TECHNOLOGY + POLICY RESEARCH INITIATIVE

PRESCRIPTION DRUG SPENDING REFORM BENEFITS SENIORS AND DOES NOT HARM INNOVATION

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Senate Finance Committee Hearing

Lower Health Care Costs for Americans:
Understanding the Benefits of the Inflation Reduction Act

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BOSTON UNIVERSITY

Boston University Questrom School of Business

I. SUMMARY OF REMARKS

1. The Inflation Reduction Act of 2022, signed into law by President Biden on August 16, 2022, includes several provisions to lower prescription drug costs for Medicare beneficiaries and reduce drug spending by the federal government.[1] This legislation was passed amidst strong public support for the government to address high and rising drug prices and a strong empirical evidence on the expected benefits of reform to taxpayers and seniors to improve affordability and access. Provisions of the law are now beginning to take effect. The provisions already implemented are helping millions of seniors access needed medicines. These reforms are also fiscally responsible, projected to save taxpayers money and reduce the federal deficit by tens of billions of dollars over the next decade. Expanding insurance for prescription drugs will positively impact pharmaceutical company profits and consequently reward innovation. Other provisions that impact pricing incentives are, by design, intended to have a minimal impact on pharmaceutical innovation. Strong intellectual property rights, public support for basic research and the development of new medicines, and targeted incentives for private companies to bring new innovative drugs to the U.S. market remain in place. IRA reforms are built upon the success of previous policies aiming to improve prescription drug access for Americans and promote affordability for patients and payers, while supporting innovation.

II. MY BACKGROUND AND EXPERTISE

2. I am Rena M. Conti, Ph.D., Dean's Research Scholar, Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University. I am also the co-director of the Technology Policy and Research Institute, a joint program of Boston University's Business and Law Schools. Between 2006 and 2018, I was faculty at the University of Chicago. I am a graduate of Harvard University's Interfaculty Initiative in Health Policy, concentration economics. My research focuses on the economics of the pharmaceutical industry. I have published over 100 peer reviewed articles, many in top economics, policy and medical journals. I have taught health economics and strategy in the pharmaceutical industry for two

[1] https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf, Secs. 11001-11004.

decades. My research work is supported by grants, including from the National Cancer Institute, the Leukemia and Lymphoma Society, the American Cancer Society and Arnold Ventures.[2]

III. FAR FROM BEING 'FREE,' THE US PHARMACEUTICAL MARKET IS A PRODUCT OF PRIVATE ACTIVITY SUPPORTED BY GOVERNMENT[3]

3. Most American consumers of pharmaceuticals are well insured; and insurance, while not universal, is publicly subsidized. The government grants pharmaceutical companies patents establishing a monopoly period when generic versions of a drug cannot be sold. No drug can be sold without meeting, or exceeding, regulations for safety, efficacy, and manufacturing quality. Both patent protection and regulatory protection serve to curtail would-be lower cost and quality entry and competition in the market, and conversely assure pharmaceutical companies that do meet the bar higher prices and profits. New drugs are brought to the market by private companies. But the creation of virtually every new drug relies on the federal government's funding of basic science through research grants to scientists and training researchers who go on to work for pharmaceutical companies. More direct public support for drug development activities has become prominent as science has become complex and the costs and risks to bring drugs to market have grown.

4. Over the past decades, government policy has further shaped the pharmaceutical market to promote innovation, competition and to improve their affordability:

- The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) amended regulation of prescription drug exclusivity to facilitate the sale of generic drugs and ensure adequate time for branded products to achieve a return on investment. Forty years later, this change has resulted in a robust generics market.
- Similarly, in 2010, the Biologics Price Competition and Innovation Act established an abbreviated pathway for biosimilar approval to encourage

[2] This testimony benefited from comments by Matt Vogel, Marta Wosinska, Richard Frank and research work with my collaborators including David Cutler, Kao Ping Chua and Amitabh Chandra. Shane Savage and Alma Moskowitz provided expert research assistance.

[3] Conti, R.M., Frank, R.G., & Cutler, D.M. (2024). The Myth of the Free Market for Pharmaceuticals. *New England Journal of Medicine, 390(16)*, 1448-1450. doi: 10.1056/NEJMp2313400

innovation and competition among biologic products. This pathway has not yet fully matured.

- In 2005, Congress passed the Medicare Modernization Act (MMA) establishing Medicare insurance coverage for prescription drug dispensed by pharmacies (Part D).
- The Affordable Care Act (ACA) in 2010 further expanded access to insurance for millions of previously uninsured patients. Both coverage expansions, and the resulting reductions in out-of-pocket costs, generated increased sales and profits for the pharmaceutical industry.
- The 21st Century Cures Act[4] in 2016 helps accelerate new medicine development and bring innovations to patients who need them faster and more efficiently.

5. With few exceptions, however, previous policy changes have focused on reducing the consumer portion of drug reimbursement. Pharmaceutical companies have taken advantage of our system to inflate the prices of brand drugs, and forestall competition. As a result, seniors and taxpayers are facing affordability challenges.

6. This is the mistake the IRA aims to fix.

IV. WHY ARE IRA REFORMS TO THE US PHARMACEUTICAL MARKET NEEDED?

7. In prior Congressional testimony, I detailed the strong empirical evidence for reform (Attached).[5]

8. In short, the IRA was motivated by three overarching concerns:

- High brand drug spending by taxpayers and seniors;[6]
- Increasing brand drug prices through drug company evasion of competition; and
- Senior access to needed treatment.

[4] https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act

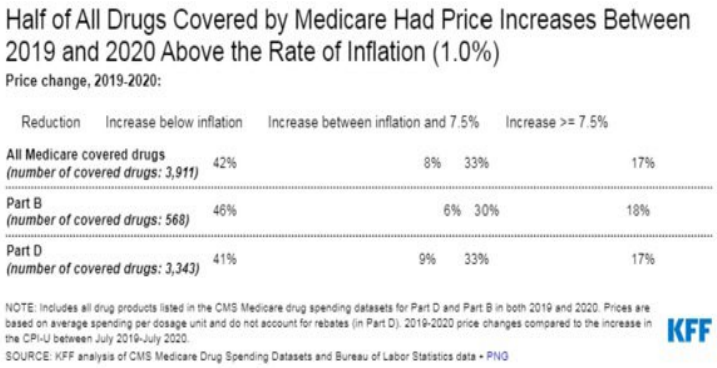
[5] Conti, R.M. (2022). Prescription Drug Spending Reform Will Not Harm Innovation and Will Benefit the American Public, U.S. Senate, Finance Committee. Attached.

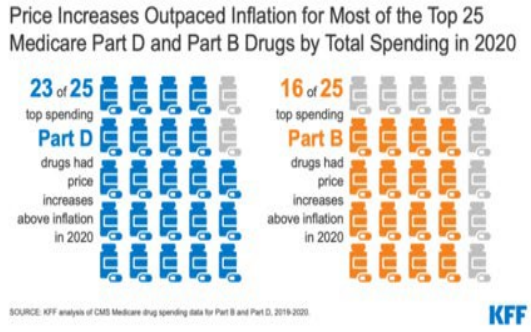
[6] Conti, R.M., Turner, A., & Hughes-Cromwick, P. (2021). Projections of US Prescription Drug Spending and Key Policy Implications. *JAMA Health Forum*, *2*(1), e201613. doi:10.1001/jamahealthforum.2020.1613

9. First, on spending. Per capita U.S. spending on drugs is the highest globally. In 2023, the US spent close to $1 Trillion dollars on prescription drugs,[7] and this spending represents approximately 14% of overall healthcare spending. Despite this, Americans regularly pay far more for prescription drugs than patients in other comparable countries. The United States also spends more on prescription drugs on a per capita basis than other countries in the Organization for Economic Co-operation and Development (OECD): the U.S. figure of $1,310 per person is more than twice the $646 per person in other OECD countries.[8]

10. Second, on drug price increases. Increases over time in the prices for brand drugs have added to access and affordability challenges (**Figure 1**). Spending on pharmaceuticals has risen by 20% over the past 10 years; an average of 2% per year. U.S. spending on pharmaceuticals is forecast to grow 0–3% CAGR over the next 5 years.[9] According to a recent analysis by the non-partisan Kaiser Family Foundation, half of all Part D covered drugs (50% of 3,343 drugs) and nearly half of all Part B covered drugs (48% of 568 drugs) had price increases greater than inflation between July 2019 and July 2020. Moreover, 23 of the top 25 Part D drugs and 16 of the top 25 Part B drugs had price increases above inflation between 2019 and 2020.

FIGURE 1: PRICE TRENDS PAID BY MEDICARE BENEFICIARIES OUTPACE INFLATION.





[7] IQVIA. The Global Use of Medicines 2024 – Outlook through 2028. January 2024.

[8] Bosworth, A, Sheingold, S, Finegold, K, Sayed, B.A., De Lew, N, Sommers, B.D. (Issue Brief No. HP-2023-25). Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. October 2023.

[9] To put these figures in broader context, industry reports expect global medicine spending through 2025 to amount to about $1.6 trillion. Projected global spending on pharmaceuticals by IQVIA is expected to be higher than the pre-COVID forecast.

11. Increases in the prices of existing branded drugs are the direct result of pharmaceutical companies evading competition.[10,11] Reports released by the U.S. House of Representatives' Oversight Committee detail companies egregious and widespread manipulation of our system to delay competition from lower-priced generics and biosimilars of such drugs a decade or more after launch.[12] The revenues reaped from these activities are not primarily directed into research and development efforts. Instead, high prices, price increases and significant profits lead to higher executive compensation, dividend payments to stockholders and stock buybacks.

12. Third, on drug access and affordability for seniors. Seniors use most drugs sold in the U.S., and while much of this use is on relatively inexpensive generic drugs, they are responsible for paying prices at the pharmacy counter that reflect high list prices of the drugs. Medicare Part D and Part B require cost sharing based on the list prices of drug. Consequently, when companies price their drug high and then increase prices over time, seniors pay more at the

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[10] See for example, Cubanski J, Neumann T. Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020. KFF Issue Brief. February 2022.

Annual price increases are also inconsistent with the notion that prices are optimized for profit maximization at launch and appear unrelated to approval of supplemental indications, additional information about the benefits associated with treatment, and potential increases in manufacturing costs. See Bennette CS, Richards C, Sullivan SD, Ramsey SD. *Steady Increase in Prices for Oral Anticancer Drugs after Market Launch Suggests a Lack of Competitive Pressure*. Health Affairs (Millwood). 35(5):805-12. May 2016.

[11] In fact, evidence suggests pharmaceutical companies target U.S. payers for drug price increases, while at the same time decreasing prices in other countries. Celgene's Revlimid and Teva's Copaxone took significant price increases to increase revenue in the U.S. at the same time as cutting prices in other countries. In a new study of cancer drugs, pharmaceutical companies are observed to increase prices in the U.S. that exceed inflation, while at the same time prices stayed stable or declined in Germany and Switzerland. When Abbvie pursued price increases on Humira, it claimed it did so because it was being 'forced' to reduce prices in other countries. While it may make common sense for firm to offset 'losses' with gains, this pricing behavior by pharmaceutical companies controverts the companies' own statements to Congress suggesting the prices of prescription drugs in the U.S. are untethered to those in other countries. See my previous testimony for more detail and citations.

[12] See for example, U.S. House of Representatives. *Drug Pricing Investigation AbbVie—Humira and Imbruvica*. Staff Report Committee on Oversight and Reform. May 2021.

The report states "New documents show that these settlements allowed AbbVie to delay competition far beyond what its own internal assessments of the strength of its patent portfolio predicted. In 2014, AbbVie's executives estimated that three to five biosimilar competitors would enter the market by the first quarter of 2017. AbbVie ultimately entered into settlement agreements with four of these competitors, delaying their entry into the market until 2023."

U.S. House of Representatives. *Drug Pricing Investigation Teva—Copaxone*. Staff Report Committee on Oversight and Reform. September 2020.

U.S. House of Representatives. *Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid*. Staff Report Committee on Oversight and Reform. September 2020.

pharmacy counter. This results in access and affordability challenges for beneficiaries requiring treatment. This has become especially problematic in Medicare Part D, which prior to IRA reform did not cap annual cost sharing, leaving many seniors to contend with catastrophic financial burdens related to needed medical care.

V. IRA POLICY PROVISIONS INCREASE AFFORDABILITY AND ACCESS TO DRUGS FOR SENIORS AND TAXPAYERS

13. The IRA includes multiple provisions to address high and rising drug costs in the Medicare program.[13,14] The IRA:

- Requires rebates to be paid on drugs whose prices exceed inflation.
- Gives Medicare the authority to negotiate prices for a subset of high spend, long lived brand drugs.
- Caps the out-of-pocket costs to seniors of insulin and adult vaccines; and
- Redesigns Medicare Part D to cap the out-of-pocket costs of drugs for seniors and provides expanded subsidies to ensure seniors have insurance coverage.

14. Together, these reforms are expected to improve access to pharmaceuticals for seniors and cost savings for Medicare and its beneficiaries. These changes are expected to reduce the number of prescriptions senior do not fill or ration due to their expense. American workers will also benefit from this change. Commercial insurers and employers will likely benefit by incorporating negotiated drug prices into their policies.[15] With access improvements, increased uptake of medicine and better health will likely follow. Reform will also benefit taxpayers. The fiscal effect of the IRA is net positive. CBO estimates that the drug pricing provisions in the law will reduce the federal deficit by billions over the next decade (2022-2031).[16] Importantly, the

[13] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/#bullet03

[14] Centers for Medicare and Medicaid Services. Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments. March 15, 2023.

[15] Conti, R.M., Frank, R.G., & Nichols, L.M. (2021). How Do Commercial Insurance Plans Fare Under Proposed Prescription Drug Price Regulation? *JAMA Health Forum*, *2*(12), e214242. doi:10.1001/jamahealthforum.2021.4242

[16] CBO. Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14, September 7, 2022. Available from: https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

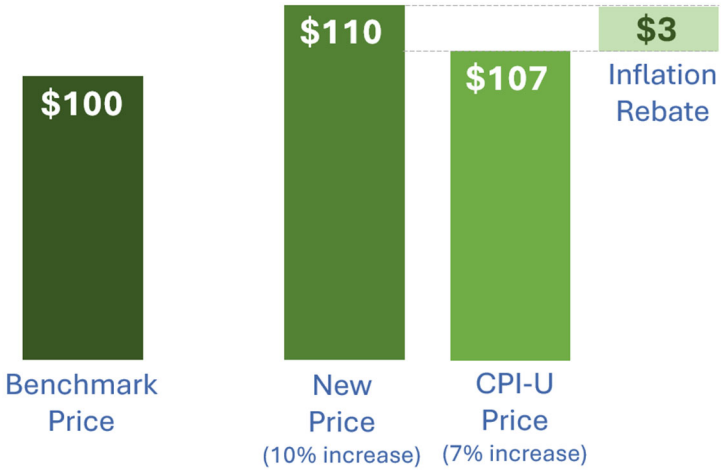
IRA leaves in place opportunities for pharmaceutical company profitability, thereby maintaining incentives to invest in new drugs. Expected increases in use will benefit pharmaceutical companies.

15. Below, I provide additional detail on these key drug provisions of the IRA.

A. Inflation rebates

16. First, the law requires manufacturers of single-sourced drugs covered under Medicare Part B and Part D to pay rebates to Medicare if the prices of those drug exceed the overall rate of inflation in the economy. For example, if the drug was $100 in the benchmark period, and the firm raises prices 10% in a year to $110, but inflation was 7% in that same year, the excess $3 is expected to be paid back to the federal government (**Figure 2**). Inflation rebates bring a restraint to drug price growth in Medicare that is already operative in state Medicaid plans and some other countries. It is expected that inflation rebates will attenuate drug price growth rates.

FIGURE 2: AN ILLUSTRATION: IRA POLICY REQUIRES DRUG COMPANIES TO PAY A REBATE ON DRUG PRICE INCREASES WHEN THEY EXCEED INFLATION.[17]



[17] Author created this figure.

B. Negotiation

17. Second, the IRA requires Medicare to negotiate prices for a subset of high spend, brand drugs that have been sold in the US market for close to a decade or more.[18] By focusing on long-lived drugs U.S. policy differs dramatically from other countries that set prices for drugs at launch. The type of negotiation envisioned by IRA is not novel. Negotiation methods that resemble this program are used by the Veteran's Administration, the Department of Defense and state Medicaid agencies.

18. Certain types of drugs are excluded from negotiation. Exclusions are intended to minimize impacts on innovative activities. Drugs excluded from negation include:

- Those with Medicare spending of less than $200 million in 2021 (increased by inflation for subsequent years).
- Those with a generic or biosimilar available and delays selection of biologic drugs for negotiation by up to two years if a biosimilar product is likely to enter the market in that time.
- Those that are less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA-approval or licensure date.
- "Small biotech drugs" (until 2029), defined as those which account for 1% or less of Part D or Part B spending and account for 80% or more of spending under each part of that manufacturer's drugs.
- Drugs with an orphan designation as their only FDA-approved indication; and
- All plasma-derived products.

19. Among drugs meeting all eligibility criteria, the law requires CMS to select drugs for negotiation in rank order, from highest to lowest gross annual Medicare spending until reaching the annual cap on the number of new drugs being selected. The first set of negotiations, on 10

[18] This is an authority the Medicare program did not have before IRA passage. See Conti, R.M., Dusetzina, S.B., & Sachs, R. (2020). How The ACA Reframed the Prescription Drug Market and Set the Stage for Current Reform Efforts. *Health Aff (Millwood)*, *39*(3), 445-452. doi:10.1377/hlthaff.2019.01432

Part D drugs, began in 2023. Negotiated prices on those drugs were released in August 2024, and will go into effect in 2026.[19]

20. In future years, CMS will select for negotiation additional drugs, including drugs covered under Part B, growing to a maximum of 20 new drugs selected each year (**Figure 3**).[20]

FIGURE 3: SCHEDULE OF IRA NEGOTIATION PROVISIONS BY IMPLEMENTATION YEAR, NUMBER OF PRODUCTS AND MEDICARE BENEFIT.

Negotiation year	Implementation year	# of Products	Benefit
2023/4	2026	10 Drugs	Part D only
2025	2027	15 Additional drugs	Part D only
2026	2028	15 Additional drugs	Part B and D
2027 and beyond	2029 and beyond	20 Additional drugs	Part B and D

C. Capping the out-of-pocket price of insulin and adult vaccines

21. Third, starting in 2023, IRA lowers the price of selected drugs to support individual health and public health goals, notably insulin and adult vaccines and caps out of pocket costs to seniors.

22. Medicare beneficiaries have a high prevalence of diabetes[21] and there are disparities in diagnosis and treatment.[22] Most people with Medicare coverage access insulin through Medicare Part D, which covers injectable insulin, inhaled insulin, and disposable "patch" pumps. Medicare Part B provides coverage for insulin when it is medically required to be administered through non disposable insulin pumps.[23]

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[19] https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf

[20] https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf

[21] Centers for Medicare and Medicaid Services. (2020). "Diabetes period prevalence by state, 2020." Retrieved from: b2diabetes-state-current-year.jpg (1536×600) (ccwdata.org)

[22] Centers for Medicare and Medicaid Services. "Diabetes disparities in Medicare fee-for-service beneficiaries. Retrieved from: Diabetes Disparities in Medicare (cms.gov)

[23] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Report on the Affordability of Insulin. December 16, 2022. https://aspe.hhs.gov/reports/insulin-affordability-rtc

23. IRA caps insulin out-of-pocket spending at $35 per month's supply of each insulin product covered under a Medicare Part D plan, with similar limits for out-of-pocket costs for insulin supplied under Part B and reduces out-of-pocket drug spending in Medicare in other ways. These provisions will make insulin more affordable for people covered by Medicare and will likely increase their adherence to recommended treatment protocols.[24]

24. Similarly, vaccines are necessary to reduce the spread of disease, prevent serious illness, and limit adverse health consequences. Access to vaccines for older Americans, most of whom are covered by Medicare, is particularly important because changes in the immune system in older age can increase susceptibility to infectious diseases.[25] For individuals with Medicare, vaccines are covered through a combination of Medicare Part B and Part D, depending on the vaccine.[26]

25. Part D vaccine coverage historically included cost-sharing requirements (**Figure 4**).[27,28,29]

[24] McAdam-Marx, C., Ruiz-Negron, N., Sullivan, J. M., & Tucker, J. M. (2022). The effects of patient out-of-pocket costs for insulin on medication adherence and health care utilization in patients with commercial insurance; 2007-2018. Journal of Managed Care & Specialty Pharmacy, 28(5), 494–506. https://doi.org/10.18553/jmcp.2022.21481

[25] Haynes, L. (2020, October 15). Aging of the Immune System: Research Challenges to Enhance the Health Span of Older Adults. Frontiers. Retrieved February 13, 2023, from https://www.frontiersin.org/articles/10.3389/fragi.2020.602108/full.

[26] Medicare Interactive. (2023). Vaccines and immunizations. Medicare Interactive. Retrieved February 13, 2023, from https://www.medicareinteractive.org/get-answers/medicare-covered-services/preventive-services/vaccines-andimmunizations.

[27] Congress. (2021, June). Medicare vaccine coverage and payment. MedPAC. Retrieved February 10, 2023, from https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-documentlibrary/jun21_ch7_medpac_report_to_congress_sec.pdf.

[28] Carr, T. (2017, April 28). Why Does My Shingles Vaccine Cost So Much? Consumer Reports. Retrieved February 10, 2023, from https://www.consumerreports.org/health/why-the-shingles-vaccine-cost-so-much/.

[29] There is variation in how much seniors had to pay OOPs for vaccines based on whether they qualify for the low-income subsidy (LIS) (sometimes called 'extra help'). Out-of-pocket costs for all vaccines represented 32 percent of total vaccine costs. For LIS enrollees, out of pocket costs were 3 percent of total vaccine costs, while non-LIS enrollees paid considerably more in out-of-pocket costs as a percentage of total vaccine costs (39 percent).

FIGURE 4: OUT-OF-POCKET COSTS PER MEDICARE PART D ENROLLEE FOR PART D COVERED VACCINES, 2021[30,31]

	Enrollees Receiving Vaccines (n)	Average OOP ($)	90th Percentile OOP ($)
Vaccines			
Shingles	562,272	76.94	192.8
Tdap	136,966	27.93	66.3
Td	6,874	20.25	56.21
Hepatitis A	6,093	34.1	97.15
Hepatitis B	8,515	51.18	139.29
Others	7,823	47.41	136.13
Received any vaccine	675,882		

26. Effective January 1, 2023, the IRA eliminated enrollee cost-sharing for recommended vaccines covered under Medicare Part D. This makes coverage of vaccines under Medicare Part D consistent with coverage of vaccines under Medicare Part B, such as the flu and COVID-19 vaccines.[32]

D. Part D Redesign

27. Fourth, starting in 2024, the IRA redesigns Part D to reduce out-of-pocket payments for beneficiaries using drugs.

28. Under the pre-reform structure of Part D, there were multiple phases, including a deductible, an initial coverage phase, a coverage gap phase, and the catastrophic phase (**Figure 5**). During the coverage gap benefit phase, enrollees paid 25% of drug costs for both brand-name and generic drugs; plan sponsors paid 5% for brands and 75% for generics; and drug manufacturers provided a 70% price discount on brands. Beneficiaries faced different cost-sharing amounts for the same medication depending on which phase of the benefit they were in, and could face significant out-of-pocket costs for high-priced drugs because of coinsurance requirements and no hard out-of-pocket cap.

[30] Author Adapted from ASPE report 2023 Table 5 and Table 6.

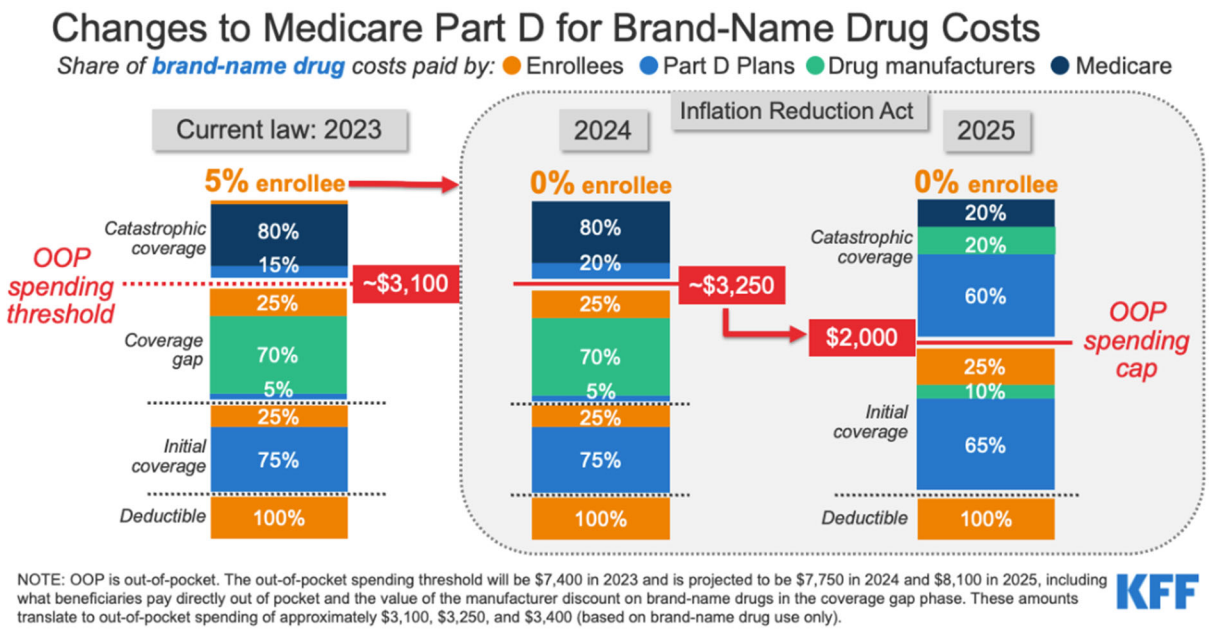
[31] Source: ASPE analysis of the CMS 2021 Medicare Prescription Drug Event (PDE) and Medicare enrollment data files. Estimates are presented for enrollees who received any Part D covered vaccines. For vaccines that require multiple doses to complete the vaccination series, estimates include all doses received in 2021. OOP = Out-of-Pocket.

[32] The law also requires state Medicaid and CHIP programs to cover all approved adult vaccines recommended by ACIP and vaccine administration, without cost sharing.

29. IRA reforms Part D benefit design through several provisions (**Figure 5**):

- Eliminating the 5% beneficiary coinsurance requirement above the Part D catastrophic coverage threshold, capping out-of-pocket costs at approximately $3,250 beginning in 2024.
- Adding a hard cap on out-of-pocket spending of $2,000 beginning in 2025 and indexed in future years to the rate of increase in per capita Part D costs.
- Reducing Medicare's liability for spending above the out-of-pocket cap. Beginning in 2025, Medicare's share of total costs above the spending cap will decrease from 80% to 20% for brand-name drugs and to 40% for generic drugs.
- Adjusting the calculation of the base beneficiary premium for 2024 through 2029, limiting premium increases to no more than 6% from the prior year.
- Providing Part D enrollees, the option to spreading out their out-of-pocket costs over the year rather than face high out-of-pocket costs in any given month.

FIGURE 5: CHANGES TO MEDICARE PART D LIABILITY FOR BRAND-NAME DRUGS.



30. In addition, the IRA expands subsidies to improve the affordability of Part D coverage for low-income seniors. The Part D Low-Income Subsidy (LIS) Program helps beneficiaries

with their Part D premiums, deductibles, and cost sharing, providing varying levels of assistance to beneficiaries at different income and asset levels up to 150% of poverty.

E. Summary of IRA provisions expected effects, and effective dates

31. **Figure 6** provides a summary of IRA's policy provisions, the timeline of provisions taking effect, the expected impact on Medicare beneficiaries and the program.

FIGURE 6: SUMMARY OF KEY IRA PROVISIONS, TIMELINE FOR IMPLEMENTATION, AND EXPECTED BENEFIT

IRA Policy Provision	Expected Effect	Effective Date(s)
Require the federal government to negotiate prices for some drugs covered under Medicare Part B and Part D with the highest total spending	Increase affordability and access to Medicare beneficiaries and program	Part D: 2026 Part B: 2028
Require drug companies to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries	Increase affordability and access to Medicare beneficiaries and program	Part D: 2022 Part B: 2023
Cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes	Increase affordability and access to Medicare beneficiaries and program	2024
Limit monthly cost sharing for insulin to $35 for people with Medicare	Increase affordability and access to Medicare beneficiaries	2023
Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and CHIP	Increase affordability and access to Medicare beneficiaries	2023
Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program	Increase affordability and access to Medicare beneficiaries	2024

32. In the next section, I provide greater detail on the expected effect on program spending, the federal budget deficit.[33] In the following section, I summarize the emerging evidence on the observed effect of reforms on beneficiary access, affordability, and innovation.

VI. EXPECTED NET EFFECTS OF THE IRA ON THE DEFICIT AND PROGRAM SPENDING

33. The IRA's reforms are expected to financially benefit taxpayers and seniors. **Figure 7** summarizes key IRA provisions and their expected effect on the budget. In this section, I briefly review how inflation rebates and negotiation will produce federal savings.

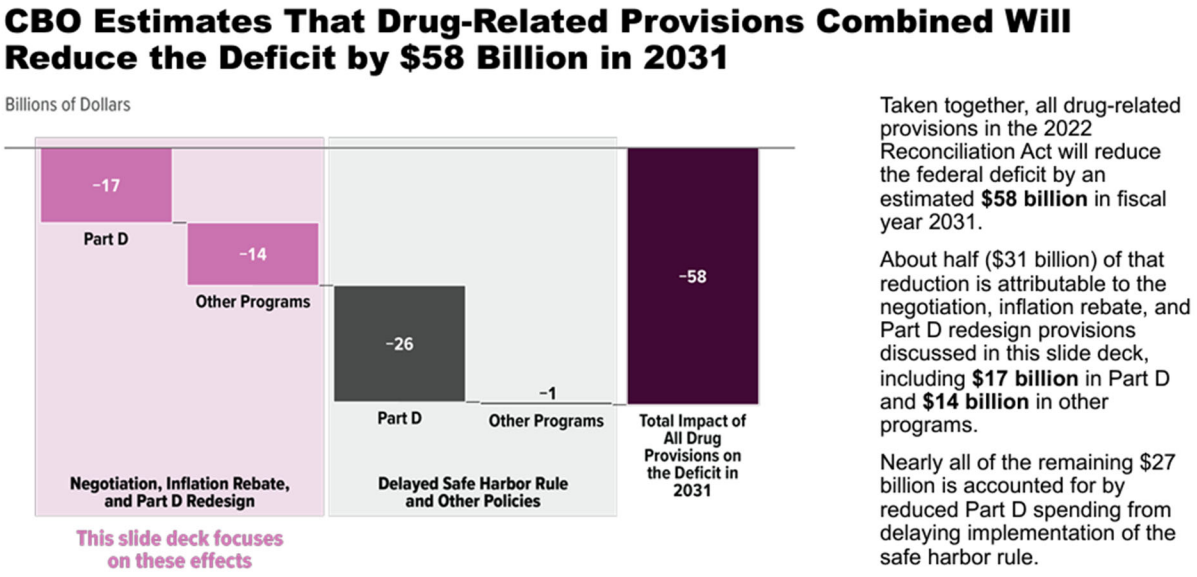
FIGURE 7: ESTIMATED SAVINGS FROM IRA PROVISIONS ACCORDING TO THE CONGRESSIONAL BUDGETARY OFFICE (CBO).

IRA Policy Provision	CBO Estimated Budgetary Impact IRA Provisions	+/- Spending
Require the federal government to negotiate prices for some drugs covered under Medicare Part B and Part D with the highest total spending	$98.5 billion in Medicare savings (2022-2031).	↓
Require drug companies to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries	Net federal deficit reduction of $63.2 billion (2022-2031).	↓
Cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes	Increase in federal spending by $30 billion (2022-2031).	↑
Limit monthly cost sharing for insulin to $35 for people with Medicare	Additional federal spending of $5.1 billion (2022-2031).	↑
Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and CHIP	Increase in federal spending by $7 billion (2022-2031).	↑
Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program	Increase federal spending by $2.2 billion (2022-2031).	↑

[33] CBO. How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. Feb, https://www.cbo.gov/publication/58850.

34. According to the non-partisan Congressional budgetary Office (CBO), taken together, all drug-related provisions in the 2022 Reconciliation Act will reduce the federal deficit by an estimated $58 billion in fiscal year 2031.[34] About half ($31 billion) of that reduction is attributable to the negotiation, inflation rebate, and Part D redesign provisions (**Figure 8**).

FIGURE 8: CBO ESTIMATES THAT COMBINED DRUG-RELATED PROVISIONS OF THE IRA WILL REDUCE THE DEFICIT.

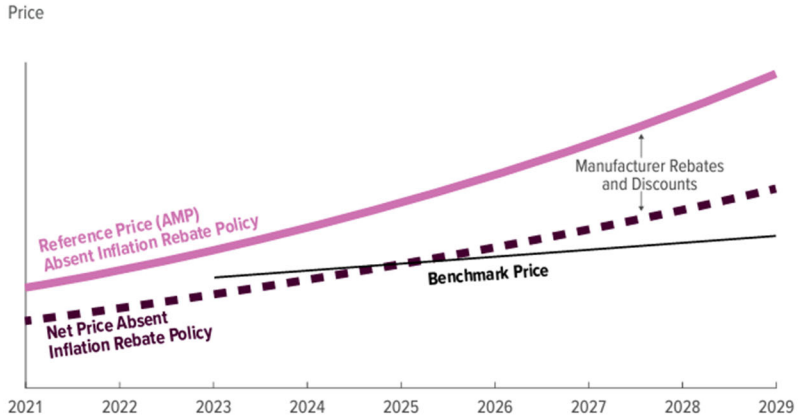


A. Effect of inflation rebates on the deficit

35. The fiscal effect of the inflation rebate provisions is significant. CBO estimates that, without the inflation rebate policy, both reference and net prices of brand-name part D drugs are expected to rise faster than inflation, while under inflation rebate provisions, CBO expects lower reference prices for many drugs and lower net prices for some drugs (**Figure 9**).

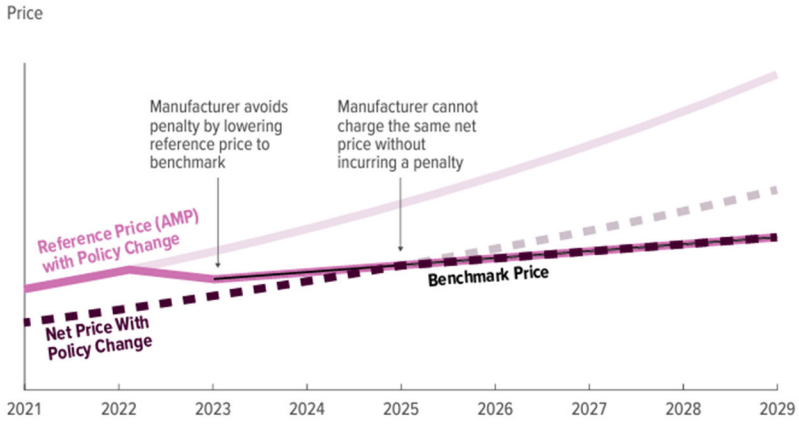
[34] CBO. How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. Feb, https://www.cbo.gov/publication/58850

FIGURE 9: CBO EXPECTS SAVINGS FROM INFLATION REBATE PENALTIES.



This illustrative figure compares prices of a hypothetical drug covered by Medicare Part D without the inflation rebate policy with the benchmark price set by the policy. The benchmark is based on the drug's 2021 price and is adjusted for inflation using the CPI-U in later years.

Starting in 2023, the manufacturer owes a penalty if the reference price exceeds the benchmark.



When the policy takes effect, the drug's reference price falls to avoid a penalty, but the net price is unaffected if the manufacturer can reduce rebates and discounts.

In this example, the manufacturer later chooses to constrain reference and net prices to avoid penalties. As a result, the drug's net price is lower in Medicare and commercial sectors after 2025.

36. Overall, CBO estimates that average net prices of that set of Part D drugs will be about 6 percent lower in 2031 than they would have been without the inflation rebate policy, generating around $7 billion in net budgetary savings.

B. Effect of negotiation on the deficit

37. The fiscal effect of drug price negotiation is significant.

38. CBO estimated that price negotiation will lower average drug prices paid by Medicare and will reduce the budget deficit by $25 billion in 2031. This will occur through the following effects:

- Part D spending will be $14 billion lower than it would have been;
- Part B drug spending will be $9 billion lower; and

- Other federal spending will be $1 billion lower on net.

39. CBO expects that net prices will also decrease for some of those drugs in both Part D and commercial markets.

VII. EMERGING EVIDENCE THAT IRA POLICIES ARE WORKING TO PROMOTE ACCESS AND AFFORDABILITY AND NOT HARM INNOVATION INCENTIVES

40. There is already evidence that the IRA is improving affordability and access for the program and Medicare beneficiaries. In this section, I summarize the emerging evidence.

A. Inflation Rebates

41. Inflation rebates are already lowering out of pocket costs for seniors in Part B.[35,36] Over the course of 2023, the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimates that 47 drugs had coinsurance rates based on inflation-adjusted payment amounts for one or more quarters of the year. Medicare enrollees who take these drugs may save as much as $618 per dose. These drugs treat medical conditions such as cancer, heart conditions, and infections. I estimate that thousands of Medicare beneficiaries are benefiting from lower out of pocket costs associated with these rebates. The larger effect of this policy is to prevent drug price increases above inflation rates.

B. Changes to Part D coverage for beneficiaries using insulin and adult vaccines

1. Insulin

42. ASPE examined out-of-pocket costs of insulin and the average cost per insulin prescription fill and estimated what would have happened to out-of-pocket spending on insulin among Medicare beneficiaries if the IRA's monthly copayment cap of $35 for a one-month

[35] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Inflation Reduction Act Research Series: Medicare Part B Inflation Rebates in 2023. (Fact Sheet No. HP-2023-28). December 2023. https://aspe.hhs.gov/reports/ira-research-series-medicare-part-b-inflation-rebates

[36] Medicare Part B covers outpatient prescription drugs and biologicals under certain conditions, for example, drugs provided as part of (or incident to) a physicians' service, and drugs furnished for use with covered durable medical equipment. Medicare Part D generally covers self-administered outpatient prescription drugs dispensed from retail or mail order pharmacies.

supply of a covered insulin product had been in effect in 2020.[37] They find the law is expected to produce better access to care and more affordability for seniors.

43. ASPE found that the national average out-of-pocket cost for Medicare beneficiaries was about $63 per fill on average. About 37 percent of insulin fills for Medicare enrollees (Part B and Part D) required cost-sharing exceeding $35 per fill, including 24 percent that exceeded $70 per fill.[38] ASPE estimated that 1.5 million Medicare beneficiaries would have benefited from the new IRA insulin cost-sharing limits if they had been in effect in 2020, with savings to those beneficiaries of about $734 million in Part D and $27 million in Part B – or approximately $500 in average annual savings per person among those benefiting from the provision (**Figure 10**).

FIGURE 10: ESTIMATED OUT-OF-POCKET SAVINGS IF INFLATION REDUCTION ACT $35/MONTH OUT-OF-POCKET INSULIN CAP HAD BEEN IN EFFECT IN 2020.

	Part D			Part B	Total
Outcome	Non-LIS	LIS	Total	Total	(Combined Part B and D)
Total IRA Savings ($ millions)	$723.2	$10.8	$734.0	$27.2	$761.16
Number of Insulin Users with Savings	1,477,327	76,503	1,517,817	31,376	1,519,856
Average Savings per Insulin User with Savings ($)	$490	$141	$484	$866	$501

Source: ASPE analysis of CMS Medicare Part D 2020 Prescription Drug Event (PDE), Enrollment, and Part B data files.
LIS = Low-Income Subsidy

44. ASPE also found that seniors gain from this provision across demography and state. The estimates indicate that substantial numbers of beneficiaries would benefit from the policy across all demographic groups analyzed (**Figure 11**). Figure 11 shows that across both Medicare Part D and B, 114,000 beneficiaries in Texas, 108,000 in California, and 90,000 in Florida are projected to have the highest number of enrollees that will benefit from the new IRA provision. Among those projected to have out-of-pocket savings, Texas ($50,395,627), Pennsylvania ($43,565,423), and Florida ($42,920,606) have the highest projected savings from the IRA's $35 insulin caps.

[37] Sayed, BA, Finegold, K, Olsen, TA, De Lew, N, Sheingold, S, Ashok, K, Sommers, BD. Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics. (Issue Brief No. HP-2023-02). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. January 2023.

[38] These estimates are only for enrollees who filled an insulin prescription and do not include potential costs for patients who did not fill their insulin due to cost or other reasons.

North Dakota ($805), Iowa ($725), and South Dakota ($725) have the highest average annual out-of-pocket savings per individual among those with savings.

FIGURE 11: ESTIMATED OUT OF POCKET SAVINGS IF IRA $35 OUT OF POCKET CAP ON INSULIN HAD BEEN IN EFFECT IN 2020 BY STATE.

State	Total Number of Enrollees in Part D and B Who Would Experience Savings	Projected IRA Savings ($)	Mean Annual Out-of-Pocket Savings Per Enrollee with Savings ($)
Alabama	29,127	$12,800,687	$439
Alaska	1,026	$613,867	$598
Arizona	28,124	$14,545,058	$517
Arkansas	15,559	$8,395,598	$540
California	108,164	$36,622,758	$339
Colorado	16,085	$8,288,613	$515
Connecticut	11,444	$6,749,195	$590
Delaware	6,066	$2,707,378	$446
District of Columbia	650	$262,462	$404
Florida	90,181	$42,920,606	$476
Georgia	45,625	$21,764,218	$477
Hawaii	3,703	$1,440,292	$389
Idaho	7,927	$4,801,119	$606
Illinois	59,718	$30,975,919	$519
Indiana	42,310	$22,876,374	$541
Iowa	18,834	$13,648,044	$725
Kansas	15,657	$10,170,650	$650
Kentucky	27,797	$12,590,086	$453
Louisiana	22,071	$9,095,485	$412
Maine	5,976	$3,169,201	$530
Maryland	21,052	$9,868,664	$469
Massachusetts	26,287	$13,248,195	$504
Michigan	66,726	$26,908,214	$403
Minnesota	27,128	$18,232,052	$672
Mississippi	15,366	$8,344,497	$543
Missouri	34,881	$18,256,529	$523
Montana	4,835	$2,913,023	$602
Nebraska	9,716	$6,576,898	$677
Nevada	10,769	$4,725,569	$439
New Hampshire	6,586	$3,533,326	$536

New Jersey	39,641	$20,239,433	$511
New Mexico	8,716	$3,856,841	$443
New York	75,601	$36,526,747	$483
North Carolina	56,921	$25,580,364	$449
North Dakota	4,527	$3,642,152	$805
Ohio	72,854	$36,536,703	$502
Oklahoma	19,556	$10,417,603	$533
Oregon	17,915	$10,586,279	$591
Pennsylvania	80,197	$43,565,423	$543
Rhode Island	4,678	$2,269,088	$485
South Carolina	31,235	$14,896,443	$477
South Dakota	4,568	$3,313,226	$725
Tennessee	39,562	$19,534,028	$494
Texas	114,242	$50,395,627	$441
Utah	11,393	$7,110,735	$624
Vermont	3,118	$2,153,816	$691
Virginia	36,461	$18,597,268	$510
Washington	28,063	$16,917,285	$603
West Virginia	12,656	$5,706,666	$451
Wisconsin	31,935	$20,064,260	$628
Wyoming	2,469	$1,597,721	$647
Total	1.5 million	$761 million	$501
Source: ASPE analysis of CMS Medicare Part D 2020 Prescription Drug Event (PDE), Enrollment, and Part B data files.			

2. Vaccines

45. ASPE also estimated the impact of the IRA vaccine provisions on seniors out-of-pocket and program costs.[39,40] They found that 3.4 million people received vaccines under Part D in

[39] Sayed, BA, Finegold, K, Ashok, K, Schutz, S, De Lew, N, Sheingold, S, Sommers, BD. Inflation Reduction Act Research Series: Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. (Issue Brief No. HP-2023-05). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September 2023.

[40] About 3.4 million (7 percent) of Medicare Part D enrollees received a Part D covered vaccine, paying a total of $234 million in out-of-pocket costs in 2021, or approximately $70 per beneficiary. Most enrollees who received a vaccine were immunized with the shingles vaccine (82 percent) with each patient paying an average of $77 in out-of-pocket costs, followed by the Tdap vaccine (21 percent) with each patient paying an average of $28 in out-of-pocket costs. In addition, on average, enrollees paid $20 out-of-pocket for the Td vaccine, $34 for the hepatitis A vaccine, and $51 for the hepatitis B vaccine. The ASPE analysis does not include vaccines for Coronavirus Disease 2019 (COVID-19) because they are covered under Medicare Part B and do not have any cost-sharing requirements. See: COVID-19 Vaccine Insurance Coverage (medicare.gov). Enrollees without the Part D low-income subsidy

2021 with annual out-of-pocket costs of $234 million. Under the IRA, these 3.4 million Medicare Part D enrollees would pay $0 in 2023, nearly $70 in out-of-pocket spending per Medicare enrollee receiving a Part D vaccine.

46. Had these provisions been in effect in 2021, ASPE found that they would have resulted in savings across a wide range of demographic groups. Improved affordability may also reduce existing racial and ethnic disparities in access to these vaccines.[41,42] State-level estimates show that California ($20,000,000), Florida ($18,000,000), and Texas ($14,000,000) had the highest total beneficiary out-of-pocket costs for all Part D vaccines and consequently will receive the most benefit from the elimination of OOPs (**Figure 12**). Reductions in OOPs should increase uptake of preventive vaccines.[43,44,45,46]

FIGURE 12: OUT-OF-POCKET COSTS FOR MEDICARE PART D ENROLLEES ON PART D COVERED VACCINES IN 2021, BY STATE

State	Number of Enrollees	Total OOP ($)	Average OOP ($)
Alabama	46,572	$2,608,021	$56.00
Alaska	4,668	$219,176	$46.95
Arizona	69,793	$5,458,900	$78.22
Arkansas	23,029	$1,993,391	$86.56
California	403,144	$20,485,565	$50.81

(LIS)* generally have the highest cost burden for prescription drugs, including vaccines. Non-LIS enrollees paid on average $86 per enrollee in 2021 for Part D vaccines, driven largely by the shingles vaccine.

[41] Vogelsang, E. M., & Polonijo, A. N. (2022). Scarier than the flu shot? The social determinants of shingles and influenza vaccinations among U.S. older adults. Vaccine, 40(47), 6747–6755. https://doi.org/10.1016/j.vaccine.2022.09.061

[42] US Department of Health and Human Services/Centers for Disease Control and Prevention. (2021, June 28). QuickStats: Percentage of Adults Aged ≥50 Years Who Ever Received a Shingles Vaccination, by Race and Hispanic Origin and Sex — National Health Interview Survey, United States, 2019. Morbidity and Mortality Weekly Report. Retrieved February 10, 2023, from https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7024a5-H.pdf.

[43] Stoecker, Charles, et al. "The Cost of Cost-Sharing: The Impact of Medicaid Benefit Design on Influenza Vaccination Uptake." MDPI, Multidisciplinary Digital Publishing Institute, 6 Mar. 2017, https://www.mdpi.com/2076-393X/5/1/8.

[44] Impact of Out-of-Pocket Cost on Herpes Zoster Vaccine Uptake: An Observational Study in a Medicare Managed Care Population - PMC (nih.gov)

[45] Carr, T. (2017, April 28). Why Does My Shingles Vaccine Cost So Much? Consumer Reports. Retrieved February 10, 2023, from https://www.consumerreports.org/health/why-the-shingles-vaccine-cost-so-much/.

[46] The Guide to Community Preventive Services. (2020, September 23). Vaccination Programs: Reducing Client Out-of-Pocket Costs. The Community Guide. Retrieved February 13, 2023, from https://www.thecommunityguide.org/findings/vaccination-programs-reducing-client-out-pocket-costs.html.

Colorado	56,425	$4,443,029	$78.74
Connecticut	48,313	$2,953,012	$61.12
Delaware	12,224	$934,702	$76.46
District of Columbia	5,038	$164,954	$32.74
Florida	227,344	$17,871,526	$78.61
Georgia	93,651	$6,946,928	$74.18
Hawaii	21,995	$1,010,558	$45.94
Idaho	17,156	$1,863,104	$108.60
Illinois	109,816	$9,910,342	$90.24
Indiana	77,232	$6,123,585	$79.29
Iowa	36,510	$4,259,984	$116.68
Kansas	28,166	$3,030,515	$107.59
Kentucky	37,289	$2,566,639	$68.83
Louisiana	37,982	$2,448,642	$64.47
Maine	24,520	$1,660,212	$67.71
Maryland	55,924	$2,941,648	$52.60
Massachusetts	97,115	$4,990,803	$51.39
Michigan	137,918	$7,912,422	$57.37
Minnesota	71,667	$6,887,417	$96.10
Mississippi	15,719	$1,371,952	$87.28
Missouri	62,795	$4,728,828	$75.31
Montana	10,920	$1,354,807	$124.07
Nebraska	20,708	$2,435,991	$117.64
Nevada	23,739	$1,862,211	$78.45
New Hampshire	16,111	$1,459,622	$90.60
New Jersey	75,358	$5,585,343	$74.12
New Mexico	24,729	$1,473,385	$59.58
New York	181,732	$9,008,318	$49.57
North Carolina	114,385	$7,743,573	$67.70
North Dakota	8,662	$1,100,209	$127.02
Ohio	135,253	$10,091,367	$74.61
Oklahoma	32,631	$2,337,476	$71.63
Oregon	53,531	$4,404,782	$82.28
Pennsylvania	177,459	$10,723,347	$60.43
Rhode Island	12,834	$877,907	$68.40
South Carolina	59,695	$4,237,362	$70.98
South Dakota	10,136	$1,443,301	$142.39
Tennessee	58,792	$4,416,899	$75.13
Texas	203,593	$13,966,302	$68.60

Utah	21,768	$2,085,598	$95.81
Vermont	9,224	$869,667	$94.28
Virginia	71,069	$5,950,166	$83.72
Washington	96,065	$7,042,902	$73.31
West Virginia	16,159	$917,539	$56.78
Wisconsin	81,269	$6,467,545	$79.58
Wyoming	4,413	$570,703	$129.32
Total	3,364,518	$234,454,174	$69.68

Source: ASPE analysis of the CMS 2021 Medicare Prescription Drug Event (PDE) and Medicare enrollment data files.
Notes: Estimates are presented for enrollees who received any Part D covered vaccines. For vaccines that require multiple doses to complete the vaccination series, estimates include all doses received in 2021.
Totals include enrollees residing in U.S. territories or outside the United States.
OOP = Out-of-Pocket

47. Another ASPE report[47] suggests IRA provisions have already increased the uptake of vaccines Part D-covered vaccines and saved beneficiaries over $400 million in 2023. The provisions also led to a 42% increase in uptake of the shingles vaccine and a 114% increase in the Tdap (tetanus, diphtheria, and pertussis) vaccine compared to 2021. Over 6 million beneficiaries also received the newly available respiratory syncytial virus (RSV) vaccine without cost sharing.[48]

C. Negotiation

48. The small list of drugs negotiated annually in Medicare have a large impact on Medicare beneficiaries. The first ten drugs eligible for negotiation are taken by about 9 million Medicare beneficiaries to treat conditions such as blood clots, diabetes, cardiovascular disease, heart failure, and autoimmune diseases, and accounted for $50.5 billion in total Part D spending between June 2022 and May 2023.[49] These ten drugs comprise twenty percent of total Part D spending in 2022. These drugs also account for $3.4 billion in out-of-pocket spending by Medicare beneficiaries in 2022. The initial drugs selected for negotiation reaped cumulative

[47] https://aspe.hhs.gov/reports/ira-elimination-vaccine-cost-sharing

[48] https://www.medicareinteractive.org/resources/dear-marci/does-medicare-cover-the-rsv-vaccine

[49] https://www.brookings.edu/articles/impact-of-federal-negotiation-of-prescription-drug-prices/

revenue after launch that far exceeded the costs of research and development.[50] Evidence suggests these drugs are clinically meaningful and consequently with reduced prices, and increased use, better health should follow.[51]

49. A recent analysis by the Brookings suggests Medicare negotiation reaped $6 billion in total or 22% on average below the pre-IRA price Part D plans negotiated net of rebates for these same drugs (**Figure 13**).[52] 51.4% of the estimated savings or $3.28 billion is accounted for by 3 drugs, Enbrel, Stelara and Eliquis. Several negotiated drugs had large rebates in the pre-IRA period (e.g., Jardiance, Januvia, Farxiga, and Novolog) and consequently it is notable that negotiations resulted in even lower prices. Also notable is that the largest price concessions from Medicare negotiation were obtained for drugs that had the lowest pre-IRA rebates because of limited pre-IRA competition, including Stelara, Enbrel, and Imbruvica. These drugs are used by seniors to manage their cancer and immunological disorders.

[50] Frank RG, Rowley C. Medicare Negotiations Won't Keep Pharma from Making a Fortune. Bloomberg. September 2022. Downloaded on December 20, 2023 from: Medicare Negotiations Won't Keep Big Pharma From Making a Fortune - Bloomberg

[51] DiStefano MJ, Levy JF, Odouard IC, Anderson GF. Estimated Savings From Using Added Therapeutic Benefit and Therapeutic Reference Pricing in United States Medicare Drug Price Negotiations. *Value Health*. 2023;26(11):1618-1624. doi:10.1016/j.jval.2023.08.004

[52] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Inflation Reduction Act Research Series: *Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program*. (Fact Sheet No. HP-2023-21). September 2023. Downloaded on November 20 2023 from: ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf (hhs.gov)

FIGURE 13: DRUGS WITH NEGOTIATED PRICES IN THE FIRST YEAR OF IMPLEMENTATION, SCHEDULED TO GO INTO EFFECT IN 2026.

Estimating Savings under IRA Negotiations Relative to Part D Plan Negotiations

For price year calendar year 2023, dollar amounts in millions

Drug Name	Part D Gross Drug Costs, 2023	Pre-IRA Manufacturer Rebates		Pre-IRA Net Sales	IRA Price Ceiling Category	Adjusted MFP Discount off Gross Sales	Sales at MFP	Savings under IRA negotiations
Eliquis	$18,275	0.49		$9,320	short monopoly	0.54	$8,464	$856
Jardiance	$8,841	0.60	b	$3,536	short monopoly	0.64	$3,164	$372
Xarelto	$6,310	0.49		$3,218	short monopoly	0.60	$2,524	$694
Januvia	$4,091	0.60	b	$1,637	long monopoly	0.78	$904	$732
Farxiga	$4,343	0.60	b	$1,737	short monopoly	0.66	$1,463	$274
Entresto	$3,431	0.49	a	$1,750	short monopoly	0.51	$1,697	$52
Enbrel	$2,952	0.29		$2,096	long monopoly	0.65	$1,025	$1,070
Imbruvica	$2,372	0.10		$2,135	short monopoly	0.35	$1,548	$587
Stelara	$2,989	0.19		$2,421	long monopoly	0.64	$1,070	$1,351
Novolog/Fiasp	$2,613	0.60	b	$1,045	long monopoly	0.75	$660	$385
Total	**$56,216**			**$28,894**			**$22,520**	**$6,374**

Note: (a) For this drug we used the rebate data reported for anticoagulants. Medpac did not analyze rebates for drugs that treat heart conditions. (b) Drugs that treat diabetes are assumed to have average manufacturer rebates of 60% based on reports from the Senate Finance Committee on insulin products. Click header row to sort.

B Center on Health Policy at BROOKINGS

50. The next 15 drugs are expected to be announced in January 2025 with negotiated prices taking effect in 2027. To provide insights regarding the Medicare price negotiation process, colleagues and I developed an eligibility database and selection model combining public and proprietary sources.[53,54] We applied these data to predict the next 15 drugs to be price negotiated by Medicare.[55]

51. Our results suggest the next 15 drugs subject to Medicare negotiation will account for $35 billion in Medicare spending and be used by 5 million Medicare beneficiaries. The second round of negotiation will target drugs directed towards different diseases than those in the first round and many of the forecast negotiated any of drugs have important clinical benefits. Because Ozempic (semaglutide) will now be within the time-on-market range for negotiation, its large footprint will make it the top contender for negotiation. The second highest drug was Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), which treats chronic obstructive pulmonary disease and asthma. Selected drugs came from diverse therapeutic categories led by oncology (40% of selected drugs in our model, up from 10% in the first round) and diabetes (27% of selected drugs vs 40% in the first round).[56]

[53] Vogel M, Kakani P, Chandra A, Conti RM. Medicare price negotiation and pharmaceutical innovation following the Inflation Reduction Act. Nat Biotechnol. 2024 Mar;42(3):406-412.

[54] Rome BN, Nagar S, Egilman AC, Wang J, Feldman WB, Kesselheim AS. Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022. JAMA Health Forum. 2023 Jan 6;4(1): e225218.

[55] We began our analysis by applying the three core requirements for price negotiation that determine the eligibility for almost all drugs. First, a product must have more than $200 million in annual gross (i.e., not including rebates or discounts) Medicare spending. Second, a product can have no marketed generic or biosimilar competition. Third, at least 7 years for small molecule drugs and 11 years for biologics must have elapsed since the product's initial Food and Drug Administration (FDA) approval. Following Medicare's implementation guidance, we defined a single "drug" to include all products marketed by a manufacturer using the same active moiety or ingredient. For example, Novo Nordisk markets three semaglutide products for Medicare beneficiaries: Ozempic and Rybelsus, for type 2 diabetes, as well as Wegovy, for cardiovascular disease in overweight patients. Under Medicare's approach, these products collectively constitute a single drug for purposes of IRA eligibility.

[56] We also predict several rounds with high spending may avoid a negotiated price due to expected generic competition. The third-highest ranked drug, Myrbetriq (mirabegron), a treatment for overactive bladder, is expected to go generic later this year, potentially avoiding selection. Pomalyst (pomalidomide), a drug used to treat multiple myeloma and Kaposi sarcoma, also faces upcoming generic competition. Pomalyst, however, is not expected to go generic until 2026, which would result in the drug being selected in 2025 for price negotiation but then deselected before the negotiated price would take effect in 2027.

D. Capping out of pocket costs in Part D

52. Many Medicare beneficiaries in Part D plans are likely to see substantial out-of-pocket cost savings from Part D reform beginning in 2024.[57] The beneficiaries most likely to benefit from these provisions include those with spending above the catastrophic threshold due to using a very high-priced specialty drug for medical conditions such as cancer, hepatitis C, or multiple sclerosis and those who take a number of high priced brand drug to manage their medical conditions. Most seniors take more than one medicine to manage health conditions. MedPac estimates that Part D beneficiaries filled between 4.2 and 5.7 prescriptions per month.[58]

53. According to a recent KFF's analysis, approximately 1.4 million Part D enrollees with higher-than-average out-of-pocket costs will save substantial amounts with a $2,000 out-of-pocket spending cap.[59] 1.4 million Part D enrollees incurred annual out-of-pocket costs for their medications above $2,000 in 2020, averaging $3,355 per person. This estimate includes 1.3 million enrollees who had spending above the catastrophic coverage threshold. These 1.4 million Part D enrollees would have saved $1,355, or 40% of their annual out-of-pocket costs, on average, if a $2,000 cap had been in place in 2020. Out of pocket savings for beneficiaries with cancer or multiple sclerosis may especially benefit. KFF estimated that in 2020, among Part D enrollees without low-income subsidies, average annual out-of-pocket spending for the cancer drug Revlimid was $6,200 (used by 33,000 beneficiaries); $5,700 for the cancer drug Imbruvica (used by 21,000 beneficiaries); and $4,100 for the MS drug Avonex (used by 2,000 beneficiaries).

54. In addition, an analysis by KFF suggests that providing full Medicare Part D LIS benefits to Part D enrollees with incomes up to 150% of poverty could help an estimated 0.4 million

[57] https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/#bullet03

[58] See MedPac Data Book July 2023, Table 10-17, https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_SEC.pdf

[59] These estimates are a conservative measure of how many beneficiaries will be helped by capping out-of-pocket drug spending under Medicare Part D starting in 2024 because they do not account for expected increases in annual out-of-pocket drug spending between 2020 and 2024/2025, the increase in the number of beneficiaries on Medicare, or higher utilization and spending associated with the increased affordability of prescription drugs due to this benefit improvement.

beneficiaries.[60] KFF estimates that annual out-of-pocket drug costs for these beneficiaries could fall by close to $300, on average, based on the difference between average out-of-pocket drug costs for LIS enrollees receiving full benefits versus partial benefits in 2020 – plus additional savings associated with more generous premium subsidies. These averages understate the potential cost savings for the smaller share of low-income enrollees facing extraordinarily high costs related to taking specialty medicines.

VIII. EVIDENCE IRA POLICIES ARE NOT HARMING INNOVATION

55. Finally, CBO has estimated that the IRA would not result in material reductions in innovation in the next decade and would have small effects over 30 years – 1 less drug over the next decade and 4 less drugs over the subsequent decade. Even then, the CBO report may have overstated reform's impact on innovation.[61] CBO's estimate does not account for the coincident increases in profits the pharmaceutical industry has realized in the past two years and is expected to increase in the next 5 years.[62]

56. The lack of significant effect on industry profits or investment activities likely reflects several facts. First, current reforms do alter patents or market exclusivities pharmaceutical companies selling their products to American consumers currently enjoy nor do they reduce insurance coverage for these products. Second, after reform, the U.S. remains the largest market for pharmaceuticals in the world and the U.S. pharmaceutical industry remains one of the most profitable sectors in our economy. Third, after reform the U.S. economy remains the most highly supportive of pharmaceutical innovation activity globally. Indeed, pharmaceutical leaders have stated that after IRA passage they are continuing to prioritize the US market.[63]

[60] https://www.kff.org/medicare/issue-brief/how-will-the-prescription-drug-provisions-in-the-inflation-reduction-act-affect-medicare-beneficiaries/

[61] Congressional Budget Office. CBO's Simulation Model of New Drug Development. Working Paper Series 2021-09. August 2021.

[62] CBO assumes pre-COVID19 growth in revenues derived from pharmaceutical sales. It does not account for the expected effects of pharmaceutical company revenue increases from COVID-19 therapeutics and vaccine sales, and outsized revenues from new product launches in oncology and immunology.

[63] See quotes in this document https://atiadvisory.com/resources/pharmaceutical-innovation-and-the-inflation-reduction-act-2023-in-review/

57. Nevertheless, before passage, members of the industry have claimed the IRA will "Decimate the hope of curing cancer and other deadly diseases"[64] and "Send us back to the dark ages of biomedical research."[65]

58. However, the reality suggests these, and other similarly dire predictions, are untethered to the facts of reform.

59. In a series of papers, my colleagues and I simulated the effect of IRA negotiation on drug company revenues and the likelihood of alterations in investments.[66,67] Our results do not support the view that Medicare negotiation will result in large-scale defunding of biopharmaceutical innovation. This is because most Medicare drug spending is exempt from negotiation.

60. We followed up on this analysis by focusing on biopharma venture capital (VC) funding.[68] VC is a key driver of innovation, with VC-backed emerging biopharma companies originating more than half of all new drug approvals. Therefore, it is reasonable to speculate that changes in funding or valuations for early-stage companies in 2022 or 2023 could be leading indicators of IRA-related changes in the broader pharmaceutical innovation ecosystem. However, we found little evidence the IRA has resulted in a meaningful decrease in the level of VC investment in new drug development.

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[64] Pharmaceutical Research and Manufacturers of America. *ICYMI: a Patient, Physician, Biotech Investor and Industry Leaders Warn About the Dangers of Government Price Setting Bill* https://catalyst.phrma.org/icymi-a-patient-physician-biotech-investor-and-industry-leaders-warn-about-the-dangers-of-government-price-setting-bill (2022). Cited in Vogel, Matthew, Rena M. Conti, and Amitabh Chandra. "Biopharma Venture Capital and The Inflation Reduction Act." *Health Affairs Forefront* (March 5, 2024).

[65] Biotechnology Innovation Organization. *New Drug Pricing Bill Could Propel Us Light Years Back into the Dark Ages of Biomedical Research* https://www.bio.org/press-release/new-drug-pricing-deal-could-propel-us-light-years-back-dark-ages-biomedical-research (2022). Cited in Vogel, Matthew, Rena M. Conti, and Amitabh Chandra. "Biopharma Venture Capital and The Inflation Reduction Act." *Health Affairs Forefront* (March 5, 2024).

[66] Rome BN, Nagar S, Egilman AC, Wang J, Feldman WB, Kesselheim AS. Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022. JAMA Health Forum. 2023 Jan 6;4(1): e225218.

[67] Vogel M, Kakani P, Chandra A, Conti RM. Medicare price negotiation and pharmaceutical innovation following the Inflation Reduction Act. Nat Biotechnol. 2024 Mar;42(3):406-412.

[68] Vogel, Matthew, Rena M. Conti, and Amitabh Chandra. "Biopharma Venture Capital and The Inflation Reduction Act." *Health Affairs Forefront* (March 5, 2024).

61. Other data reinforces our perspective. Late-stage private company and public equity valuations, IPOs, follow-on offerings, and mergers and acquisitions in biopharma largely held steady in the 18 months since passage of the IRA and have had a positive start in 2024.[69]

62. Investors also appear to recognize this reality. The stock price index of the ten largest pharmaceutical companies outperformed the broader market following passage of the IRA, and, though total US venture capital funding has fallen, the share invested in life sciences has not.

63. Indeed, companies themselves are reporting minimal effects of IRA on firm performance and innovation activities. My colleagues and I reviewed statements made to investors by drug company leaders. After IRA passage, these statements repeat objections to reform, but recognize that the IRA increases the use of drugs from the Part D redesign and the extension of first dollar coverage for insulin and adult vaccines. These and other changes will increase affordability and therefore the demand for many medicines. Moreover, while negotiation may impact their revenue, they claim the impacts are 'manageable.'

64. There is no evidence to support the industry's extreme argument, made before passage of the reforms, that drug companies will refrain from launching their new products in the U.S. if negotiation is enacted.

[69] https://www.brookings.edu/articles/early-claims-and-ma-behavior-following-enactment-of-the-drug-provisions-in-the-ira/

PRESCRIPTION DRUG SPENDING REFORM WILL NOT HARM INNOVATION AND WILL BENEFIT THE AMERICAN PUBLIC

Statement of Rena Conti, Ph.D.

Associate Professor

Department of Markets, Public Policy and Law

Questrom School of Business

Boston University

Senate Finance Committee Hearing

Prescription Drug Price Inflation: An Urgent Need to Lower Drug Prices in Medicare

Wednesday, March 16, 2022 - 10:00am

SUMMARY OF REMARKS

There is an urgent need for Congress to reform how Medicare pays for prescription drugs. Proposals to reduce drug prices, such as proposed in the recently passed House bill (H.R. 5376), will not harm pharmaceutical innovation and will improve affordability for the American public. I review the strong empirical evidence base supporting these claims.

MY BACKGROUND AND EXPERTISE

I am Rena M. Conti, Ph.D., Associate Professor of Markets, Public Policy and Law in the Questrom School of Business, and co-director of the Technology Policy and Research Institute, a joint program of Boston University's Business and Law Schools. Between 2006 and 2018, I was faculty at the University of Chicago. I am a graduate of Harvard University's Interfaculty Initiative in Health Policy, concentration economics.

My research interests are in the economics of the pharmaceutical industry. I have published over 100 peer reviewed articles, many in top economics, policy and medical journals. I have taught health economics and strategy in the pharmaceutical industry for two decades.

My research work is supported by grants, including from the National Cancer Institute, the Leukemia and Lymphoma Society, the American Cancer Society and Arnold Ventures.

OVERVIEW OF PROPOSED REFORMS AND LIKELY SAVINGS

There is a social compact between the American public and pharmaceutical companies: the industry is supported by taxpayer investments to benefit their health at an affordable price.[1] It does so by supporting all aspects of innovation and competition. Yet, some pharmaceutical companies are breaking the social compact. Pharmaceutical companies set prices of prescription drug which are so high they impose financial toxicity on the American public. 29% of Americans either can't afford their drugs or are rationing their drugs.[2] Instead of seeking the next breakthrough, companies delay competition to maintain exceptional revenue.

[1] Gruber J, Johnson S. **Jump-starting America: how breakthrough science can revive economic growth and the American dream**. NY: Public Affairs, 2019.

[2] Kirzinger A, Lopes L, Wu Bryan, Brodie M. *KFF Health Tracking Poll – February 2019: Prescription Drugs.* March 2019.

Reform provisions address these challenges in several ways.[3]

First, by imposing penalties on pharmaceutical companies to ensure that prices do not increase greater than inflation. These changes will reduce the number of prescriptions Americans don't fill or currently ration due to their expense.

Second, by extending new authority for the federal government to negotiate Medicare prices for selected drugs.[4] Negotiation will only target of drugs that have frequently manipulated the FDA rules and patent policy to extend exclusivity far beyond the intent of the legislation that created our patent system.

Third, by redesigning seniors' pharmacy coverage to cap out of pocket costs.

Reforms will generate significant savings for the American public over the next decade.[5]

For example, reform proposals aim to cap seniors' out of pocket costs for insulin at $35 dollars per prescription. For the 2.27 million seniors who use insulin daily, this will result in measurable savings.[6] American workers will also benefit from this change.

With access improvements, better health will likely follow.[7]

Reform will benefit the American public in other ways. Reform will benefit taxpayers. One government estimate suggests reform will generate $160 billion in savings over the next decade.

REFORM WILL NOT HARM INNOVATION

What these proposals will not do is harm pharmaceutical innovation.

[3] Conti RM, Frank RG, Gruber J. *Regulating Drug Prices while Increasing Innovation*. New England Journal of Medicine. 385(21): 1921-1923. November 2021.

[4] U.S. House of Representatives. *Drug Price Investigation. Lost Savings: How Prohibiting Medicare Negotiation Has Cost Taxpayers*. Staff Report Committee on Oversight and Reform. September 2021.

[5] Congressional Budget Office. *CBO's Simulation Model of New Drug Development*. Working Paper Series 2021-09. August 2021.

[6] Turner A, Conti RM, Hughes-Cromwick P. *Strategies to Advance Insulin Affordability in The United States*. Altarum's Center for Value in Health Care. September 2020.

[7] Chandra A, Flack E, Obermeyer Z. *The Health Costs of Cost Sharing*. National Bureau of Economic Research Working Paper 28439. February 2021.

Prior debates on how to make drugs more affordable have been weighed down by concerns about how reducing any drug prices will reduce the number of new 'cures'. A particularly colorful version of this claim include the head of PhRMA, the industry lobby group, threatening reform would cause a 'nuclear winter' for innovation.[8]

Those claims are not empirically based.

First, CBO reports that the proposed legislation would have very little impact on the number of new drugs produced.

The non-partisan Congressional Budget Office's report suggests that an earlier version of the latest House proposal would not result in material reductions in innovation in the next decade and would have small effects over 30 years – 1 less drug over the next decade and 4 less drugs over the subsequent decade.

Even then, the CBO report may have overstated reform's impact on innovation. CBO's estimate does not account for the coincident increases in profits the pharmaceutical industry has realized in the past two years and is expected to increase in the next 5 years.[9] CBO assumes pre-COVID-19 growth in revenues derived from pharmaceutical sales. It does not account for the expected effects of pharmaceutical company revenue increases from COVID-19 therapeutics and vaccine sales, and outsized revenues from new product launches in oncology and immunology.

Second, new drugs are not the same as new 'cures.'

In the context of reform, the key policy question for assessing the trade-off is not how many new drugs maybe lost (i.e. absolute quantity of new drugs), but what is the likely impact on breakthrough treatments by reducing prices for a limited number of older high-cost drugs (i.e quality of new drugs)?

Most of the evidence on which all sides base their claims come from the same "natural experiment", the expansion of Medicare to include the drug benefit or Medicare Part D

[8] U.S. House of Representatives, Committee on Oversight and Reform. *Drug Pricing Investigation: Majority Staff Report*. December 2021.

[9] IQVIA. *Global Medicine Spending and Usage Trends: Outlook to 2025.* April 2021.

implemented in 2006.[10] The research consistently showed that the number of new drugs grows as the market increased.

Yet, on the question of quality, the story is different. Research by Dranove and colleagues shows that the new launches following Part D implementation were almost entirely in areas where there were already existing therapies (5 or more, rather than 2 or fewer).[11] They also found that few were truly innovative. *Figure 1* from the paper highlights this point clearly.

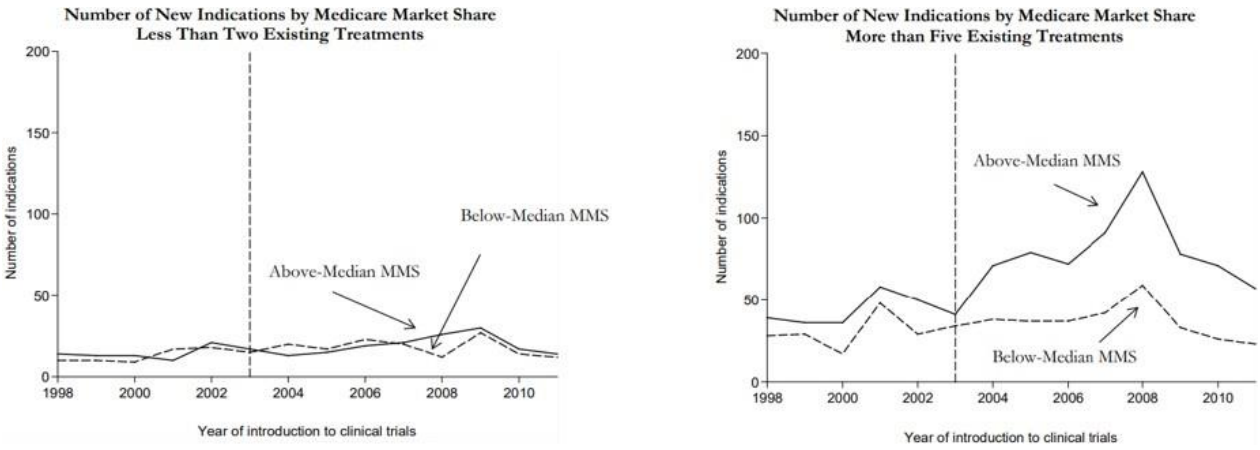

Figure 1. *Number of New Indications by Medicare Market Share Less Than or More than Five Existing Treatments*

Research by Amy Finkelstein[12] provides some insight into the possible mechanisms behind this. Her work argues that the companies took existing products that were "on the shelf" but not sufficiently profitable with the smaller market and launched them as the market grew.

[10] Blume-Kohout ME, Sood N. *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*. Journal of Public Economics. 97: 327-336. January 2013.

[11] Dranove D, Garthwaite C, Hermosilla M. *Pharmaceutical Profits and the Social Value of Innovation.* NBER Working Paper 20212. June 2014.

[12] Finkelstein A. *Static and Dynamic Effects of Health Policy: Evidence From The Vaccine Industry.* The Quarterly Journal of Economics. 119(2): 527-564. May 2004.

Research by Byrski and colleagues extends this line of analysis.[13] They examine the same data on the impact of the creation of Part D and then looked at the impact of the market expansion on new drugs, new patents, and new published science. What they found was that they could replicate the increase in new drugs found by prior studies and there was no overall evidence of increases in patenting or new published science.

In addition, most of the new pharmaceutical products (excluding generics) approved by the U.S. FDA are not new drugs at all. Data on FDA approvals from 2011 through 2021 show that of all brand name drug products approved only 32% were new molecular entities. The rest represent new version of old drugs. This is reflected in industry SEC filings and public testimony showing large R&D investments in new formulations for existing blockbuster drugs.

- Bristol-Myers spent a large part of its 2018-19 R&D dollars for line extensions for Opdivo and Yervoy existing blockbusters.
- Sanofi testified in the Senate that only 33 of its 81 R&D projects were for new chemical entities.

Third, new breakthrough treatments come from new science.

Drug innovation that is truly transformative for human health often emerges in large part from taxpayer supported research and development, even though this is rarely reflected in the pricing of the resulting drugs, nor in commensurate "payback" to the funding agencies that made them possible.

While the industry often plays an important role in bringing new drugs to market, all drugs brought to market in the U.S. can trace their discovery back to NIH-supported basic and translational science.[14]

Current reforms will not alter the American public's support for these investments.

[13] Byrski D, Gaessler F, Higgins MJ. *Market Size and Research: Evidence from the Pharmaceutical Industry*. National Bureau of Economics Research Working Paper 28858. May 2021.

[14] Kesselheim AS, Tan YT, Avorn J. *The Roles of Academia, Rare Diseases, and Repurposing in the Development of the Most Transformative Drugs.* Health Affairs (Millwood). 34(2):286-93. February 2015.

Therefore, as long as Congress continues funding the National Institutes of Health and university-based scientists, then we can be assured that the next generation of important new treatments will be in the pipeline.

Fourth, additional drivers of innovation will not be altered by reform.

The pharmaceutical industry wouldn't exist without the support of the American public in many additional ways. These include:

- Patents and other types of intellectual property protections offer the potential for economic rewards to invention of new treatments.[15]
- Public support is also linked to the later-stage development of many transformative drugs at university labs or spin-off small companies before being acquired by large manufacturers.[16] For example, the public supports private sector investments into orphan diseases, antibiotics, COVID-19 therapeutics and vaccines.[17]
- Robust financial markets which affect both the existence and pace of innovation.[18]

The American public also supports policies that protect consumers from companies taking advantage of this support. For example, the U.S. Food and Drug Administration establishes the level of testing for safety and efficacy that pharmaceutical companies must conduct to avoid patient harm. Policies such as The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, support innovation and competition.

Finally, proposed reforms are further targeted to mitigate potential harms to innovation.

Empirical evidence suggests even many of the most expensive drugs make in revenue the full costs of research and development within 5 years post-launch.[19] Under currently discussed

[15] Lerner J. *150 Years of Patent Protection*. American Economic Review. 92(2): 221-225. May 2002.

[16] Nayak RK, Avorn J, Kesselheim AS. *Public sector financial support for late stage discovery of new drugs in the United States: cohort study.* BMJ. 367(l5766). September 2019.

[17] Congressional Research Service. *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials.* March 2021.

[18] Hall B, Lerner J. *The Financing of R&D and Innovation*. Chapter 14 in **Handbook of the Economics of Innovation**, vol. 1: pp. 609-639. 2010.

[19] United States Government Accountability Office. *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*. GAO-18-40. November 2017.

reforms, drugs are only eligible for Medicare price negotiation after being on the U.S. market for more than a decade. Therefore, the proposed reforms give manufacturers plenty of time to make profits on new drugs while reducing the incentives companies currently face to forestall competition. Reform's focus on older drugs a decade or more post-launch for negotiation obviates another extreme argument the industry propounded earlier in the debate, that companies will refrain from launching their products in the U.S. if they are subject to negotiation.

THERE IS A STRONG EVIDENCE BASE FOR THE REFORMS CURRENTLY PROPOSED

U.S. pharmaceutical spending levels and trends

There were 6.3 billion prescription dispensed in the U.S. market in 2020. Older Americans use most dispensed prescription drugs and polypharmacy is common. Nearly 7 in 10 adults aged 40–79 used at least 1 prescription drug in the past 30 days in the United States (69.0%) and around 1 in 5 used at least 5 prescription drugs (22.4%).[20]

U.S. pharmaceutical spending currently represents approximately 14% of overall healthcare spending,[21] including 4% of spending in non-retail outpatient clinics and hospital settings. Spending on pharmaceuticals has risen by 20% over the past 10 years; an average of 2% per year.[22]

U.S. spending on pharmaceuticals is forecast to grow 0–3% CAGR over the next 5 years. To put these figures in broader context, industry reports expect global medicine spending through 2025 to amount to about $1.6 trillion. Projected global spending on pharmaceuticals by IQVIA, the industry gold standard, is $88 billion higher than their pre-COVID outlook.

Two types of on patent 'branded' pharmaceuticals contribute substantively to drug spending growth: new drugs and the expanded use of existing drugs. Also notable is that specialty drugs, including those in the protected Part D categories of oncology and immunology, have been

[20] Hales CM, Servais J, Martin CB, Kohen D. *Prescription drug use among adults aged 40–79 in the United States and Canada.* NCHS (National Center for Health Statistics) Data Brief. 347. August 2019.

[21] Conti RM, Turner A, Hughes-Cromwick P. *Projections of US Prescription Drug Spending and Key Policy Implications.* JAMA Health Forum. 2(1): e201613. January 2021.

[22] IQVIA Institute. *The Use of Medicines in the United States*. May 2021.

increasing as a share of spending. In 2020, specialty drugs comprised 47% of spending, up from 24% 10 years earlier. Specialty drug spending is expected to increase to 60% of total pharmaceutical spending in the U.S. by 2025.

According to a recent analysis by the Kaiser Family Foundation, half of all Part D covered drugs (50% of 3,343 drugs) and nearly half of all Part B covered drugs (48% of 568 drugs) had price increases greater than inflation between July 2019 and July 2020, which was 1.0.[23] Moreover, 23 of the top 25 Part D drugs and 16 of the top 25 Part B drugs had price increases above inflation between 2019 and 2020.[24] See Figure 2 for details.

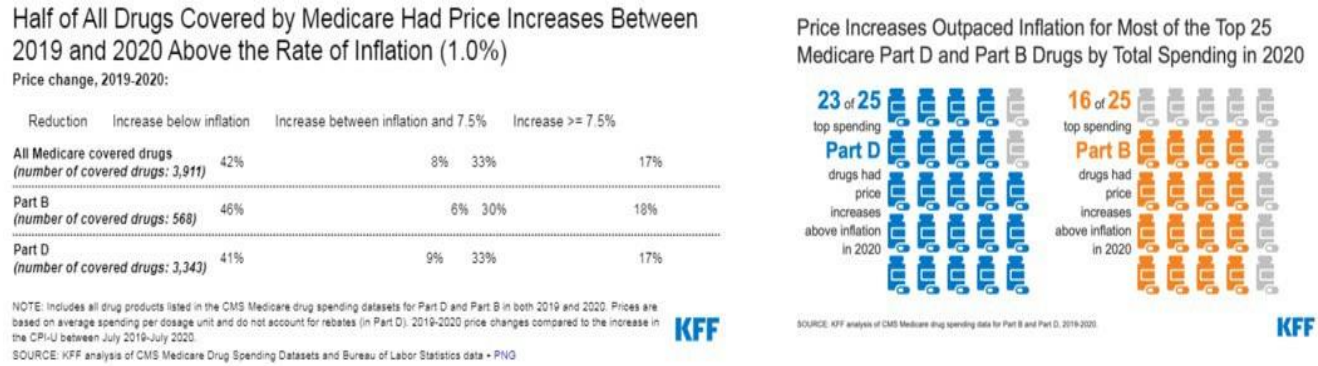

***Figure 2**: Price Trends Paid by Medicare Beneficiaries Outpace Inflation.*

High pharmaceutical prices and price inflation is a result of pharmaceutical companies breaking the social compact with the American public.

Paying high prices for new pharmaceuticals is one way among many the American public encourages innovation. The counterweight to paying high prices is competition. Our system relies on competition after patents and other exclusivities expire on pharmaceuticals to bring

[23] Cubanski J, Neumann T. *Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020*. KFF Issue Brief. February 2022.

[24] Annual price increases are also inconsistent with the notion that prices are optimized for profit maximization at launch and appear unrelated to approval of supplemental indications, additional information about the benefits associated with treatment, and potential increases in manufacturing costs. See Bennette CS, Richards C, Sullivan SD, Ramsey SD. *Steady Increase in Prices for Oral Anticancer Drugs after Market Launch Suggests a Lack of Competitive Pressure*. Health Affairs (Millwood). 35(5):805-12. May 2016.

down prices and reduce spending. We expect companies to move onto innovate the next opportunities.

Yet, there is mounting empirical evidence that this social contract has been violated by some pharmaceutical companies.[25] New reports released by the U.S. House of Representatives' Oversight Committee details drug companies egregious and widespread manipulation of our system to delay competition from lower-priced generics and biosimilars of such drugs a decade or more after launch.

Price inflation is the direct result of pharmaceutical companies ensuring their profitability in drugs by delaying competition.[26] The House Oversight's recent report on Copaxone, an MS drug, suggests Teva played many games to forestall competition, while raising prices.[27] Celgene and Bristol Myers Squibb's Revlimid,[28] a drug that treats blood cancers launched in the U.S. in 2005, and Abbvie's Humira, a drug that treats arthritis and other inflammatory diseases launched into the U.S. market in 2002 has only recently faced competition. The pricing of these drugs in the U.S. has also increased since launch. A one-month supply of Revlimid pills now costs approximately $23,000 and a one-month supply of Humira injections costs approximately $10,000.

Moreover, the significant revenues reaped from these activities by the pharmaceutical companies are not primarily directed into research and development efforts. Instead, high prices, price

[25] For an explanation and summary of activities, see Statement by Michael A. Carrier to House Judiciary Committee (Subcommittee on Antitrust, Commercial and Administrative Law). House Subcommittee of House Judiciary Committee hearing. April 27, 2021.

[26] See for example, U.S. House of Representatives. *Drug Pricing Investigation AbbVie—Humira and Imbruvica*. Staff Report Committee on Oversight and Reform. May 2021.

The report states "New documents show that these settlements allowed AbbVie to delay competition far beyond what its own internal assessments of the strength of its patent portfolio predicted. In 2014, AbbVie's executives estimated that three to five biosimilar competitors would enter the market by the first quarter of 2017. AbbVie ultimately entered into settlement agreements with four of these competitors, delaying their entry into the market until 2023."

[27] U.S. House of Representatives. *Drug Pricing Investigation Teva—Copaxone*. Staff Report Committee on Oversight and Reform. September 2020.

[28] U.S. House of Representatives. *Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid*. Staff Report Committee on Oversight and Reform. September 2020.

increases and significant profits lead to higher executive compensation, dividend payments to stockholders and stock buybacks.[29]

Why should Americans always have to pay the highest prices for pharmaceuticals?

The U.S. is the largest market for prescription drugs in the world.[30] Approximately 40% of all prescription drug sales is in the U.S. market.[31] Corporate profits off the sale of prescription drugs are expected to reach over $1.3 trillion in 2021 and the top pharmaceutical companies are more profitable than those in non-pharmaceutical industries, including the technology giants Apple and Amazon.[32]

Pharmaceutical companies strongly prefer to launch new drugs in the U.S. where they fetch the highest prices.[33] Unlike other OECD countries, U.S. payers place no limits on the prices pharmaceutical companies can charge for drugs while they are protected from competition by patents and market exclusivities. These features lead drug companies to set high prices well above standard measures of clinical and economic benefit and pursue price increases that greatly exceed the general rate of inflation.[34] In fact, evidence suggests pharmaceutical companies target U.S. payers for drug price increases, while at the same time decreasing prices in other countries. Celgene's Revlimid and Teva's Copaxone took significant price increases to increase revenue in the U.S. at the same time as cutting prices in other countries. In a new study of cancer drugs, pharmaceutical companies are observed to increase prices in the U.S. that exceed inflation, while

[29] U.S. House of Representatives. *Industry Spending on Buybacks, Dividends, and Executive Compensation*. Staff Report Committee on Oversight and Reform. July 2021.

[30] International Federation of Pharmaceutical Manufacturers & Associations. *The Pharmaceutical Industry and Global Health. Facts and Figures 2021.* April 2021.

[31] United States Government Accountability Office. *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*. GAO-18-40. November 2017.

[32] Ledley FD, McCoy SS, Vaughan G, Cleary EG. *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*. JAMA. 323(9): 834-843. March 2020.

[33] National Academies of Sciences, Engineering, and Medicine. **Making Medicines Affordable: a National Imperative**. Washington, DC: National Academies Press. 2018.

[34] Schondelmeyer SW, Purvis L. *Rx Price Watch*: *Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2019*. AARP Public Policy Institute. November 2019.

at the same time prices stayed stable or declined in Germany and Switzerland.[35] When Abbvie pursued price increases on Humira, it claimed it did so because it was being 'forced' to reduce prices in other countries. While it may make common sense for firm to offset 'losses' with gains, this pricing behavior by pharmaceutical companies controverts the companies' own statements to Congress suggesting the prices of prescription drugs in the U.S. are untethered to those in other countries.[36]

While many expensive biologics remain without competition in the U.S., inexpensive biosimilars have been available since 2006 within Europe. In 2021, biologics represented 34% of spending in Europe on pharmaceuticals.[37] Despite 2020 being impacted by the COVID-19 pandemic, the volume of biosimilar prescribing in the EU is estimated to have generated a record high in savings from biosimilar competition, of €5.7 billion (about $6.8 billion USD) in savings versus the pre-biosimilar cost of the originator by 2020.

When reforms reduce the option for companies to pursue such behavior, pharmaceutical companies will move onto seek revenue by investing in innovative treatments. When the Supreme Court ruled that companies could no longer pay to delay generic entry, the companies that were doing that instead started to pour money into research and development.[38]

American public 'financial toxicity' related to high and growing pharmaceutical prices.

Expanded pharmaceutical insurance coverage has benefited many. Yet, too many seniors are locked out of the promise of pharmaceuticals currently available. The prices of some drugs seniors need to stay alive – such as Tysabri and Rebif for MS and Revlimid and Imbruvica for cancer - are now so high that they exceed the costs of a private university education. A recent survey suggests 18 million Americans

[35] Vokinger KN, Hwang TJ, Carl DL, Laube Y, Ludwig W-D, Naci H, Kesselheim AS. *Price changes and within-class competition of cancer drugs in the USA and Europe: a comparative analysis*. The Lancet Oncology. March 2022.

[36] Pharmaceutical company executives have dismissed this as a possibility, stating repeatedly that there is no direct relationship between U.S. drug prices and foreign prices. See U.S. House of Representatives. *Drug Pricing Investigation AbbVie—Humira and Imbruvica*. Staff Report Committee on Oversight and Reform. May 2021; and PhRMA. Complaint, in Litigation Challenging Legality of the Administration's Most Favored Nation Rule. December 4, 2020.

[37] IQVIA. *The Impact of Biosimilar Competition in Europe*. December 2021.

[38] Li X, Lo AW, Thakor RT. *Paying Off The Competition: Market Power And Innovation Incentives*. NBER Working Paper 28964. June 2021.

can't pay for the drugs they need.[39] The substantial costs of cancer care on patients are now so common they are termed 'financial' toxicity, a play on the commonly encountered medical toxicities patients experience with chemotherapy.[40]

My own work on this topic focuses on the blood cancers, multiple myeloma (MM) and chronic lymphocytic leukemia (CLL), which represent a small percentage of all cancers, but for which treatment costs are among the highest. Treatment advances in both cancer types have resulted in greater survivorship and improved quality of life for patients. Nevertheless, my research group has found that close to half of the blood cancer patients we surveyed report financial difficulties associated with cancer treatment. Reports of financial burden commonly include an inability to pay for basic necessities such as food and utility bills, the presence of medical debt and high out of pocket burdens relative to income.

There is also underuse. In my study, reports of financial burden are associated with worrisome deficits in care - medication non-adherence including skipping medication, taking less medication or not filling recommended prescriptions at all. In other work, while new drugs have transformed calls for the elimination of HIV[41] and the hepatitis C virus by 2030[42] into tangible goals, these drugs remain underused.

The status quo also imposes costs on taxpayers. Finally, these behaviors harm workers in the form of higher health insurance premiums and lower wages.

CONCLUSIONS

In summary, the consequences of continued Congressional inaction on pharmaceutical prices are simply untenable. Currently, 29% of Americans either can't afford their drugs or are rationing their drugs. Proposed reforms will not harm innovation. Proposed reforms will not alter the

[39] Witters D. *In U.S., an Estimated 18 Million Can't Pay for Needed Drugs*. Gallup. September 21, 2021.

[40] National Institutes of Health, National Cancer Institute. *Financial Toxicity Associated with Cancer Care – Background and Prevalence.*

[41] U.S. Department of Health and Human Services. *HIV National Strategic Plan: A Roadmap to End the Epidemic for the United States 2021-2025*. 2021.

[42] Hofmeister MG, et al. *Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013-2016.* Hepatology. 69: 1020-1031. November 2018; Centers for Disease Control and Prevention. *CDC Estimates Nearly 2.4 Million Americans Living with Hepatitis C.* Press Release. November 2018.

American public's substantial support for basic science, product development, strong universities, nor a highly favorable funding environment. Proposed reforms will not alter patents or market exclusivities pharmaceutical companies selling their products to American consumers currently enjoy nor reduce insurance coverage for these products.

After reform, the U.S. will remain the largest market for pharmaceuticals in the world. After reform, the U.S. pharmaceutical industry will remain the most profitable sector in our economy. After reform, the U.S. economy will remain the most highly supportive of innovation activity globally. Consequently, pharmaceutical companies will continue to invest in innovative products and investors will remain invested in this sector.

What these reforms do represent is a modest step towards limiting the economic burden placed on Americans from pharmaceutical companies' manipulations of our system. In doing so, they help restore the social compact between pharmaceutical companies and the American public.