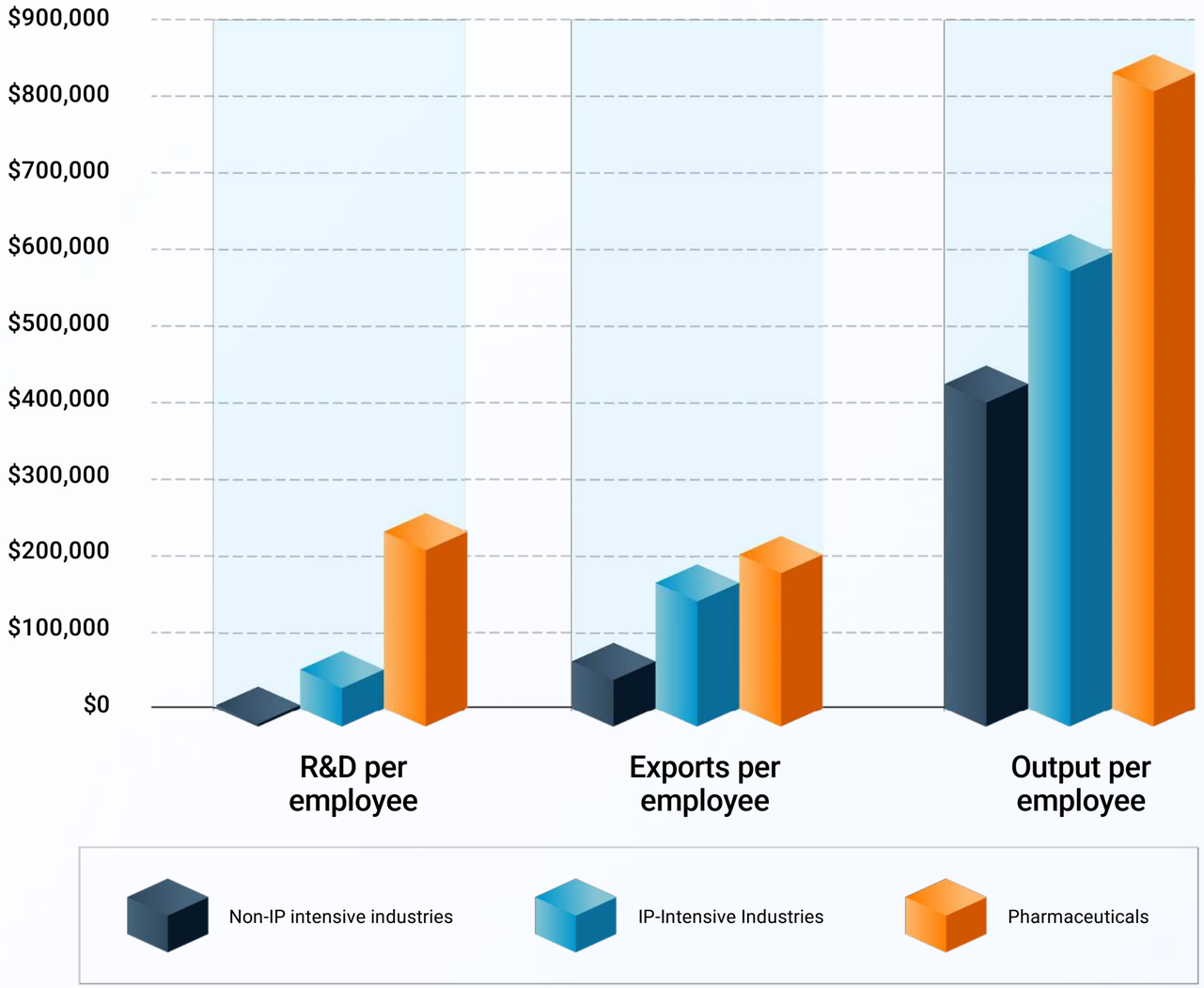
America’s strong **intellectual property** (IP) protections fuel groundbreaking treatment advances, supported by an efficient regulatory system and a strong trade agenda. Our IP framework supports competition and drives down costs by encouraging innovators to develop competing brands and supporting the development of lower-cost generics and biosimilars. This framework also drives research after regulatory approval and the development of new uses for medicines that generate substantial value and benefit for patients. Yet, competition from around the globe places America is in a race to maintain its position as the leader in biopharmaceutical innovation and continue to drive economic growth and national security in the 21st century.

The U.S. innovation ecosystem fosters economic growth

America's biopharmaceutical sector nurtures a dynamic startup and emerging company ecosystem:

- **Global R&D leadership.** The U.S. is responsible for 55% of global biopharmaceutical investment in R&D
- **Investment in U.S. businesses.** More than half of venture capital biopharmaceutical investment is in U.S. startups
- **Manufacturing impact.** The industry's manufacturing footprint is in 48 states, encompassing over 1,500 facilities

Pharmaceutical sector outperforms peer industry averages on key indicators



Source: Chandra, A., et al. (2024). Comprehensive measurement of biopharmaceutical R&D investment. Nat. Rev. Drug Discov, 23, 652-653. https://doi.org/10.1038/d41573-024-00131-2 ; PhRMA Analysis o Pitchbook data. (2022). Companies and Deals. Seattle, WA: PitchBook Data Inc. https://pitchbook.com/data ; TEConomy. (2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. https://www.teconomypartners.com/wp-content/uploads/2024/05/The-Econ-Impact-of-U.S.-Biopharma-Industry-2024-Report.pdf

U.S. IP framework promotes innovation, competition and affordability

Intellectual property protection facilitates the risk taking necessary to develop medicines, while competition lowers prices over time

Research and Development

- On average it takes 10 - 15 years to bring a new drug to market
- Only 1 in 10 products that begin clinical testing are ultimately approved

FDA Approval

Brand Competition

End of Effective IP Protection

- After 2 years on average, first-in-class medicines have 1 competitor
- Competition decreases net prices by as much as 60%
- Just 1 in 5 medicines earns more than the average cost to bring it to market

13 years on average to generic competition

Generic/Biosimilar Entry

- Prices fall up to 85% within 12 months of generic introduction
- Generics and biosimilars remain treatment options for decades

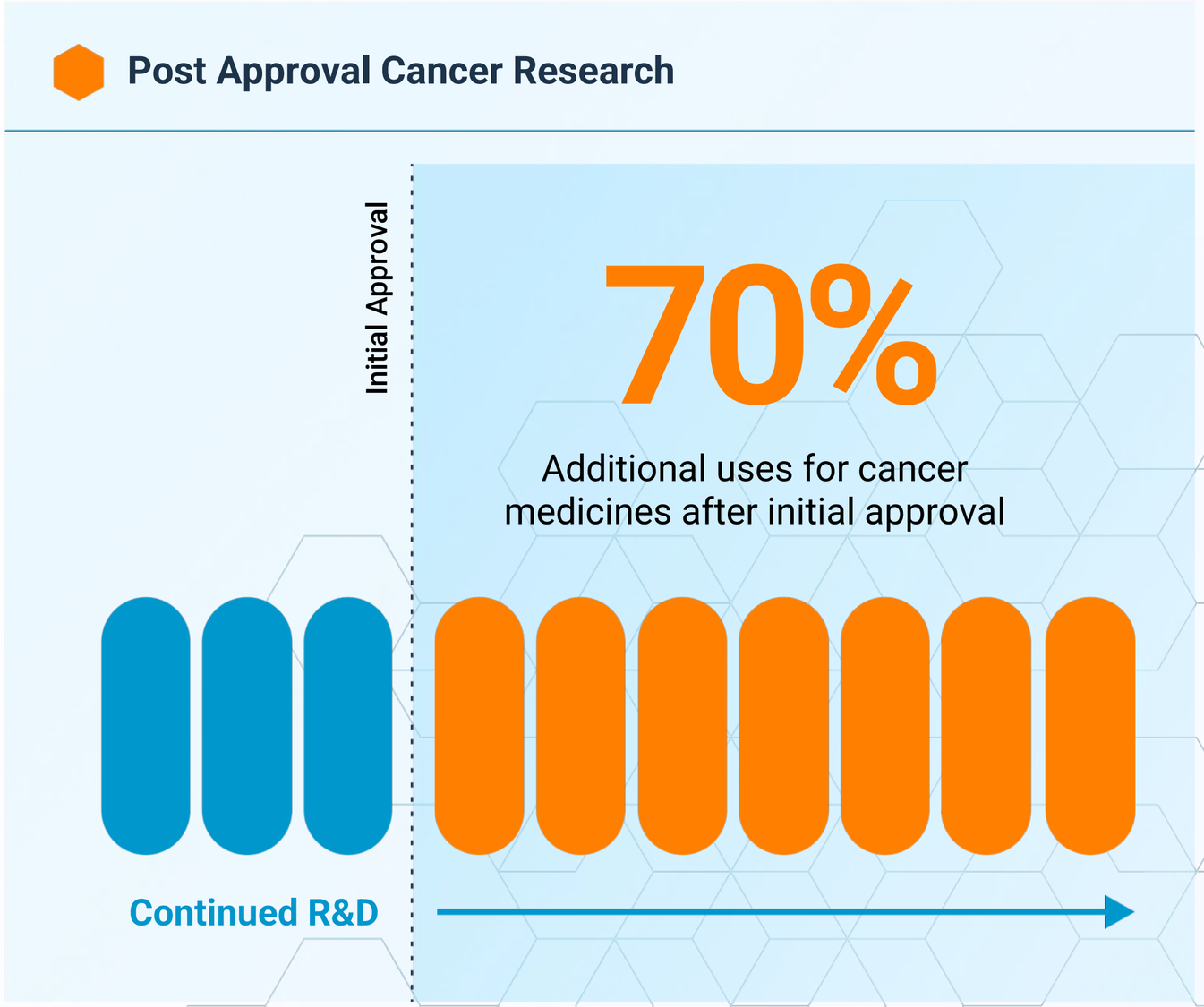
Source: DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of health economics, 47, 20-33. https://doi.org/10.1016/j.jhealeco.2016.01.012 ; Tufts University. (2014). Briefing: Cost of Developing a New Drug. https://f.hubspotusercontent10.net/hubfs/9468915/TuftsCSDD_June2021/pdf/Microsoft+PowerPoint+–+Tufts+CSDD+briefing+on+R%26D+cost+study+–+Nov+18,+2014.pdf ; FDA. (2024). Estimating Cost Savings from New Generic Drug Approvals in 2022. https://www.fda.gov/media/182435/download?attachment ; Hernandez, I., Cousin, E. M., Wouters, O. J., Gabriel, N., Cameron, T., & Sullivan, S. D. (2024). Price benchmarks of drugs selected for Medicare price negotiation and their therapeutic alternatives. Journal of Managed Care & Specialty Pharmacy, 1-11. https://doi.org/10.18553/jmcp.2024.24153

Post approval R&D drives new treatments and value for patients

Companies continue to invest in R&D following a drug's approval. This research leads to critical advances:

- **More uses.** A medicine originally approved for one type of cancer is found to be effective for another type
- **More people.** A medicine is proven effective for children or at earlier stages of a disease
- **More convenience.** A longer acting tablet, or an injection for in-home use

For some conditions, post-approval R&D is particularly crucial. The average cancer medicine is tested in **24 additional clinical trials** following initial FDA approval.



Source: Grabowski, H., DiMasi, J. A., & Long, G. (2024). Postapproval Innovation For Oncology Drugs And The Inflation Reduction Act: Article examines postapproval innovation for oncology drugs and the Inflation Reduction Act. Health Affairs, 43(10), 1400-1409. https://doi.org/10.1377/hlthaff.2024.00202

Scientific innovation creates opportunity for more efficient FDA processes

A predictable regulatory environment is a key component of America's biopharmaceutical leadership. Yet, there are opportunities to make the FDA more efficient to support the next generation of cures.

American innovators depend on strong trade agreements

The substantial investment necessary to develop and manufacture new medicines in the United States requires **trade policy** that:

- Boosts American exports by negotiating new trade agreements that expand market access
- Defends American workers by ensuring that foreign countries comply with global IP commitments
- Reduces free-riding on American innovation
- Strengthens American supply chains

$101 billion in U.S. exports

in 2023 makes the biopharmaceutical sector the largest exporter among R&D-intensive industries

Source: U.S. Bureau of Economic Analysis. International Accounts Products for Detailed Goods Trade Data. Accessed at: https://www.bea.gov/international/detailed-trade-data.

Our Solutions

1. **Protect intellectual property at home and abroad.** Preserve the uniquely American system that balances incentives for innovation with affordability.
2. **Modernize the FDA to keep pace with scientific innovation.** Rapidly harness the full potential of data, AI and other advanced technologies for predictable, efficient and transparent review of medicines.
3. **Defend American workers and limit free-riding on American innovation through strong trade agreements.** Ensure global compliance with commitments to respect innovators.

02

Protect the U.S. from the harms of price setting

The **Inflation Reduction Act (IRA)** allows the government to set prices for medicines in the Medicare program. In particular, the law introduced a “pill penalty” where small molecule medicines like pills and tablets can be price-set 9 years post-FDA approval, sending a message to manufacturers and investors: stop developing medicines that come in pill form. Not only does the IRA undermine competition, including biosimilar and generic entry that lowers costs for patients, but it has destabilized the Part D market and threatens access to medicines at doctors’ offices and pharmacies. At the state level, efforts to impose price setting compound these problems by giving bureaucrats the power to arbitrarily set prices within states across the country. Setting prices for medicines undermines the doctor-patient relationship and puts future innovation at risk.

IRA's "pill penalty" threatens essential medical advances

The IRA allows for price setting at 9 years post-approval for small molecule medicines, commonly pills, versus at 13 years for large molecules.

For small molecule medicines, biopharmaceutical companies **earn one-third** of average lifetime sales revenues between years 9 - 13.

As a result, this "pill penalty" discourages development, leading to an estimated **188 fewer small-molecule advances** over the next 20 years.

Harms of Price Setting Small Molecule Drugs at 9 Years

Source: IQVIA. (2024). Medicare's Drug Price Negotiation Program: The Disproportionate Impact on Small Molecules. https://www.iqvia.com/locations/united-states/blogs/2024/12/medicares-drug-price-negotiation-program ; Philipson, T., Ling, Y. & Chang, R. (2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf; Medicare's Price Controls Today Mean Higher Healthcare Spending Tomorrow, 2025. https://www.realclearhealth.com/blog/2025/02/10/medicares_price_controls_today_mean_higher_healthcare_spending_tomorrow_1090260.html

Pills are easier for patients to take and efficient for the health care system

Not every treatment can be made into a pill, but when it can, there are key advantages:

- **Lower cost.** No additional expense for hospitals and providers to administer treatment
- **More convenient, better outcomes.** Nearly doubles the likelihood a patient will take their medicine
- **Patient preference.** Most patients prefer pills over shots; 90% of cancer patients would choose pills

Today's small molecule breakthroughs become tomorrow's low-cost options

Over the past 10 years low-cost options have saved over **$3 trillion**

Unfortunately, the pill penalty upends incentives for generics, putting additional cost savings and efficiencies at risk

Source: Philipson, T., Ling, Y. & Chang, R. (2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf; AAM (2024), The U.S. Generic & Biosimilar Medicines Savings Report, https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf

IRA price setting is not negotiation

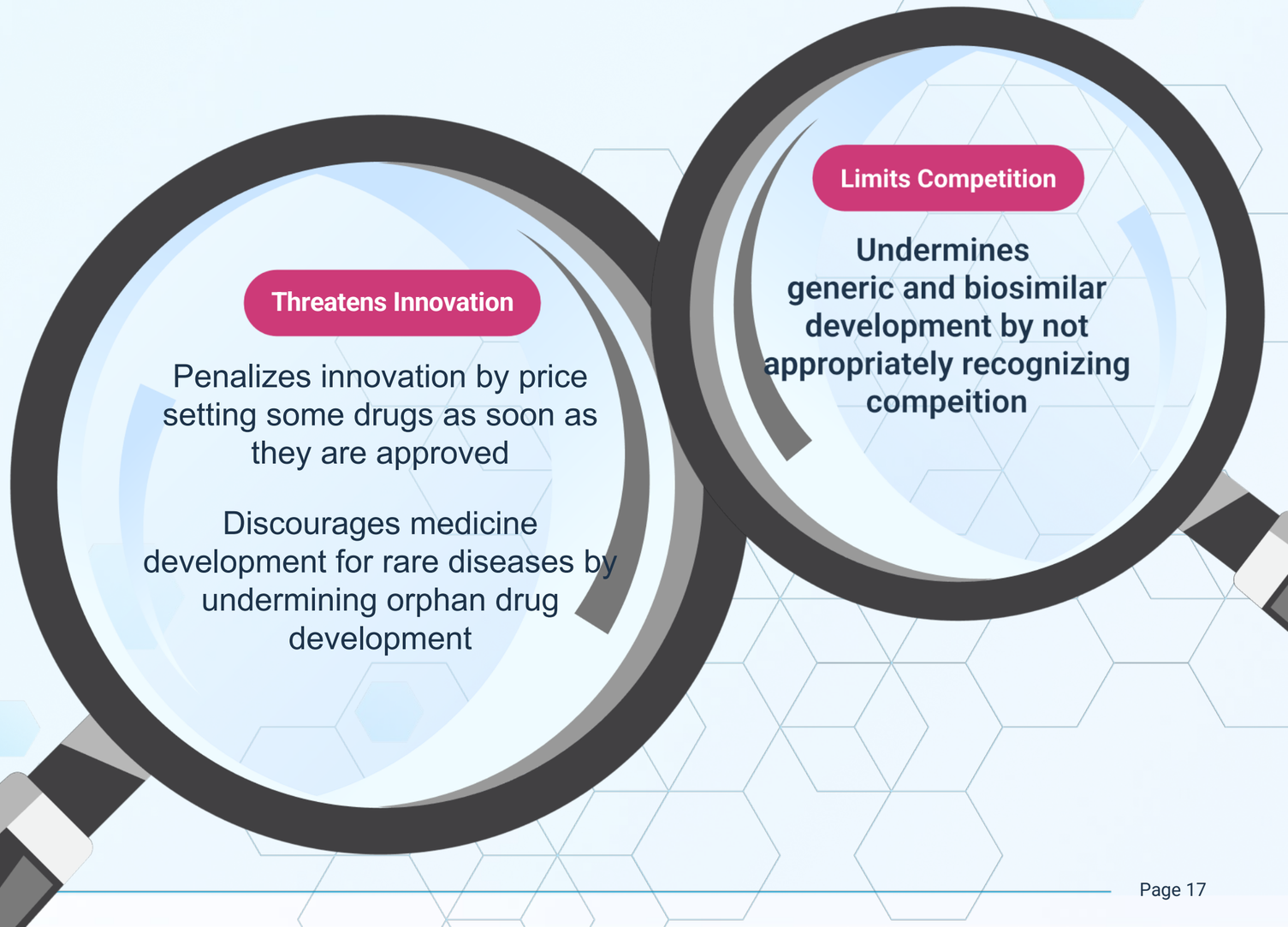
Companies who do not accept the government's price face a choice:

Pay up to a 1900% tax which could amount to billions annually

OR

Pull all of their medicines from Medicare and Medicaid, threatening patient care

Bureaucratic overreach in price setting implementation magnifies harms

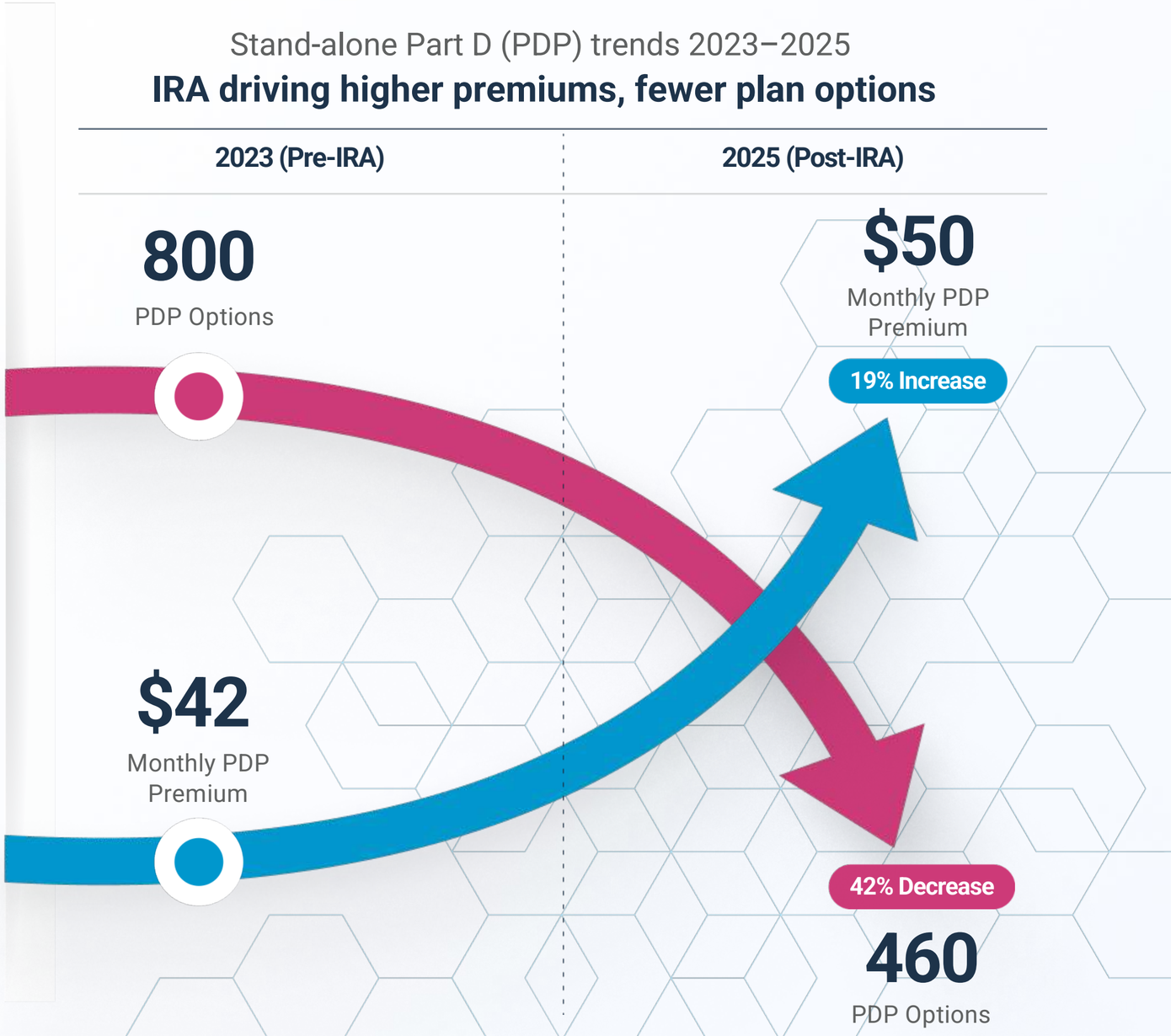


Source: Philipson, T., Ling, Y. & Chang, R. (2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf

IRA increased premiums, reduced access in Medicare Part D

Medicare Part D has offered broad access to medicines and choice of plans for almost 20 years. However, the Inflation Reduction Act (IRA) is undermining Part D, resulting in reduced coverage, higher premiums and fewer plan options:

- **More restrictions.** 9 in 10 plans say they are increasing coverage restrictions due to IRA
- **Fewer choices.** Formulary disruptions driven by price setting puts patient access to Part D medicines at risk for millions of patients, including more than 5 million taking anticoagulants alone
- **Higher out-of-pocket costs.** 3.5 million patients may see higher out-of-pocket costs for medicines subject to IRA price setting



Source: Magnolia. (2024). Inflation Reduction Act Payer Insights Report. Chartbook: Summary of Key Findings. https://www.magnoliamarketaccess.com/wp-content/uploads/MMA_IRA-Payer-Insights-Survey-4.0_Chartbook_2024.07.31.pdf ; Avalere. (2025). IPAY 2027 Negotiated Drugs Expand Impact on Beneficiaries. https://avalere.com/insights/ipay-2027-negotiated-drugs-expand-impact-on-beneficiaries; Milliman. (2024). Expected Impact of the Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program on Medicare Part D Beneficiary Out-of-Pocket Costs. https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2024-Articles/6-25-24_Expected-OOP-Cost-Impact-Drug-Price-Negotiation.pdf
Avalere analysis of PDP offerings and premiums using 2023 and 2025 Landscape data released by CMS, excludes LIS beneficiaries enrolled in $0 premium plans. Data is rounded

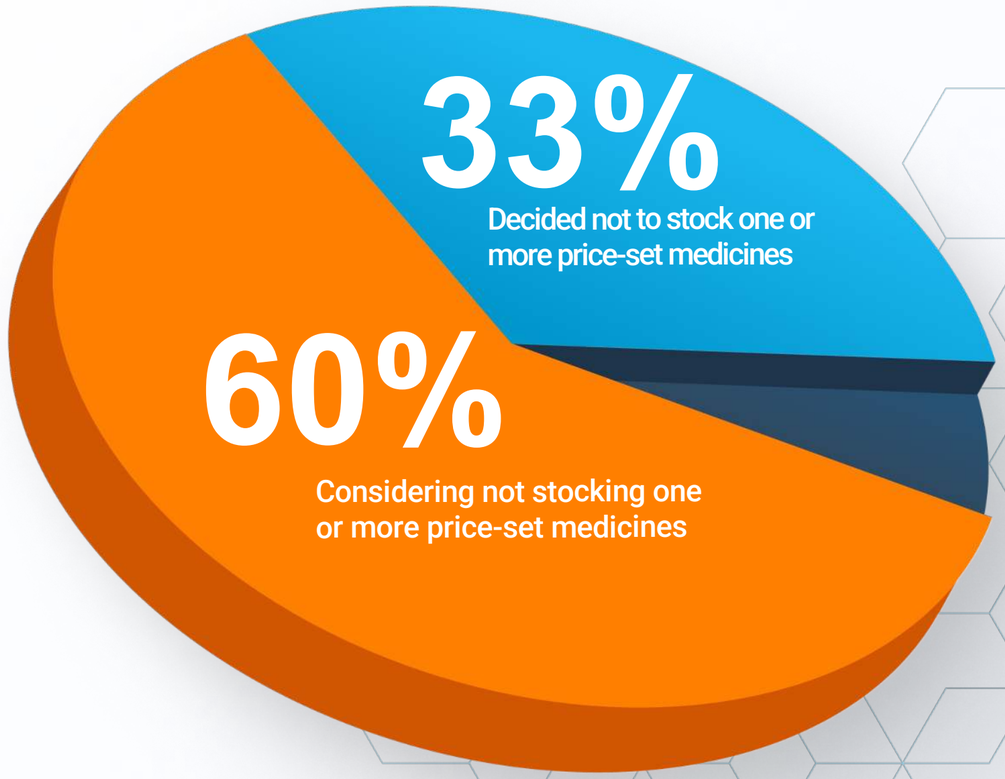
Medicare price setting threatens access to medicines at the pharmacy counter

CMS has failed to ensure timely pharmacy reimbursement of price-set drugs and CMS guidance has added program integrity risks for the supply chain.

Due to typical differences between prices at which pharmacies acquire price-set drugs and the amount Part D plans will reimburse under the IRA, each pharmacy stands to **lose $11,000 in weekly cash flow and could forfeit an average of $43,000 in annual revenue** due to payment delays.

The payment delays caused by the IRA could lead to reduced medication availability, reduced staffing and even pharmacy closures.

Percent of pharmacists not stocking price-set medicines



Patient access is at risk.
Independent and regional chain pharmacies account for over three-fourths of pharmacies in rural areas

Source: National Community Pharmacists Association. (2025). https://ncpa.org/newsroom/news-releases/2025/01/27/ncpa-cms-third-independent-pharmacies-wont-carry-drugs-negotiated; https://ncpa.org/newsroom/news-releases/2025/01/30/new-analysis-finds-medicare-drug-price-negotiation-program Huadamuz, J., Alexander, GC., Kanter, G. & Qato, D. (2024). Health Affairs. https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00192; https://www.japha.org/article/S1544-3191(22)00233-3/fulltext

IRA price setting for physician-administered drugs hurts physicians and does not help patients

-$31B

Decrease in physician payments due to IRA price setting*

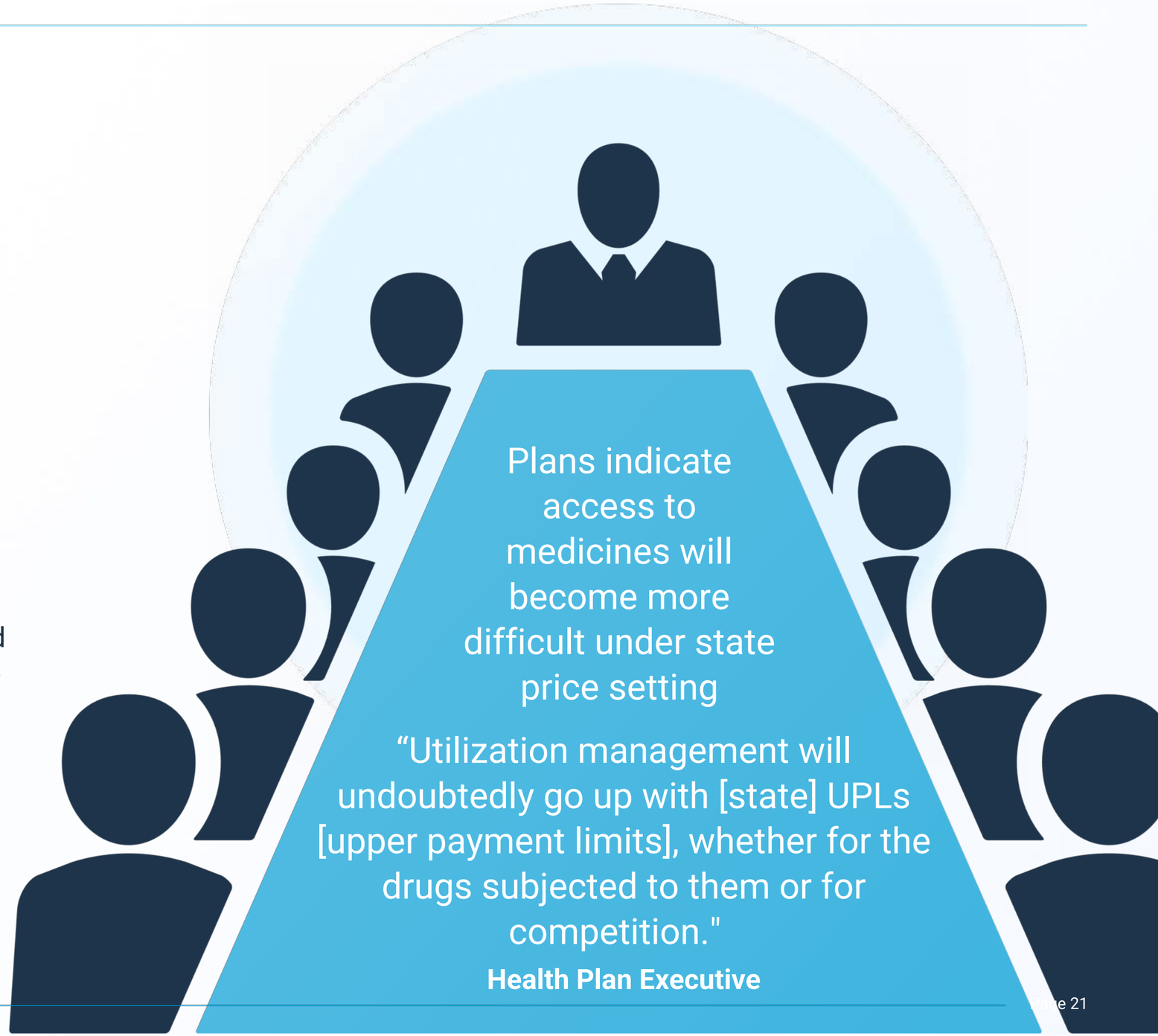
<0.1%

Beneficiaries will have lower out-of-pocket costs for Medicare Part B medicines**

*Assumes MFPs set below statutorily-defined ceiling prices.
**Applies only to Traditional Medicare beneficiaries who are taking price-set medicines
Source: Avalere. (2024). Commercial Spillover Impact of Part B Negotiations on Physicians. https://avalere.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

State price setting boards threaten patient access

- **No guaranteed savings for patients.** In a survey of Colorado health plans representing 7 million people, all but one plan responded that savings from price-controlled medicines would not be passed onto patients.
- **Increased costs to states.** State funding for price setting boards exceeds $10 million, without $1 saved to date. One state's internal analysis found that price setting could increase state employee plan costs by almost $8 million.



Source: Partnership to Fight Chronic Disease. (2024). Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs. https://www.fightchronicdisease.org/sites/default/files/FINAL%20PFCD%20Avalere%20PDAB%20Insurer%20Research.pdf ; Myers and Stauffer LC. (2024). PDAB Upper Payment Limit (UPL) Analysis. https://dfr.oregon.gov/pdab/Documents/20241002-PDAB-document-package.pdf

Our Solutions

1. **Fix the pill penalty.** Allow all medicines to compete for 13 years before eligibility for government price setting.
2. **Reverse bureaucratic overreach to preserve innovation and market competition.** Ensure the government does not set prices for medicines that already face generic or biosimilar competition, and preserve incentives to develop new uses for medicines.
3. **Ensure patient access to Part D medicines at pharmacies and restore appropriate provider payment in Medicare Part B**. Make prices available in a way that protects pharmacies and fix provider reimbursement for price-set medicines.
4. **Prevent further expansion of government price setting and maintain patient choice of medicines.** Preserve a pricing environment that provides incentives for innovation and delivers early access to medicines.

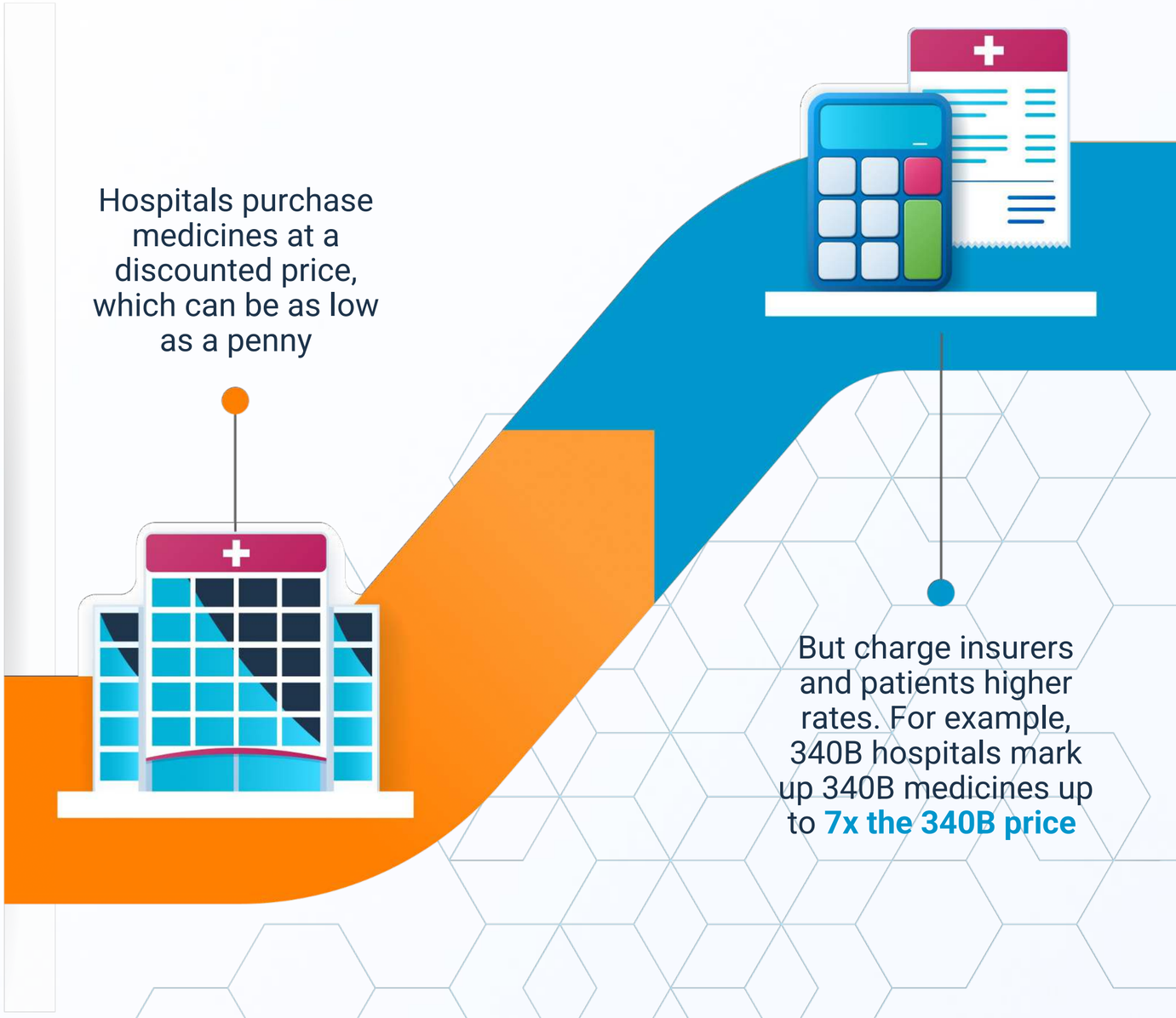
03

Stop the abuse in the 340B hospital markup program

Under the **340B program**, the federal government requires that drug manufacturers sell outpatient medicines to certain hospitals and clinics at heavily discounted prices. These entities then mark up these medicines to obtain reimbursement for an amount much higher than they paid, passing the bill to patients, taxpayers, the government and employers. Hospitals and clinics are prohibited by law from getting 340B pricing on a medicine that also generates a Medicaid rebate or that is price-set under the IRA. However, independent officials have repeatedly said these violations are widespread. 340B's hidden tax drives use of more expensive medicines, shifts care into costly hospital settings and fuels consolidation, while leaving patients and underserved communities behind.

Hospitals generate profits by marking up medicines they purchase at a discounted price

Hospitals, pharmacies and other entities collected **$64 billion** from their participation in the 340B program in 2023 but most face no requirements to use these profits to expand charity care or lower patient costs.

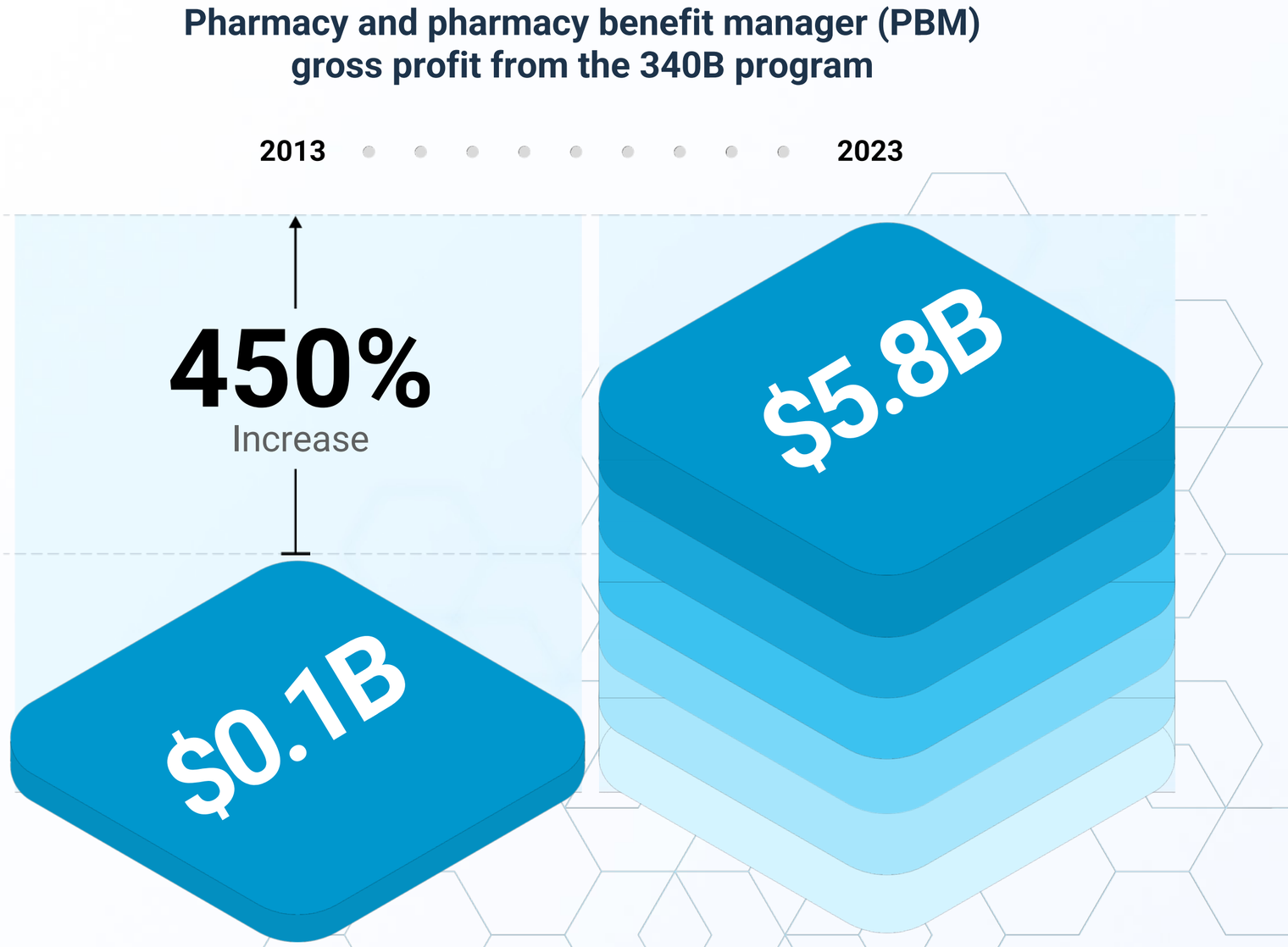


Source: Robinson, J. C., Whaley, C., & Dhruva, S. S. (2024). Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. New England Journal of Medicine, 390(4), 338-345. https://doi.org/10.1056/NEJMsa2306609

Large for-profit conglomerates exploit 340B to pad profits rather than help patients

Even though eligibility for 340B is limited to not-for-profit hospitals and clinics, **10 of the top-20** companies on the Fortune 500 list generate revenue from 340B.

In particular, PBM profits from 340B have grown significantly in recent years.



Source: Fortune. (2024) Fortune 500 Global Ranking. https://fortune.com/ranking/global500/ ; BRG. (2025). The Pharmaceutical Supply Chain, 2013–2023. https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf

340B is a hidden tax that raises costs, undermines competition and fuels vertical integration

Discourages use of lower cost medicine options

Biosimilar adoption is 23 percentage-points lower among commercially insured patients at 340B eligible hospitals compared to non-340B hospitals

Shifts patient care into more expensive hospital settings

Costs at 340B hospitals are about 3x what independent physician offices charge for the administration of treatments to patients with commercial insurance

Reduces competition by promoting consolidation

340B incentivizes hospital acquisition of independent physician practices and leads to many common procedures, like x-rays and blood tests, more than doubling in price

Source: BlueCrossBlueShield. (2023). Hospital outpatient prices far higher, rising faster than physician sites. https://www.bcbs.com/news-and-insights/white-paper/ambulatory-payment-classifications-site-neutral-analysis ; EBRI. (2021). Higher Lab Costs, Equivalent Value: Evaluating the Cost of Lab Services in Hospital Outpatient Departments, Physician Offices, and Stand-Alone Lab Facilities. https://www.ebri.org/docs/default-source/fast-facts-(public)/ff-393-locationx3-1apr21.pdf?sfvrsn=84e73a2f_6 ; Robinson, J. C., Whaley, C., & Dhruva, S. S. (2024). Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. New England Journal of Medicine, 390(4), 338-345. https://doi.org/10.1056/NEJMsa2306609 ; Bond, A. M., Dean, E. B., & Desai, S. M. (2023). The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program: Study examines the role of financial incentives in the uptake of biosimilar drugs in Medicare. Health Affairs, 42(5), 632-641. https://doi.org/10.1377/hlthaff.2022.00812

340B drives up costs for employers and the government

Employers

$5 billion

in extra drug costs for self-insured employers in 2021

States

$32 billion **or $391 per enrollee**

in increased annual Medicaid spending between 2014 - 21

Federal government

About 2.5x higher

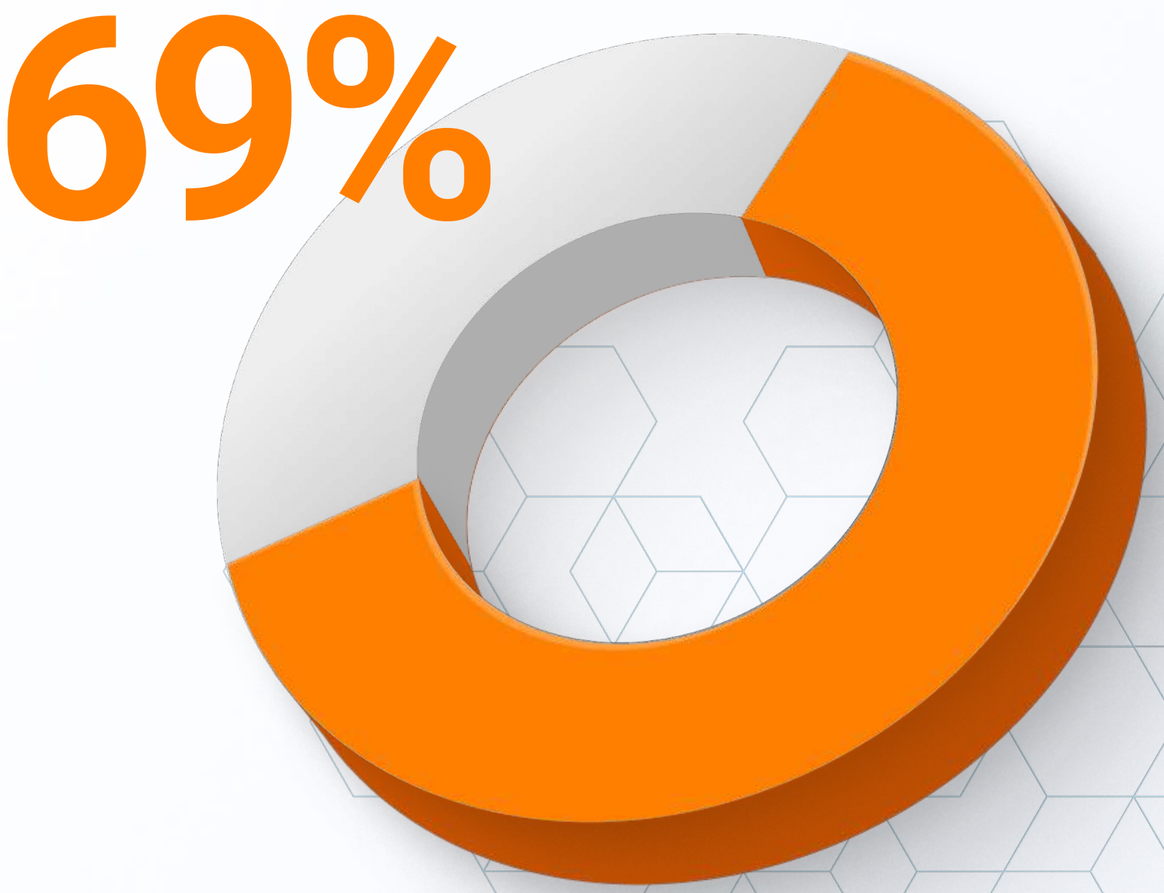
per-beneficiary Medicare Part B drug spending at 340B vs. non-340B hospitals

Source: IQVIA. (2024). The Cost of the 340B Program Part 1: Self-Insured Employers. https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-part-1-self-insured-employers ; Health Capital Group. (2024). The 340B Drug Purchasing Program and Per-Enrollee Medicaid Costs. https://www.healthcapitalgroup.com/340b-and-total-medicaid ; GAO. (2015). Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. https://www.gao.gov/products/gao-15-442

340B hospitals are not using profits to help patients

Despite continuous double-digit program growth, most 340B hospitals provide **less charity care than the national average** for all hospitals.

In addition, 340B hospitals are expanding into higher-income areas, rather than lower-income areas, threatening patient access to care in undeserved communities.



69% of 340B hospitals* provide lower rates of charity care than the average for all hospitals

Source: AIR340B. (2023). Charity Care at 340B Hospitals is on a Downward Trend. https://340breform.org/wp-content/uploads/2024/03/2023-Charity-Care-Report-Final-1.pdf
*340B disproportionate share hospitals

Government agencies have failed to help prevent duplicate discounts and blocked private market solutions to ensure program integrity

Illegal duplicate discounts

Hospitals are prohibited by law from getting a 340B discount on a medicine that also generates a Medicaid rebate or is price-set under the IRA

No oversight

Government agencies have failed to implement effective procedures to prevent and address illegal activity

Blocked solutions

Manufacturers that announced plans to implement reasonable business practices to ensure basic program rules are followed have faced government threats of exclusion from Medicare and Medicaid in addition to fines

Patients often pay more as a result of the 340B program

340B price reductions are not required to be shared with patients. In fact, **patients can be charged multiple times** what the hospital or clinic paid for the medicine. Perverse incentives further increase the costs for patients.

Higher out-of-pocket costs

Increasing drug prices

More expensive hospital settings and treatments

Higher premiums, eroding wage growth

Source: Robinson, J. C., Whaley, C., & Dhruva, S. S. (2024). Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. New England Journal of Medicine, 390(4), 338-345. https://doi.org/10.1056/NEJMsa2306609

Our Solutions

1. **Do not stand in the way of private market solutions that would ensure program compliance and limit illegal activity.**
   Ensure manufacturers can verify eligibility and compliance with federal law before providing 340B pricing.
2. **Pursue comprehensive reform.**
   Ensure the 340B program lowers medicine costs for low-income patients and prevent further abuse through legislative change.

04

Rein in the middlemen to put patients over PBM profits

Pharmacy benefit managers (PBMs) act as middlemen between health plans and manufacturers to manage drug coverage and reimbursement, receiving significant rebates and discounts for medicines. PBMs and the insurance conglomerates that own them control patient access to medicines and set out-of-pocket costs for patients. Not only do patients not benefit from rebates and discounts at the pharmacy counter, PBMs often prefer higher priced medicines and divert patient assistance, making patients pay more. In the end, 50% of drug spending goes to someone who did not make the medicine.

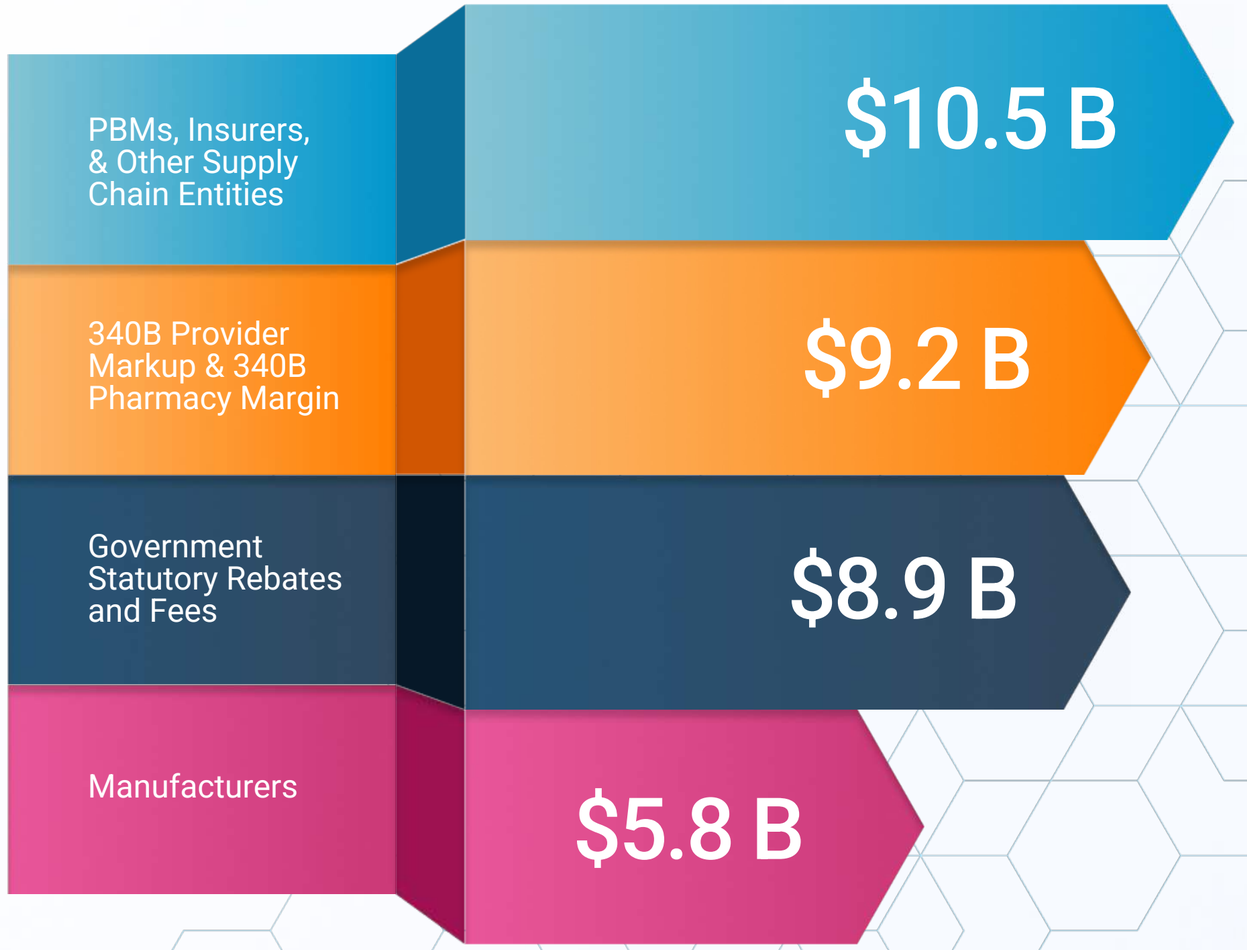
PBMs and insurers account for the largest share of growth in brand medicine spending

PBM compensation is often tied to the list price of a medicine. At the same time, PBMs employ a range of practices that limit access and increase costs, including:

- **Preference for high list prices.** PBMs may favor higher list price medicines over lower-priced brands, generics and biosimilars
- **Patient steering.** PBMs steer patients to pharmacies they own, which grossly overcharge for medicines
- **Non-medical switching.** PBMs force stable patients to switch drugs for non-medical reasons

Amount of increase in brand medicine spending by entity

2022-2023 (in billions)



Source: Federal Trade Commission. (2024). Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf ; U.S. Department of Health and Human Services Office of Inspector General. (2022). Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending. https://oig.hhs.gov/reports/all/2022/part-d-plan-preference-for-higher-cost-hepatitis-c-drugs-led-to-higher-medicare-and-beneficiary-spending/ ; House Committee on Oversight and Accountability. (2024). The Role of Pharmacy Benefit Managers in Prescription Drug Markets. https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf

Patients pay more than their fair share of costs for drugs

In 2021, **Medicare beneficiaries paid 4x more than their insurer** for 79 of the top 100 rebated Part D drugs.

When patients face deductibles and coinsurance, their cost sharing is based on a medicine's full list price, not the discounted price their insurer pays after manufacturer rebates.

Net price reflects manufacturer rebates. Patients benefit when cost sharing is based on the net price.

Medicine list price: **$400**
Manufacturer rebate to plan/PBM: **$260 (65%)**
Net cost to plan: **$140**

Cost-sharing based on net price

25% patient coinsurance based on **net price**: **$35**

Total cost to plan: **$105**

Cost-sharing based on list price

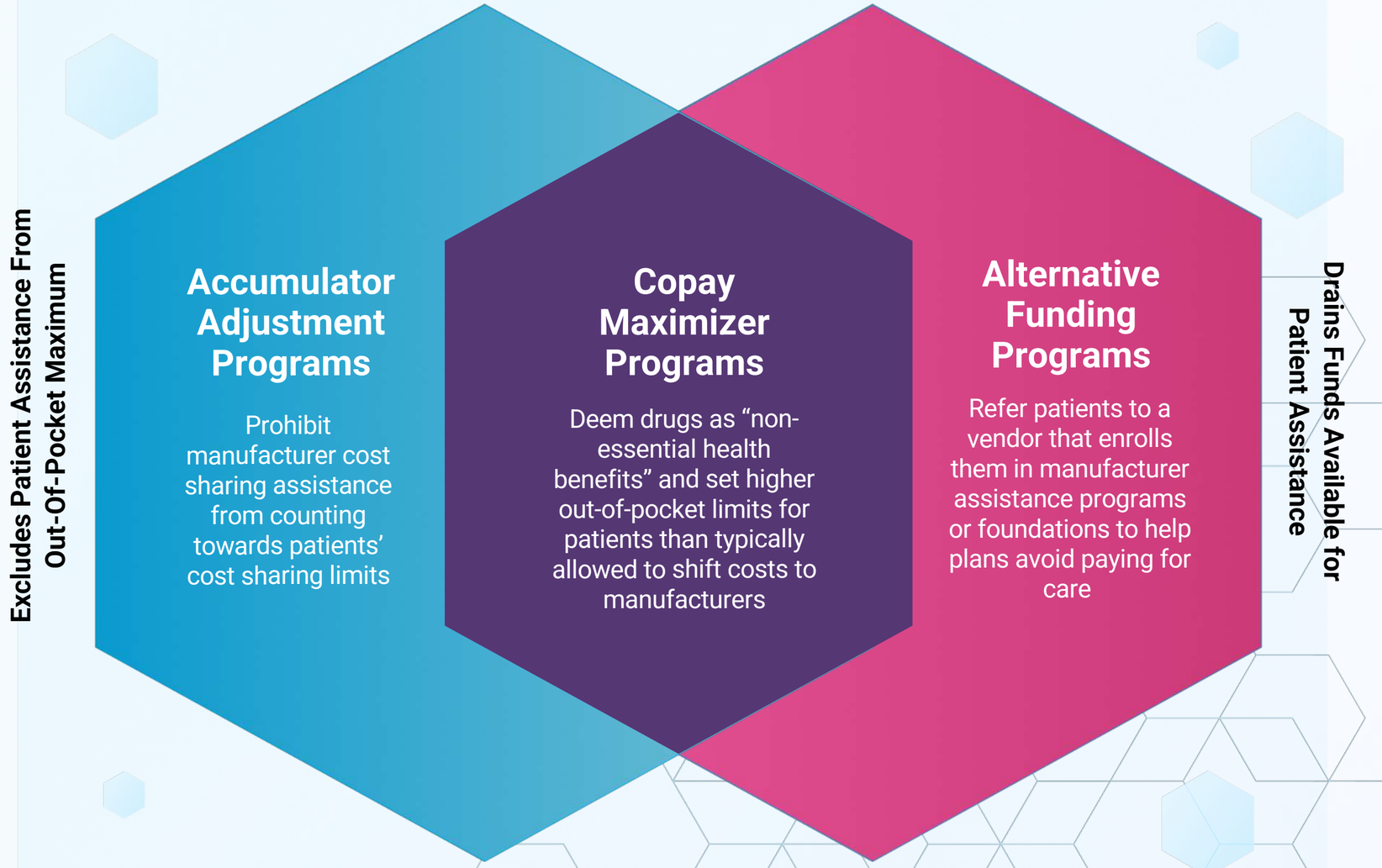
25% patient coinsurance based on **list price**: **$100**

Total cost to plan: **$40**

Source: GAO. (2023). Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending. https://www.gao.gov/products/gao-23-105270

Middlemen divert patient assistance to avoid paying for patient care

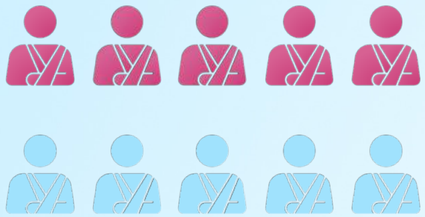
Manufacturers provide patient assistance to help people access and afford their medicines. Payers and PBMs exploit this assistance, absorbing **$5 billion** of the funds intended for patients through complicated schemes that help them avoid paying for medicines.



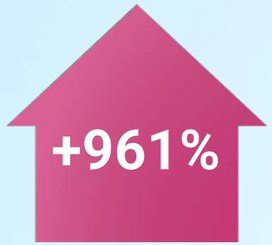
Source: Fein, A. J. (2024). Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow. https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html ; IQVIA. (2024). 2023 Update: Six Years of Deductible Accumulators and Copay Maximizers. https://www.iqvia.com/locations/united-states/blogs/2024/03/2023-update-six-years-of-deductible-accumulators-and-copay-maximizers ; Health Capital Group. (2024). The 340B Drug Purchasing Program and Per-Enrollee Medicaid Costs. https://www.healthcapitalgroup.com/340b-and-total-medicaid ; GAO. (2015). Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. https://www.gao.gov/products/gao-15-442

Insurer abuses challenge patient access

Insurer tactics that limit patient access are widespread



Almost half of insured adults say their health insurance plan has required prior authorization in the past year



The 3 largest PBMs increased the number of medicines excluded from formulary between 2014 to 2022

Source: AmerisourceBergen. (2023). Assessing the impact of formulary exclusion on healthcare costs and outcomes for patients on therapy for certain chronic conditions. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/formulary_excl_issue_brief.pdf ; American Medical Association. (2023). 2023 AMA prior authorization physician survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

As a result, patients may never initiate treatment or experience substantial delays

94%

Almost all physicians report delays in patient access with prior authorization

One in three cancer patients who faced a rejection at the pharmacy experienced a treatment delay of 2+ weeks

Source: IQVIA. (2024). Access Challenges in the Cancer Patient Journey: How barriers to oral oncology affect patient initiation and persistency. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/iqvia-access-challenges-in-oncology-report-white-paper-2024.pdf ; Joszt, L. (2019). How Prior Authorization, Step Therapy Result in Medication Discontinuation and Worse Outcomes. https://www.ajmc.com/view/how-prior-authorization-step-therapy-result-in-medication-discontinuation-and-worse-outcomes-

Insurance conglomerates reduce accountability, efficiency and prevention

Nearly **80% of prescriptions** are controlled by the three largest vertically integrated PBMs: CVS Caremark, Express Scripts and OptumRx.

Commercial insurers and PBMs pay their vertically integrated pharmacies **more than twice as much as they pay unaffiliated pharmacies** for generic cancer medicines, according to the FTC.

Source: Federal Trade Commission. (2025). Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf

Insurance conglomerates own PBMs, pharmacies and providers so they can drive profits at every step of a patient's treatment journey by:

Steering patients to the providers they own, who follow care protocols set by the insurer

Dictating which medicines are covered, what patients pay and what hoops patients must jump through to get access to care

Requiring patients to use pharmacies owned by their PBM, which are paid more than independent pharmacies for the same drug

Our Solutions

1. **Share savings negotiated between manufacturers and PBMs directly with patients.** Base patient cost sharing on the net price of medicines.
2. **Delink PBM compensation from the price of medicines.** Limit PBM compensation to flat service fees.
3. **Ensure patients benefit from manufacturer assistance programs and foundation support.** Prohibit use of copay maximizer programs, accumulator adjustment programs and alternative funding programs.
4. **Hold health plans accountable for providing patient care.** Increase oversight and transparency of practices like utilization management.