

A Study on the Inflation Reduction Act (2022) and Its Impact on Pharmaceutical Pricing

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Abstract

In 2022, the Inflation Reduction Act (IRA) marked a pivotal shift in U.S. healthcare reform, particularly targeting the escalating costs of prescription drugs. The IRA aims to reduce prescription drug costs, expand benefits, and improve federal healthcare's sustainability by introducing inflation rebates, Medicare Part D redesign, and allowing price negotiations for expensive prescription drugs (American Action Forum, 2022; KFF, 2024). This paper evaluates the IRA's impact on Medicare beneficiaries, drug manufacturers, generic markets, and future pharmaceutical innovation. It also analyzes the legal difficulties aroused by stakeholders in the pharmaceutical industry and estimates potential extended outcomes for the U.S. healthcare and pharmaceutical landscape. Drawing on global pricing strategies, this analysis also highlights how U.S. policy innovations align or diverge from international regulatory frameworks (Sarnak et al., 2017; Tevis et al., 2024). This research paper also comments on how the IRA is incorporating financial policy tools with directives of public health, possibly working as an example for value-driven compensation in countries with wealth. The law's conceptual framework merges market corrective methods aimed to settle pricing transparency and asymmetry in information in the pharmaceutical industry using Keynesian interventionist principles. The act could be the catalyst in the creation of private-public partnerships to reconsider the cycle, such as the innovation-to-market for vital drugs.

Keywords

Inflation Reduction Act, Inflation Rebates, Medicare Drug Price Negotiations, Out-of-Pocket Caps, Pharmaceutical Pricing

1. Introduction

The United States allocates the highest proportion of its gross domestic product

(GDP) to healthcare spending (Anderson & Hussey, 2001; Sarnak et al., 2017). Its per capita pharmaceutical expenditure has surpassed \$1400—significantly exceeding the \$466 to \$939 range observed in comparable developed countries (Cubanski & Neuman, 2021). This impacted both public insurance programs, like Medicare and Medicaid, and individual patients who face unaffordable out-of-pocket costs for essential medicines.

Health Care	US	Other Developed Countries
% of GDP spent on Health Care	17.8%	9.6% (Australia) - 12.4% (Switzerland)
Population with Health Insurance	90%	99% - 100%
Private Health Insurance	55.3% (Highest)	
Administrative cost of care	8%	1% - 3%
Pharmaceutical cost/Capita	\$1443	\$466 - \$939
Health Care	US	Other Developed Countries

Source: <https://pubmed.ncbi.nlm.nih.gov/29536101/>. Data: 2013-16 from key international organizations including the Organization for Economic Co-operation and Development (OECD).

The Inflation Reduction Act (IRA) aims to deal with these issues via a complete set of amendments focusing on the prices of prescription drugs. The regulation introduces inflation rebates for increases in prices, Medicare Part D redesign, and a novel framework for drug prices' direct negotiations. It is crucial to analyze the method IRA might use to reorganize healthcare consumption, pharmaceutical markets, and the vitals of drug modification.

The execution of the IRA can set precedents for the upcoming administrative framework throughout the healthcare industry, like therapy of genes, high-priced treatment of rare diseases, and biologics. Beyond addressing financial necessity, the IRA constitutes a reorientation in the political equilibrium of power amid pharmaceutical sectors and government buyers.

Assessing the IRA requires positioning it within a continuum of past healthcare reforms—from the Health Security Act in Clinton's era to the Affordable Care Act's limiting power over the cost of drugs. The Biden government tried to correct a continuous gap in the policy of Medicare that held back price-controlling efforts from getting coverage for prescription drugs. Particularly, the U.S. is now only one of the OECD nations where the government does not have authority over medication prices before this law.

2. Results

Key provisions of IRA.

2.1. Inflation Rebates

The drug manufacturers have to pay rebates to Medicare if medication costs sur-

pass inflation as declared mandatory by the IRA (KFF, 2024; Cubanski et al., 2023). It is applicable for both Part B (outpatient drugs administered by medical practitioners) and Part D (outpatient retail prescription drugs). There is no cap on these inflation rebates; and any non-compliances have serious consequences—at least 125% of the payable rebate amount.

Medicare Part B inflation rebates:

Inflation Rebates are imposed annually for Part B covered drugs, which are single source drugs and biologics which do not have therapeutic or biosimilar equivalent. Except for specific biosimilars, vaccines, and low-price medicines (less than \$100 beneficiary annually).

This provision is expected to generate substantial government savings over a decade.

According to the Congressional Budget Office (CBO), the estimated amount is \$56 billion (Cubanski et al., 2023). The Consumer Price Index for All Urban Consumers (CPI-U), which reduces sudden increases in prescription prices yet provides predictability to the framework, plays a role in the standard calculation of inflation rates. This upgrade is identical to German (Golec & Vernon, 2020; Tevis et al., 2024) and Australian structures. Where there is an existence of inflation-based caps on medicine price modification.

$$\text{Inflation Rebate} = (\text{No. Of Units sold in the quarter}) \times (\text{Amount by which the Medicare payment exceeds the inflation-adjusted benchmark quarter}).$$

	Drugs Approved (Dec.1, 2020 Or Prior)	Drugs Approved (After Dec.1, 2020)	MFP Status Change (Drugs Subjected to MFP in the Previous Year but not anymore)
Benchmark Quarter	2021-3Q	3 rd full calendar Quarter after the drug was first marketed	1 st Quarter of Previous Year
Benchmark CPI-U	2021-January	1 st month of the 1 st full Quarter after the drug was first marketed	July of the year before Previous Year.
Inflation Rebate Owed Beginning	Beginning 2023-1Q	6 full Quarters after the drug was first marketed	
Invoicing	CMS will invoice within 6 months of rebate quarter		
Payment	Due within 30 days after receipt of the invoice.		
Penalty	At least 125% of rebate amount, in case of failure to pay.		

*Inflation Adjustment = (CPI-U of Current Qtr.)/(CPI-U for Benchmark Qtr.)

*IR is excluded from ASP, Medicaid Best Price and AMP

Medicare Part D inflation rebates:

IRA imposes mandatory annual rebates on covered Part D drugs and biologi-

calls when their prices increase steeper than the inflation rebate. Except for specific biosimilars, vaccines, and low-price medicines (less than \$100 beneficiary annually).

$$\text{Inflation Rebate} = (\text{No. Of Units sold in the quarter}) \times (\text{Amount by which the Medicare payment exceeds the inflation-adjusted benchmark quarter}).$$

	Drugs Approved (Dec.1, 2020 Or Prior)	Drugs Approved (After Dec.1, 2020)	MFP Status Change (Drugs Subjected to MFP in the Previous Year but not anymore)
Benchmark Quarter	Jan 1-Sep 30, 2021	1 st calendar year after the drug was first marketed	Previous Year
Benchmark CPI-U	2021-January	Jan. After the 1 st full calendar after the drug was first marketed	Jan. of the previous Year.
Applicable Period	12-month period starting Oct 1 of each year.		
Inflation Rebate Owed	Beginning Oct.1, 2022-Sep.30, 2023 applicable period. Beginning 6 full Quarters after the drug was first marketed		
Invoicing	CMS will invoice within 9 months after the applicable period.		
Payment	Due within 30 days after receipt of the invoice.		
Penalty	At least 125% of rebate amount, in case of failure to pay.		

2.2. Redesigning of Medicare Part D

Medicare Part D will be fundamentally redesigned early in 2025 (Doshi et al., 2025):

- \$2000 annually will be capped as the out-of-pocket cost for beneficiaries.
- The donut hole/coverage gap will be removed.
- The Catastrophic stage will change price burdens:
 - Share of Medicare will drop from 80% to 20%.
 - 60% will be provided by prescription drug plans (PDPs), rather than 15% previously.
 - 20% will be funded by the manufacturers at this stage.

This focuses on the reduction of patient burden by switching price responsibility to the manufacturers and the insurers (Doshi et al., 2025; Lieneck et al., 2022). The redesign introduces risk-pooling mechanisms that create incentives for Medicare Part D plan sponsors. Also, it curbs financial exposure to consumers. In chronically ill patients who dropped the prescription earlier because of affordability challenges, there might be a rise in drug adherence rates (Zheng & Sandhu, 2023). Moreover, there might be a need to review the contracting methods of drug lists for pharmaceutical manufacturers.

Coverage: Medicare Part D									
Ranges	Deductible		Initial		Donut Hole		Catastrophic		
Current	0	\$560	\$560	\$5160	\$5160	\$11,886	\$11,886		
IRA Re-Design		\$560	\$560	\$6320	\$0	\$0	\$6320		
Patient OOP Cap	\$2000								
Example: Drug Cost:	\$100,000								
Ranges	Deductible		Initial		Donut Hole		Catastrophic		Total
Patient									
Current	100%	\$560	25%	\$1150	25%	\$1682	5%	\$4406	\$7798
IRA Re-Design	100%	\$560	25%	\$1440					\$2000
Plan									
Current			75%	\$3450	5%	\$336	15%	\$13,217	\$17,003
IRA Re-Design			65%	\$3744			60%	\$56,208	\$59,952
Manufacturer									
Current					70%	\$4708			\$4708
IRA Re-Design			10%	\$576			20%	\$18,736	\$19,312
Government									
Current							80%	\$70,491	\$70,491
IRA Re-Design							20%	\$18,736	\$18,736

The overall price of the drug will figure out the implications for rebates by the manufacturers.

Drug Spending	Impact on Manufacturers
Below \$27,000	Favorable (Plans take the hit)
\$27,000	No Impact
Above 27,000	Un-Favorable (Manufacturers begin to take higher share of rebate burden compared to Plans)

2.3. Negotiations in Drug Pricing

Under the IRA, the Secretary of the Department of Health and Human Services (HHS) is authorized to directly negotiate the Maximum Fair Price (MFP) for eligible drugs (Arad et al., 2024). The Centers for Medicare & Medicaid Services (CMS) selected ten drugs covered under Medicare Part D and engaged in Maximum Fair Price (MFP) negotiations with respective manufacturers to bring about \$1.5 bn in OOP savings to beneficiaries when MFPs goes into effect on Jan 1, 2026

(Basu et al., 2023; Mulcahy, 2022).

Maximum number of drugs subject to price negotiation:

2026	10 (From Part D)
2027	15 (from Part D)
By 2031	Max 100 from (Part B, D)

Negotiation Eligible Drugs

No Competition: Single source drugs without generic or biosimilar competition with participating manufacturers.

Must be certain years post FDA approval:

Small Drug Molecule	9 years post FDA Approval
Biologics	13 years post FDA Approval

High Medicare gross expenditures: Drugs selected for the first round had a minimum of \$1Bn dollar spend in Medicare.

Maximum Fair Price (MFP):

MFP is a mandated ceiling price that depends upon the number of years since FDA approval. Govt. can demand a lower price based on: Pharma manufacturer's revenue for the drug, recovery of R&D costs, cost of sales, remaining years of exclusivity and evidence regarding alternative treatments as well as comparative effectiveness.

Year Since FDA Approval	MFP: Max % of N-FAMP
9 - 12	75%
12 - 16	65%
>16	40%

The IRA gives CMS the authority to directly negotiate the drug prices with the manufacturers instead of depending on third-party Pharmacy Benefit Managers (PBMs) (Mulcahy, 2022; Tevis et al., 2024), unlike the earlier attempts like the ones under the Medicare Modernization Act (2003). This establishes transparency requirements in the setting of prices, with the inclusion of therapeutic substitutes, and integrates the power of negotiation within CMS. Several negotiation rounds, counteroffers or offers, final MFPs' publication, and foundation of a conventional structure that was missing in the U.S. law before are involved in the process.

The penalties for the manufacturers for misreporting the data are an additional safety in the negotiation process; the amount of the penalty may reach \$1 million

per day. Having such strict penalties indicates CMS's intention to enact full transparency and compliance. Additionally, efficiency and cost thresholds per QALY (quality-adjusted life year) are often applied by HTA (health technology assessment) officials in the United Kingdom (NICE) or Canada (CADTH). Preferably, the gross expenditures, accessibility of therapeutic alternatives, and time since approval are the focus—which makes the MFP structure exclusively American.

August 1, 2024—The negotiation period ended with agreement reached for negotiated prices between CMS and participating drug companies for 10 selected drugs (Saba et al., 2024).

Drug Name	Participating in Drug Company	Agreed to Negotiated Price for a 36-day Supply CY 26	List Price (for 34-day Supply CY 23)	Discount of Negotiated Price from 2023 List Price	Number of Part D Enrollees Who Used Drug, CY 23
Januvia	Merck Sharp Dohme	\$112.00	\$527.00	79%	\$4,001,590,599
Ozempic/Wegovy (Class)	Novo Nordisk Inc	\$119.00	\$532.00	78%	\$2,817,700,999
Farxiga	AstraZeneca	\$178.50	\$555.00	68%	\$2,501,705,994
Enbrel	Amgen	\$2,295.00	\$6,747.00	66%	\$2,501,705,710
Jardiance	Boehringer Ingelheim	\$178.00	\$570.00	68%	\$5,768,020,713
Stelara	Janssen	\$5,109.00	\$24,373.00	79%	\$3,165,130,997
Xarelto	Janssen	\$197.00	\$570.00	65%	\$5,309,706,100
Eliquis	Bristol Myers Squibb	\$211.00	\$551.00	62%	\$10,418,108,105
Entresto	Novartis	\$220.00	\$624.00	68%	\$3,308,706,100
Imbruvica	AbbVie	\$111.00	\$16,564.00	99%	\$802,553,999

Source: Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026.

3. Discussion

3.1. Findings and Early Implications

3.1.1. The Expected Price Reduction and Savings

Part D beneficiaries will restore \$1.5 billion in out-of-pocket prices when MFPs take place in 2026, as approximated by CMS. The redesigned catastrophic stage will reduce government spending, but there will be an increase in financial exposures for the insurers and the manufacturers.

As suggested by CBO, there will be a potential saving of \$288 billion in government spending on drugs over a decade because of the inflation rebate and price negotiation provisions (Cubanski et al., 2023; KFF, 2024). Companies might implement value-based contracts and reimbursement plans that are linked to outcomes, which might ultimately result in modifications to strategy in drug prices.

Part D redesign is expected to benefit employer-sponsored retiree drug coverage plans, which might experience lesser expenses via EGWP (Employer Group Waiver Plans), in addition to decreasing Medicare's out-of-pocket costs. The split-

ting of payments over several months instead of payment in full could boost the rate of adherence to the treatment for high-cost beneficiaries who earlier met the catastrophic threshold.

3.1.2. Effect on Pharmaceutical Pricing Plans

- The manufacturers may launch a new drug at a higher price to mitigate the impact of inflation rebates, commercial rebates and penalties (Nasir et al., 2013).
- To have lasting protection prior to price negotiation, the manufacturers may divert R&D from biologics rather than small molecules.
- May encourage brand-name companies to promote and adopt biosimilars and generics, which could reduce intellectual property hurdles.

To increase their exclusivity in the market, firms could purposefully make more investments in lifecycle management techniques that involve combination therapies, reformulations, and moving to “bio betters” (improved biologics) (Blume-Kohout & Sood, 2013; Vaughan et al., 2024). Also, there will probably be further institutional investor examinations, especially in companies of biopharmaceuticals whose route relies strongly on post-approval intimations susceptible to MFP price reductions.

3.1.3. Impact on Generic and Biosimilar Markets

The IRA could unintentionally decrease incentives for the launch of generic and biosimilar products (Mulcahy et al., 2018; Alderfer et al., 2021):

- A smaller price gap may decrease the retail chances for generics.
- Plans might give priority to branded medicines, posing rebates on lower-cost generics.
- Marketing of biosimilar approvals may be done by producers to avoid negotiation setoff.

There is a possibility of facing reduced profitability because of narrower ranges of net prices by biosimilar producers, especially when renowned companies actively reduce prices to maintain share in the market. Deals that are known as “pay-to-launch,” in which pharmaceutical companies support biosimilars to become part of the market with a view to avoiding MFP designation, might grow. Such plans for anti-competitive behavior will be kept track of as foretold by the Federal Trade Commission

3.2. Legal and Policies Difficulties

3.2.1. Lawsuits of Industry

Several pharmaceutical companies like Merck, AstraZeneca, and Johnson & Johnson and trade groups like PhRMA have criticized the IRA’s legitimacy. Significant points of disagreement include:

- Fifth Amendment (Takings Clause): Claims that the mandatory discounts amount to an uncompensated government appropriation of private property.
- Eighth Amendment (Excessive Fines): Claims penalties for noncompliance are

inflicting and excessive.

- Separation of Powers: Argues that pricing authority was irrationally delivered by Congress without satisfactory judicial survey.

Despite various degrees of successful outcomes, these cases are gaining traction in federal courts. Even if participating in Medicare voluntarily eliminates the charges of coercion, it is a crucial precedent in law that is under debate. A verdict in support of industry plaintiffs can reorganize the limitations of regulation in federal prices in the future, as the legal field is monitoring the present scenario carefully.

3.2.2. Response of Judiciary

Federal courts have justified the IRA largely to date, highlighting:

- The pattern of negotiated price by government in programs such as the Veterans Health Administration.
- The Supreme Court might review appeals in the future, which could impact federal authority over drug pricing for approximately 10 years.

The controversy might remain on IRA's unequivocal standards on the evaluation of judiciary for MS determinations, and it could be utilized as the core point of appeals. Programs like Medicaid drug rebate agreements escaped judicial scrutiny considering previous involvement with conditional federal spending, as observed by the experts of law (Rogers, 2023; Ropes & Gray LLP, 2022).

3.3. Broader Implications

3.3.1. Innovations and R&D Investments

Pharmaceutical R&D preferences may be reshaped by the IRA:

- Reduced engagement in the development of small molecule drugs.
- Additional approvals do not readjust negotiations, so there is a decline in seeking new indications for existing medicines.
- Reluctance to utilize federal resources such as NIH support could be a factor in less MFP calculations.

Investors may divert funds into non-public funded ventures or international platforms, splitting R&D ecosystems into two segments. If the prime candidates of micro bio-tech firms, notably those that prioritize single assets, are dependent on early price negotiation, then these firms could come under pressure on valuations. Until carve-outs of policies are put into effect, populations of pediatrics and creativity in rare diseases might decrease.

CEOs of many biopharmaceuticals have already predicted a change in capital allocation of R&D; rare disease resources and biological oncology have taken the place of small-molecule chronic therapies. Because of their low return rates as part of the IRA structure, this decision might end up in the lack of funding for essential public health needs like anti-infections and treatments for mental health. Some diseases might see a severe shortage of advancement due to the shortage of additional incentives like tax credits, guaranteed purchase agreements, or federal grants (Golec & Vernon, 2020; Vaughan et al., 2024).

3.3.2. Market Dynamics

- Patent Litigation: Early settlement of branded firms with generic challengers may delay the negotiation in price.
- As firms look for calculated collaborations to manage the competitive landscape in accordance with the IRA, pay-to-launch agreements could come up.

This might result in decreased legal expenditure but could give rise to greater FTC investigation of non-compete clauses and agreements for licenses. Within this framework of regulation, patent tickets and secondary patents will experience new cost-benefit reviews.

3.3.3. Access and Utilization

To be able to manage increased financial risk, insurance plans could limit formularies or implement consumption management, regardless of how lowering expenses could improve access (Lieneck et al., 2022; Sachs & Frank, 2025).

It could set restrictions on the ability of patients to reach the latest therapies, even with a less negotiated price. Transparency in access policies and formulary planning should be supported by stakeholders to ensure that IRA fulfills its intended objectives for health equity.

4. Materials and Methods

This research paper refers to a policy analysis structure, scrutinizing the content on the IRA, execution documents from the Centers for Medicare & Medicaid Services (CMS), and associated industry and legal literature. Second-party data was collected from reports by the government, different peer-reviewed articles, and judicial decisions to estimate possible effects of legislation.

Some of the key questions answered are:

- What impact will IRA have on Medicare and beneficiary costs?
- What are the expected results for pharmaceutical modification and pricing strategies?
- How is the legal situation evolving the implementation of the Act?

Stakeholder evaluations drawn from policy reports from think tanks, such as the Brookings Institution and RAND Corporation, legal proceeding summaries, and financial simulation calculations are all covered by this study to assure impartiality and comprehensive relevance. Comparative case studies that specifically analyzed European reference pricing models and Canadian Patented Medicine Prices Review Board (PMPRB) practices add significance to the outcomes of specific mechanisms of the U.S.

This research paper also implements a legal hermeneutic style, studying the IRA's legal language to figure out whether it is enforceable or has loopholes. To qualitatively analyze the readiness of the industry, insights obtained from the interviews with pharmaceutical compliance officers and policy analysts have been used. Rebate pass-through percentages, generic substitution patterns, and formulary coverage rates are some of the key performance indicators (KPIs) labelled for

empirical evaluation for the near future after MFP pricing has been applied.

5. Conclusion

In decades, the most essential reforms to U.S. pharmaceutical pricing were introduced by the Inflation Reduction Act. It risks the modification in coming years, the stability of the industry, and generic competitiveness, although it offers considerable assurance for lowering Medicare expenses and beneficiary costs. The amount of federal pricing authority will be decided by the legal battles in progress, while the Act's extended outcomes will be revealed by the responses of the market. It is vital to track the effects on access, insurance plans, and the wide-ranging healthcare system as the IRA's provisions come out.

This paper brings out why a rational policy structure is necessary—one that balances high cost at the same time, managing incentives for the evolution in biomedical sciences. The IRA is a fundamental initiative, but continuous stakeholder collaboration, data systems that are transparent, and flexible government are vital to make it successful. The IRA can set a model—a note for caution—for international adjustments on drug pricing in the future as other countries are noticing development in the U.S. pharmaceutical industry.

With the aim to fulfill the IRA's goals without limiting the progress scientifically, cooperation of policies between the agencies—CMS, FDA, NIH, and FTC—will hold significance. For the possibility of making changes, impact reviews on periodic policies and real-time evaluation dashboards should be developed. The IRA may also have a positive effect on the strategies regarding worldwide drug procurement, especially in markets that are developing and striving to achieve an equilibrium between access to cutting-edge therapies and cost-effectiveness.

Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

References

- Alderfer, J., Hansen, R. A., & Mattingly, T. J. (2021). Understanding Authorized Generics—A Review of the Published Clinical Data. *Journal of Clinical Pharmacy and Therapeutics*, 46, 1489-1497. <https://doi.org/10.1111/jcpt.13426>
- American Action Forum (2022). *The Inflation Reduction Act's Healthcare Provisions*. <https://www.americanactionforum.org/insight/the-inflation-reduction-acts-health-care-provisions/>
- Anderson, G., & Hussey, P. S. (2001). Comparing Health System Performance in OECD Countries. *Health Affairs*, 20, 219-232. <https://doi.org/10.1377/hlthaff.20.3.219>
- Arad, N., Hoover, G., Evans, R., & McClellan, M. B. (2024). *Medicare Drug Price Negotiations: Policy Implications of the First 10 Drugs' Features*. Health Affairs Forefront. <https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiations-policy-implications-first-10-drugs-features>
- Basu, A., Veenstra, D. L., Devine, B., Carlson, J. J., & Sullivan, S. D. (2023). *Medicare Drug Price Negotiations: A Principles-Based Guide for CMS*. Health Affairs Forefront.

- <https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiations-principles-based-guide-cms>
- Blume-Kohout, M. E., & Sood, N. (2013). Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development. *Journal of Public Economics*, 97, 327-336. <https://doi.org/10.1016/j.jpubeco.2012.10.003>
- Cubanski, J., & Neuman, T. (2021). *The Facts on Medicare Spending and Financing*. Kaiser Family Foundation. <https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/>
- Cubanski, J., Neuman, T., & Freed, M. (2023). *FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program*. Kaiser Family Foundation. <https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/>
- Doshi, J. A., Li, P., Klebanoff, M. J., & Lin, J. K. (2025). Inflation Reduction Act Provisions and Medicare Part D Out-Of-Pocket Costs for Specialty Drugs. *JAMA Health Forum*, 6, e251387. <https://doi.org/10.1001/jamahealthforum.2025.1387>
- Golec, J., & Vernon, J. A. (2020). Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms. *Pharmacoeconomics*, 28, 615-628.
- KFF (Kaiser Family Foundation) (2024). *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*. Issue Brief. <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>
- Lieneck, C., McLauchlan, M., Adachi, V., & Billings, R. (2022). Stakeholder Perspectives of the Inflation Reduction Act's (2022) Impact on Prescription Drugs: A Narrative Review. *Pharmacy*, 11, Article 187. <https://doi.org/10.3390/pharmacy11060187>
- Mulcahy, A. W. (2022). *Medicare Drug Price Negotiation: Key Decisions to Reach a 'Fair Price.'* RAND Commentary. <https://www.rand.org/pubs/commentary/2022/11/medicare-drug-price-negotiation-key-decisions-to-reach.html>
- Mulcahy, A. W., Hlavka, J. P., & Case, S. R. (2018). *Biosimilar Cost Savings in the United States: Initial Experience and Future Potential*. RAND Corporation.
- Nasir, K., Salami, J. A., & Mossialos, E. (2023). Prescription for Affordable Health Care: Promise and Perils of IRA Tackling Financial Toxicity. *Journal of the American College of Cardiology*, 81, 1502-1504. <https://doi.org/10.1016/j.jacc.2023.02.028>
- Rogers, H. A. (2023). *Constitutional Challenges to the Medicare Drug Price Negotiation Program (CRS Report No. R47682)*. Congressional Research Service. https://www.congress.gov/crs_external_products/R/PDF/R47682/R47682.1.pdf
- Ropes & Gray LLP (2022). *Congress Paves Way for Drug Pricing Reforms with Passage of Inflation Reduction Act of 2022*. <https://www.ropesgray.com/en/insights/alerts/2022/08/congress-paves-the-way-for-drug-pricing-reforms-with-passage-of-the-inflation-reduction-act-of-2022>
- Saba, M., Aggarwal, T., Ramanathan, A., & Spanbauer, S. (2024). The Reality of Medicare Part D Drug Price Negotiations under the Inflation Reduction Act. *Health Management, Policy and Innovation*, 9, 1-9. <https://hmpi.org/2024/11/18/the-reality-of-medicare-part-d-drug-price-negotiations-under-the-inflation-reduction-act/>
- Sachs, R., & Frank, R. G. (2025). *Analyzing the Expansion of the Medicare Drug Price Negotiation Program to Part B*. Brookings.

<https://www.brookings.edu/articles/analyzing-the-expansion-of-the-medicare-drug-price-negotiation-program-to-part-b/>

Sarnak, D. O., Squires, D., Kuzmak, G., & Bishop, S. (2017). *Paying for Prescription Drugs around the World: Why Is the U.S. An Outlier? Issue Brief*. The Commonwealth Fund.

https://www.commonwealthfund.org/sites/default/files/documents/media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf

Tevis, D., McGough, M., Cubanski, J. & Cox, C. (2024). *How Medicare Negotiated Drug Prices Compare to Other Countries*. Kaiser Family Foundation.

<https://www.kff.org/health-costs/issue-brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/>

Vaughan, G., Du, R., & Ledley, F. D. (2024). Modeling Impact of Inflation Reduction Act Price Negotiations on New Drug Pipeline Considering Differential Contributions of Large and Small Biopharmaceutical Companies. *Clinical Trials*, 22, 88-99.

<https://doi.org/10.1177/17407745241259112>

Zheng, J., & Sandhu, A. T. (2023). The Inflation Reduction Act Expands Prescription Drug Affordability: Decades in the Making. *Journal of the American College of Cardiology*, 81, 2112-2114. <https://doi.org/10.1016/j.jacc.2023.03.415>