Medicare Drug Price Regulation

Small Savings, Large Innovation Losses

John F. Cogan, Daniel L. Heil, and Casey B. Mulligan

The 2022 Inflation Reduction Act (IRA) included major changes to the way Medicare pays for prescription drugs. Foremost among these is the requirement that pharmaceutical manufacturers negotiate Medicare drug prices with the federal government. This is a major departure from Medicare's long-standing policy of relying on market-determined prices to keep drug costs down for seniors and disabled persons.

Economic theory predicts that these government-imposed price ceilings will have negative consequences on drug development. They will lower the return on investment, leading to a decline in new drug research and development, fewer new drugs and indications, and a reduction in applications of existing drugs to new therapies. Manufacturers will seek to mitigate price restrictions by altering products, bundling price-regulated drugs with unregulated drugs, raising prices in related markets, and modifying drug marketing and distribution activities. Meanwhile, distortions in relative prices will result in suboptimal treatment choices by health plans, pharmacy benefit managers, and patients, further reducing drug efficacy.

This essay analyzes the IRA's impact on Medicare and innovation with a model that incorporates manufacturers' pricing responses. President Joe Biden and congressional IRA supporters promised that the law's price regulations will produce substantial savings for the federal government and Medicare recipients with little or no impact on innovation. We find the opposite to be true. A fully phased-in IRA drug-pricing policy will produce minimal savings for the Medicare program and its enrollees. These savings are small compared to the costs of lost innovation.

We estimate that under a fully phased-in IRA policy, manufacturers will raise average launch prices by 11 percent and 2 percent for Part D and Part B drugs, respectively. These price increases will offset more than half of the estimated savings to the Medicare program and the program's enrollees, reducing the small savings that would occur in the absence of the price response to negligible amounts. The policy will reduce Medicare drug expenditures by 11.7 percent before accounting for drug manufacturers' price increases and by only 5.3 percent after accounting for them. Medicare's total expenditures would fall by 2.3 percent before manufacturers increase their drug prices and by 1.1 percent after the price increase. A large majority of lower-income enrollees will gain no financial benefit from these reductions since government programs already finance most of their premiums and co-payments.

Middle- and upper-income enrollees will save less than 0.1 percent of their income. In contrast, the societal costs from reduced innovation remain sizable after accounting for manufacturers' pricing responses. Our findings bolster conclusions from earlier research that the IRA's cost to society outweighs any small financial benefits to the government and Medicare recipients.

PRICING RESPONSES TO THE IRA NEGOTIATION PROGRAM

The IRA requires Medicare to negotiate the prices of certain high-expenditure prescription drugs sold within Part B and Part D. Drugs are subject to negotiated agreements after they have been on the market for nine years for new chemical entities and thirteen years for biologics.[1] Under the program, manufacturers are free to set their own launch prices subject to limits on price increases over time. The Centers for Medicare and Medicaid Services (CMS) has established prices for ten Part D drugs, with the negotiated rates set to take effect in 2026. In January 2025, CMS announced the next fifteen drugs that will be subject to the regulation.[2]

Although the criteria the government will use to guide its negotiations are opaque, the underlying law, the underlying economics, and the Congressional Budget Office (CBO) indicate that Medicare prices established during the years prior to a drug's price regulation will play a crucial role. The statute establishes a linkage by expressing the upper limits on the negotiated price as the drug's current net price or a percentage of a drug's preregulated list price. This linkage draws from the long-standing Medicaid provision requiring manufacturers to pay rebates to the Medicaid program that are fixed percentages of a drug's average commercial price.[3] Effectively, the preregulation price acts as a reference for the negotiated price. The negotiated price reduction can be considered a discount of, or a rebate against, this reference price. This regulatory linkage provides manufacturers with a financial incentive to set higher prices during the reference period than they would in the absence of regulation.

To understand the incentives that reference pricing creates, consider a drug manufacturer that is launching a new drug and must contemplate the drug's future price path. In the absence of any regulation, the manufacturer sets a profit-maximizing path. Now suppose a regulation is imposed that allows the manufacturer to freely set the drug's launch price during an initial period but limits the maximum allowable price to a fraction of that price thereafter. Under the regulation the initial price serves as a reference price, and the initial period serves as a reference period. Since the regulation would dictate a price below the profit-maximizing price, increasing it would increase profits while the price regulation is in effect (the regulated period). But the manufacturer can only increase the regulated price by raising the reference price. This raises the reference price above its profit-maximizing level, reducing profits during the reference period. Any increase in regulated-period profits from the higher regulated price therefore comes at the cost of lower profits from the higher reference price. The manufacturer will increase the drug's reference price as long as the gain in regulated-period profits exceeds the loss during the reference period.

Assuming linear cost and demand curves, a manufacturer's optimal drug price response depends on only two factors: the rebate size and the drug's regulated-period market share.[4] The manufacturer's price response will increase with the size of the negotiated rebate, but only up to a certain point. Thereafter, it declines. Intuitively, at the extremes, when the rebate is nearly zero (equivalent to nearly no price regulation), a reference

price increase will result in only a small increase in profits during the regulated period. Similarly, when the rebate approaches one (when almost the entire selling price is rebated to the government), a reference price increase will produce only a small rise in regulated-period profits. The magnitude of negotiated rebates is still uncertain. The CBO initially projected that negotiated rebates would average 50 percent of net prices.[5] Despite these projections, the CMS reported that the average rebate was only 22 percent of net prices among the first ten selected drugs.[6] In response, the CBO now expects that over the long term, rebates will be between 25 and 50 percent.[7]

The market share is the discounted value of a drug's expected future profits during the regulated period relative to its expected total profits (measured in the absence of regulation). The larger the regulated-period market share, the larger the reference price response. Intuitively, for any given reference price increase, the larger the share of revenue earned during the regulated period, the greater the increase in regulated-period profits compared to the reference-period loss.

Importantly, manufacturers' price responses will differ between Part D and Part B drugs. In Part D, prices are independently negotiated in the commercial and Medicare markets, allowing manufacturers to raise the Part D reference price without affecting commercial pricing. In contrast, Part B drug prices are legislatively tied to their commercial prices (Part B pays a drug's average sales price). Raising the Part B reference price requires increasing commercial prices above their profit-maximizing level. Since Part B sales make up only 25 percent of commercial sales, the resulting profit loss is greater than for Part D drugs, leading to a smaller price response.[8] Another implication is that the policy will drive commercial price increases for Part B drugs but not for Part D drugs.

EMPIRICAL ESTIMATES OF MANUFACTURERS' PRICE RESPONSE

For our empirical analysis, we assume a 50 percent rebate. Regulated-period market shares are derived from CMS drug expenditure data and, for Part B drugs, supplemented with SSR Health sales data. To simplify the report, we adopt the commonly used assumption in pharmaceutical industry analyses that revenues serve as a proxy for profits during a drug's years of market exclusivity.

Table 1 shows the regulated-period market shares and the expected reference price increases from a fully phased-in IRA policy. Manufacturers are expected to raise the typical Part D drug's reference price by 11.3 percent. The expected price increase is slightly larger for biologics than for small molecules. For the typical Part B drug, the reference price increase is only 1.7 percent. Small-molecule drugs within Part B have higher regulated market shares than biologics, but they account for a small share of total Part B drug expenditures.

The change in Medicare expenditures can be computed from available sales data for any given rebate. For Part D drugs, the change in manufacturer revenues equals the change in Medicare expenditures. For Part B drugs, the calculation is more complex, as manufacturer revenue changes also affect commercial sales. By knowing Medicare Part B drug revenues as a share of total Part B sales, we can determine the percentage change in revenues from Part B sales alone.

Table 2 shows the IRA policy's impact on Medicare expenditures after incorporating manufacturers' price responses and comparing them to changes under static assumptions. The static changes

TABLE 1 PRICE EFFECTS OF REFERENCE PRICING FOR SELECTED DRUGS WITH 50 PERCENT REBATE (PERCENT REDUCTION)

	Regulated period market share	Change in reference period price
All Part D drugs	34%	11.3%
Small molecule	33%	10.7%
Biologics	39%	13.7%
All Part B drugs	6%	1.7%
Small molecule	17%	5.0%
Biologics	4%	1.1%

Notes: The regulated period begins nine years after approval for small-molecule drugs and thirteen years for biologics. A 10 percent discount rate is used to calculate the market share. Combined market shares for small-molecule drugs and biologics are weighted by the share of CMS expenditures for each drug type.

TABLE 2 EFFECTS OF REFERENCE PRICING ON MEDICARE DRUG EXPENDITURES WITH 50 PERCENT REBATE (PERCENT REDUCTION)

	With price response	Without price response	Share of revenue reduction offset by reference pricing
Part D brand-name drugs	–7.5%	–16.9%	–55.7%
Part B brand-name drugs	–4.5%	–9.4%	–51.4%
Parts D and B brand-name drugs	–6.6%	–14.6%	–54.8%
All Parts D and B drugs	–5.3%	–11.7%	–54.8%
Total Medicare expenditures	–1.1%	–2.3%	–54.8%

Notes: The regulated period begins nine years after approval for small-molecule drugs and thirteen years for biologics. A 10 percent discount rate is used to calculate the market share. The change in expenditures without the pricing assumes no price or quantity changes.

assume that manufacturers do not alter reference prices and holds the quantity of drugs sold in each period constant. Compared to the static estimates, reference pricing reduces the policy's impact on Medicare drug expenditures by more than 50 percent. Part D expenditures on brand-name drugs would fall by 7.5 percent after accounting for manufacturers' pricing responses. Part B drug expenditures on brand-name drugs would fall by 4.5 percent. Branded drugs account

for approximately 80 percent of total Medicare drug expenditures, while generic drugs compose the remainder.[9] Using this estimate, total Part D expenditures would decline by 6 percent and total Part B expenditures by 3.6 percent. Drug expenditures in both programs combined would decline by 5.3 percent. The savings to the entire Medicare program amount to 1.1 percent of its total expenditures.

IMPACT ON ENROLLEES

The small reductions in Medicare expenditures, either before or after accounting for manufacturers' price responses, suggest that savings to Medicare enrollees will be correspondingly small. The 3.6 percent reduction in Medicare Part B expenditures will lower Part B fee-for-service premiums by the same percentage. In 2023 this would have amounted to an annual reduction in the standard premium of nine dollars. For a typical fee-for-service enrollee with no supplemental Medigap coverage, cost-sharing payments would have declined by a similar amount.[10]

The 6 percent reduction in Medicare Part D expenditures will lower the basic Part D premium by the same percentage. To calculate the reduction in Part D co-payments, we use the 2021 Medical Expenditure Panel Survey (MEPS). For each Part D enrollee, we reduce drug expenditures (insured plus co-payments) by 6 percent and apply the Part D statutory deductible and coinsurance rates to the result. Under this approach, Medicare Part D co-payments decline by 4.4 percent. Overall Medicare Part D expenses per enrollee are estimated to decrease by 5 percent after accounting for the manufacturers' price response. In 2023 this would have reduced annual Part D premiums by eighteen dollars and annual cost sharing by twelve dollars per enrollee.

Table 3 shows the distributional effects of the IRA pricing policy on households with Part D enrollees before and after accounting for the manufacturers' pricing response. The savings in drug expenses would be small for all income groups. Few low-income Medicare Part D enrollees would receive any financial benefit from lower Medicare drug prices since most are enrolled in Part D's Lower Income Subsidy program or Medicaid, which cover all or nearly all premiums and co-payments. After accounting for the price response, Part D enrollees in households with incomes in the higher quintiles would experience about a 5 percent reduction in their Part D expenses. For households in the middle-income quintile in 2023, this amounts to about fifty-one dollars per year. For households in the upper-income quintile, the annual savings amount to sixty-five dollars.[11]

The Part D savings, expressed as a percentage of income, are similarly very small for all income groups. After accounting for the price response, the savings are less than 0.1 percent for enrollee households in the middle-income quintile and smaller for households in the highest- and lowest-income quintiles. These small savings are only partly due to the manufacturers' pricing responses. In the absence of any price response, the savings for each of these income groups would still be less than 0.2 percent.

LOST INNOVATION

Economists have long emphasized that drug price restrictions, by lowering the return on investment, lead to less research and development. Eventually, fewer drugs and new therapies are discovered, and valuable medicines become less available.[12] The ultimate outcome is poorer health and higher nondrug healthcare costs. Following the approach taken by earlier analyses, we assume that changes in drug manufacturer revenues are the drivers behind drug innovation. As Table 4 shows, the combined effect on total brand name drug revenue with reference pricing would be 2.1 percent, or about $11 billion, in 2023. The

TABLE 3 EFFECTS ON PART D RECIPIENT HOUSEHOLDS

	Without price response			
	Percent change			
	Premium	*Cost-sharing*	*Total savings*	*Total savings (% of income)*
Lowest quintile	–1.5%	–0.9%	–1.1%	0.05%
Middle quintile	–13.5%	–9.0%	–10.9%	0.18%
Highest quintile	–13.5%	–8.8%	–11.3%	0.07%
	With price response			
	Percent change			
	Premium	*Cost-sharing*	*Total savings*	*Total savings (% of income)*
Lowest quintile	–0.7%	–0.4%	–0.5%	0.02%
Middle quintile	–6.0%	–3.9%	–4.8%	0.08%
Highest Quintile	–6.0%	–3.8%	–5.0%	0.03%

Notes: Savings are based on the 2021 MEPS-HC total prescription drug spending for Part D recipient households.

TABLE 4 ANNUAL EFFECTS ON MANUFACTURER REVENUE FROM DRUG PRICE NEGOTIATIONS

	With price response	Without price response
Percent change in US brand name drug revenue	–2.1%	–4.6%
Change in drug revenue (billions)	–$10.9	–$24.1

Note: Revenue effects assume all brand name single-source drugs would be subject to IRA price regulations.

2 percent impact on manufacturers' revenues for US-branded drugs, which are relevant for assessing the policy's impact on innovation, are slightly less than 50 percent of the static reductions.[13]

To estimate the foregone drugs' social cost, we apply methodologies developed by Mulligan and Philipson et al.[14] Table 5 shows estimates of the annual net costs to society under each of these methodologies, before and after accounting for the price response. The difference between the estimates provided by the two approaches is substantial. The latter is nearly forty times the former. This disparity reflects the considerable

TABLE 5 THE NET OPPORTUNITY COST OF REDUCED DRUG INNOVATION, BY MANUFACTURERS' SHARE OF SOCIAL SURPLUS OF NEW DRUGS (BILLIONS)

Description	Manufacturers' share of social surplus from new drugs	With price response	Without price response
Philipson et al.	0.8%	–$196.3	–$433.4
Mulligan	26.6%	–$4.5	–$10.0

Note: We assume research and development expenditures as a share of manufacturer's revenue are 15 percent.

uncertainty about which new medicines and drug therapies will or will not come to market and the value of these drugs to society. For example, the Mulligan method assumes that only those drugs with the smallest net benefit to society will be foregone, while the Philipson et al. method assumes drugs with an average societal benefit will be foregone. Although the differences are large, both estimates bolster the conclusion reached by Philipson, Ling, and Chang that the IRA's costs to society are substantial and likely outweigh the policy's benefits.[15]

The Biden administration had proposed to shorten the number of years that a drug has been on the market before its price is subject to negotiations. The new Trump administration has yet to take a position either on the current policy or the Biden administration's proposal. Our analysis suggests that shortening the reference period has diminishing effects on Medicare expenditures because manufacturers will respond with larger price increases during the reference period. We estimate that shortening the Part D reference period by four years would only reduce Medicare Part D expenditures by an additional 3.6 percentage points. In extreme cases, shortening the reference period may even add to government expenditures and raise enrollee premiums and cost sharing.

CONCLUSION

Our analysis has several limitations. The Part D estimates are based upon gross, as opposed to net, Medicare expenditures, and our Part B estimates are based only on the subset of drugs that are also sold in commercial markets. Our analysis does not account for other features of the IRA policy that are likely to significantly affect drug prices and innovation, such as its larger financial penalty on follow-on drugs than originator drugs and on new indications for previously approved drugs. Finally, our analysis does not account for the fact that manufacturers are likely to respond to the IRA in ways other than by raising prices. Manufacturers may, for example, bundle regulated and unregulated products together and use tie-in sales to mitigate the impact of the price regulation. They may also change or eliminate volume discounts and modify their drug education and advertising programs. Our analysis suggests that Medicare savings from price regulation are even less when the model includes additional margins for manufacturers to influence the regulated price. In this sense, our focus on reference pricing is both quantitatively conservative and analytically advantageous in providing regulatory-impact results that are independent of competition and demand parameters.

Our finding that drug manufacturers will raise prices in anticipation of government price regulation is not new. But the underlying economic rationale for doing so differs from conventional reasoning, as do its implications for commercial prices. Our estimates indicate that the savings to the government and Medicare enrollees from a fully phased-in IRA policy are likely small. In contrast, the societal losses from reduced innovation may be substantial. Together they indicate that the social costs of the IRA policy outweigh its benefits.

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NOTES

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1. For a summary of the IRA, see Juliette Cubanski et al., "Explaining Prescription Drug Provisions in the Inflation Reduction Act," Kaiser Family Foundation, January 24, 2023, https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

2. See "HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors," Centers for Medicare and Medicaid Services, press release, January 17, 2025, https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower.

3. Omnibus Budget Reconciliation Act of 1990.

4. More specifically, the demand curves in the regulated and reference periods are proportional to one another, and the cost curves are identical to one another. Under these conditions the result holds for all market structures: monopolistic, oligopolistic with perfect and imperfect substitutes, and competitive. Under these assumptions the price response is equal to $((1-b)/1+Tb^2)Tb$, where b is equal to 1 minus the rebate, and T is equal to the regulated period market share divided by 1 minus the regulated market share.

5. "Alternative Approaches to Reducing Prescription Drug Prices," Congressional Budget Office, October 2024, https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.

6. "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026," Center for Medicare and Medicaid Services, 2024, https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

7. Congressional Budget Office, "Alternative Approaches to Reducing Prescription Drug Prices."

8. Authors' calculations based on SSR Health and CMS Part B drug spending data. For more details, see Cogan et al., "Can Price Ceilings Increase Prices?"

9. The US Department of Health and Human Services (2022) found that branded drugs account for about 80 percent of retail and nonretail drug purchases. "HHS Standard Values for Regulatory Analysis, 2024," US Department of Health and Human Services, January 25, 2024, https://aspe.hhs.gov/sites/default/files/documents/cd2a1348ea0777b1aa918089e4965b8c/standard-ria-values.pdf.

10. We assume that enrollees face the standard 20 percent Part B coinsurance rate for all Part B drugs. We rely on simpler assumptions than our Part D calculations because individual Part B drug expenditures are not available in the Medical Expenditure Panel Survey.

11. Households in the top quintile are more likely to pay larger premiums due to the income-related monthly adjustment amount. In addition, higher-income households are disproportionately married and therefore more likely to have two Part D enrollees.

12. For examples, see surveys by Kevin A. Hassett, "Price Controls and the Evolution of Pharmaceutical Markets," American Enterprise Institute, 2004, https://www.aei.org/research-products/working-paper/price-controls-and-the-evolution-of-pharmaceutical-markets/; Daniel P. Kessler, "The Effects of Pharmaceutical Price Controls on the Cost and Quality of Medical Care: A Review of the Empirical Literature," June 2004, https://plg-group.com/wp-content/uploads/2014/03/The-effect-of-pharmacetuical-price-controls-on-the-cost-and-.pdf; Elizabeth J. Jensen, "Research Expenditures and the Discovery of New Drugs," *Journal of Industrial*

Economics 36 (1987): 83–95. See the bibliography in the companion paper for additional sources.

13. Medicare expenditures for branded drugs sold in the Part D program are estimated to decline by 14.6 percent before accounting for manufacturers' pricing responses and 6.6 percent after accounting for them. For Part D drugs, the change in Medicare expenditures equals the change in manufacturer revenue multiplied by Medicare's share of total sales of Part D brand-name drugs. Based on National Health Expenditure data for 2023, revenues from Medicare Part D sales account for 22 percent of total US branded drug sales. Thus, the reduction in Part D revenues will produce a 3.2 percent decline in manufacturer revenue without accounting for the price response and 1.5 percent after accounting for it. Manufacturer revenues on Part B drugs, including commercial, would decline by 1.3 percent.

14. The Mulligan method is derived from Casey B. Mulligan, "The Value of Pharmacy Benefit Management," Working Paper No. 30231 (NBER, 2022). The Philipson et al. method is from Tomas J. Philipson and Troy Durie, "Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health," University of Chicago, November 21, 2021, https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/issue-brief-drug-pricing-in-hr-5376-11.30.pdf; and Tomas J. Philipson, Yier Ling, and Ruiquan Chang, "The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act," October 5, 2023, https://ecchc.economics.uchicago.edu/2023/10/09/policy-brief-the-potentially-larger-than-predicted-impact-of-the-ira-on-small-molecule-rd-and-patient-health-2/.

15. Philipson et al., "The Impact of Price Setting at 9 Years on Small Molecule Innovation."

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