ECONOMICS WORKING PAPERS

Can Price Ceilings Increase Prices? Reference Pricing and the Inflation Reduction Act

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Economics Working Paper 25103

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January 12, 2025

The Inflation Reduction Act (IRA) of 2022 marks a significant shift in Medicare's approach to purchasing prescription drugs by mandating price negotiations between the federal government and drug manufacturers. This paper presents a theoretical model of manufacturer pricing behavior under the IRA and provides empirical estimates of the likely price response. If negotiated prices are set at 50 percent of reference prices, Part D and Part B drug prices will rise by 11 percent and 2 percent, respectively, cutting projected Medicare savings in half. Enrollee savings from a fully phased-in IRA pricing policy are minimal. Medicare already covers almost all cost-sharing and premium payments for low-income enrollees, so their savings are minimal. For middle- and upper-income households, the savings amount to less than 0.1 percent of household income. The reduced innovation from the price regulations imposes significant long-term costs. Shortening the reference period further amplifies price increases with little additional benefit for the federal government or Medicare recipients.

Keywords: Medicare, prescription drugs, Inflation Reduction Act, Medicare Part D, Medicare Part B, Medicare prescription drug price negotiations, Reference pricing
JEL Codes: D4, D42, D43, H5, H51, H53, I1, I11, I12, I13, I18, L1, L12, L13, O3, O31, O32, O38

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Introduction

The 2022 Inflation Reduction Act (IRA) authorized 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 policy is a major departure from the longstanding policies Medicare has used to secure prescription drugs for seniors and disabled persons. From its inception in 2003, Part D has relied on competition among drug manufacturers, pharmacy benefit managers, and Medicare drug plan sponsors to hold down Medicare drug prices. From Medicare Part B's inception in 1965, the program has reimbursed hospitals and other payors for the cost of physician-administered drugs according to market-determined sales prices, net of rebates.

Economic theory predicts that government-imposed price ceilings, either in the form of strict price controls, reference pricing, or mandatory price negotiations, will have negative consequences for drug development. Price restrictions lower the return on investment, leading to less safe and efficacious drugs, and fewer new indications and earlier lines of therapy for existing drugs. Manufacturers will seek to mitigate or circumvent entirely price restrictions by altering products, bundling price-regulated drugs with unregulated drugs, raising prices in related markets, and by modifying drug marketing and distribution activities to reduce gross expenditures in an attempt to avoid price regulation. Distortions in relative prices will result in suboptimal treatment choices by health plans, PBMs, and patients, further reducing drug efficacy.

This paper analyzes the long-run impact of the IRA price negotiation policy on Medicare drug prices, expenditures and premiums, manufacturer revenues, and innovation. The point of departure of our analysis from previous studies is that we incorporate manufacturers' pricing responses to the imposition of regulated prices. A key feature of the IRA specifies that drug prices are subject to negotiated agreements only after they have been on the market for a certain time period. This feature establishes a reference period during which manufacturers are free to set launch prices, subject to limitations on price increases over time. Prices set during this period potentially serve as reference prices that, along with other factors, determine regulated prices, which can be considered as a discount from or rebate against the reference price. This linkage

provides a financial incentive to manufacturers to set higher prices during the reference period in advance of regulation than they would in the absence of regulation.[2]

This paper presents a simple model of manufacturers' drug pricing decisions that provides for a deeper understanding of the incentives that drive manufacturers to raise prices. For example, it is often asserted that with reference price regulation, a manufacturer will raise the drug's reference price to offset losses in profits on sales during the regulation period. Our analysis shows that, on the contrary, a manufacturer does so because the higher reference price generates *higher profits in the regulated period which are partially offset by losses in the reference period*.

Examining the effect of drug price regulation on pricing in a reference market is not entirely new to U.S. policy analysis. The Office of Management and Budget (2022) has long viewed price regulations with significant skepticism based on "economic theory and actual experience." The Congressional Budget Office (1996) has recognized that manufacturers will raise commercial prices in response to the Medicaid program's closely related policy of requiring rebates on drugs procured for that program. Duggan and Scott Morton (2006) have empirically documented the magnitude of this price response. More recently, Arad and McClellan (2022a, 2022b) in describing the IRA negotiation policy's impact specifically note the likely manufacturer pricing increase. What our paper adds to this literature is a theoretical analysis of why this occurs. It also provides empirical estimates of the likely pricing response for most single-source drugs. Our key finding is that the manufacturers' pricing response is highly sensitive to negotiated rebates on reference period prices. We estimate that if negotiated prices are set at 50 percent of reference prices, as CBO originally assumed, manufacturers will respond by raising the typical Medicare Part D drug price during the reference period by about 11 percent and the typical Part B drug price by 2 percent.

We also find that drug manufacturers' Medicare revenues and Medicare expenditures, while sensitive to the negotiated rebate, are relatively insensitive to the share of a drug's lifecycle revenues earned from sales during the regulated period. This finding has important implications for the Biden Administration's proposal to shorten the reference period. Shortening the reference period increases the share of a drug's expected lifecycle revenue that would be affected by the

[2] The effect of a price ceiling on the reference market is analytically similar to the effect, in a cost-plus price-control regime, of a price ceiling on costs (Joskow and Rose 1989).

regulation period. The increased share only marginally reduces Medicare drug expenditures and, if the share is large enough, can even produce a counterproductive increase in expenditures.

We estimate that the manufacturers' price response to a fully phased-in IRA policy with a 50 percent rebate reduces the projected savings to the Medicare program by half. After accounting for the manufacturers' price response, a fully phased-in IRA policy with the same rebate would reduce Medicare drug expenditures by 5 percent and total Medicare spending by 1 percent.

We estimate that middle-income Medicare enrollees who have the basic Part D plan will save only $51 per year after accounting for manufacturers' price responses. The savings are less than 0.1 percent of the median income of households with Part D enrollees. Few Part D enrollees with incomes in the lowest quintile of the U.S. income distribution would receive any savings because their premiums and cost sharing payments are covered by the federal government. The federal government could have achieved a comparable financial benefit to Part D enrollees, without any adverse consequences for drug innovation, by directly subsidizing premiums and payments at an annual cost of $2.3 billion, rather than through a comprehensive program of drug price regulation. The premium savings for Part B enrollees are even smaller, amounting to about $600 million annually.

Finally, after accounting for price responses, a fully phased-in IRA negotiation policy still produces potentially large adverse consequences for innovation and consumer welfare that have been demonstrated by the extensive literature on the effects of prescription drug price controls.[3] For each dollar of federal budget savings, $0.57 to $24.60 of patient welfare is lost as a result of poorer health outcomes due to the decline in innovation. The wide range reflects the considerable uncertainty about the effects of price regulations on innovation.

Section 1 discusses the key elements of the IRA price negotiation policy for our analysis. Section 2 presents the theoretical model and its implications for drug prices. Section 3 presents empirical estimates of the size of the price responses for Medicare Part D and Part B drugs. We perform a retrospective analysis of manufacturers' likely price responses had the IRA policy

[3] See for example surveys by Hassett (2004) and Kessler (2004). See also the pioneering work of Jensen (1987). Also, see studies of European price controls and their implications for the U.S by Brouwers, Silverstein, and Wolff (2004), Danzon (1997), Danzon and Furukawa (2003), Danzon and Ketcham (2003), Kyle (2003), Danzon, Wang and Wang (2005), Santerre, and Vernon (2006), Giacotto, Santerre, and Vernon (2005), and Golec and Vernon (2010). For a discussion of the effects of the IRA price negotiation policy see Philipson and Durie (2021) and Philipson, Ling, and Chang (2023).

been in effect earlier and covered four widely used Medicare drugs: Revlimid and Forteo, which had large Part D expenditures, and Alimta and Neulasta, which had large Part B expenditures. All four drugs have recently faced generic competition and were, therefore, not subject to the IRA's price regulations. We then consider the policy's separate impact on typical Medicare Part D and Part B drug prices. Section 4 presents the effects on Medicare expenditures, Part D enrollee premiums and copayments, and Part B premiums. Section 5 estimates the policy's impact on innovation and patient welfare. Section 6 estimates the impact of the Biden Administration's proposal to shorten the reference period. Section 7 concludes with a discussion of the limitations of our analysis.

1 The IRA Price Negotiation Policy

The Inflation Reduction Act (IRA) empowers the federal government with the authority to negotiate prescription drug prices on drugs sold within the Medicare program. Covered drugs are limited to branded drugs which do not face competition from generics or biosimilars currently, or in the near future, and which have been on the market for at least 9 years for small molecules and 13 years for biologics. The policy is phased-in, initially covering drugs with the largest gross expenditures.[4] By 2029, the IRA negotiation policy will cover 80 drugs.

The failure by a manufacturer to enter negotiations results in steep financial penalties in the form of either a confiscatory 95 percent excise tax on all U.S. product sales or a prohibition against the sale of its drugs in the Medicare and Medicaid programs.[5] These penalties have led many observers to conclude that the negotiations are a rather one-sided affair.

Although the criteria the government will use to guide its negotiations are opaque, the underlying law, the underlying economics, and the Congressional Budget Office indicate that

[4] For a summary of the IRA see Cubanski (2023). The law excludes drugs facing generic or biosimilar competition, drugs with a single orphan drug designation, plasma drugs, drugs with less the $200 million in Medicare sales in 2021, and small biotech companies until 2029. Negotiations on the first 10 chosen drugs are currently underway. Eventually, the policy will cover all qualifying drugs sold under Medicare Parts B and D. In the first two years, only Medicare Part D drugs are subject to negotiations. Beginning in the third year, 15 to 20 additional drugs per year with the highest Medicare expenditures are to be chosen from a combined list both of Part D and Part B drugs.

[5] More specifically, the law imposes an initial excise tax equal to 65 percent of, rising quarterly by 10 percentage points quarterly, to 95 percent, or the company must withdraw all products from the Medicare and Medicaid programs. Furthermore, a company which charges a Medicare Part D or Part B beneficiary, provider, or plan sponsor a price in excess of a drug's negotiated price is subject to a fine equal to 10 times the difference between the price charged and the program's "maximum fair price".

Medicare prices established during the years prior to a drug's price regulation will play a crucial role in negotiations. 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 pre-regulated list price.[6] This linkage draws from the long-standing Medicaid provision which requires manufacturers to pay rebates to the Medicaid program that are fixed percentages of a drug's average commercial price.[7] In the Medicaid program, the commercial price serves as the benchmark or reference price. In the IRA, a drug's Medicare price prior to the regulated period serves the same purpose.

Drugs are highly heterogeneous in terms of their ingredients, manufacturing processes, dosage amount, dosage frequency, and physiological effects, to name a few. As such, there cannot be a single price for all drugs. While markets determine prices through drug-by-drug supply and demand, regulators need another method. In some countries, drug prices are set based on cost-effectiveness, which would be complicated in the IRA context because the law prohibits methodologies that treat extending the life of an elderly, disabled, or terminally ill individual differently than extending the life of an individual who is younger, non-disabled, or not terminally ill. Both internationally and in the U.S., regulators often look instead to prices determined elsewhere—the reference market. The French Health Products Pricing Committee, for example, sets prices based on the prices in a basket of other European countries. The Trump administration proposed a similar policy for Medicare Part B, although it was not implemented. Prior to 2025, Medicare Part B prices were already linked to commercial prices, and as noted above, reference prices in commercial markets are used to determine Medicaid drug prices.

Finally, as a general rule in negotiations, the initial positions of the bargainers and deviations from them are important in determining the eventual outcome because they affect the gains and losses from any negotiation. The statute's requirement that a drug's price be subject to regulation only after the drug has been on the market for 9 or 13 years is a means of establishing an initial benchmark price for both negotiating partners. Indeed, CBO incorporated this general rule in modeling the impact of H.R.3, the 2019 House-passed drug price regulation bill that

[6] Specifically, the limits are set in terms of the average manufacturer price paid by non-federal purchasers for the drug. The limits are 75% for drugs with 9 to 12 years since approval, 65% for drugs with 12 to 16 years since approval, and 40% drugs with more than 16 years since approval.
[7] Omnibus Budget Reconciliation Act of 1990.

preceded the IRA. In estimating the fiscal impact of the IRA, CBO has also expressed the negotiated price outcome as a percentage of the unregulated net price paid by Medicare.

The IRA requires the federal government to consider other factors in its negotiations. These include manufacturers' R&D, production and distribution costs, the extent of federal financial support for the drug's discovery, the drug's comparative effectiveness in improving health outcomes, and the cost and availability of therapeutic alternatives. However, neither the law, nor its implementing regulations, nor the recently concluded negotiations of the first 10 selected drugs specify how the federal government will use them.

2 The Theoretical Model

2.1 Oligopoly and monopoly comparative statics

To examine the impact of the Medicare price negotiation policy we employ a model in which manufacturers maximize profits over two markets: a reference market in which the manufacturer charges an unregulated price and a regulated market in which the manufacturer's maximum price is a fraction of the reference period price. As we will see, for Part D drugs, both markets are Medicare Part D markets differing by time. Similarly for Part B drugs, the regulated market is the Medicare Part B drug market. However, because Part B and commercial prices are legislatively tied together, the reference market includes both the Medicare Part B and commercial markets.

Let $\pi_f(p_f,P_f)$ and $T\pi_r(p_r,P_r)$ denote the market-specific profit function in the reference and regulation markets, respectively. By expressing each profit function in terms of the manufacturer's price p and a homogeneous index P of competitor prices, we are taking a differentiated products view of prescription drug markets. The competitors may be manufacturing different molecules to treat the same condition (Lichtenberg and Philipson 2002). Even competitors making the same molecule may be treated as differentiated by consumers due to perceptions of brand, reliability, and other less tangible factors.

The prices p and P are net, as opposed to gross, prices and are assumed to reflect privately negotiated rebates to pharmacy benefit managers, Medicare plan sponsors, and Medicare providers. The monopoly manufacturer is the limiting case where P does not affect profits. Combined profits are:

$$\pi_f(p_f, P_f) + T\pi_r(p_r, P_r) \quad (1)$$

where the parameter T allows for proportional differences between the profit functions. Reasons for proportional differences include a different duration of the regulation period than the reference period, different numbers of potential consumers in each market, and/or time discounting. In Appendix A we relax this assumption and allow for differences between the π_f and π_r functions that result from differences in the price-sensitivity of demand between the markets. For simplicity, we assume that marginal costs are constant and equal in the two markets.

In the absence of regulation, a manufacturer would set its profit maximizing prices in each market independently of the other market. We denote these prices as p_f^* in the reference period and p_r^* in the regulated market. In the oligopoly case, we assume that the competition is symmetric so that competitors also set their prices at p_f^* and p_r^*.

The regulation sets the maximum regulated-market price p_r as a weighted average of ρ and the reference price p_f:

$$p_r = bp_f + (1-b)\rho \quad (2)$$

$$P_r = bP_f + (1-b)\rho \quad (3)$$

Equation (3) assumes that competitors face the same regulatory constraint. Notice that the regulation has two parameters, b and ρ. The $b \in [0,1]$ parameter indicates the sensitivity of the regulated price to the reference-market price. The parameter ρ represents other factors affecting the regulated price, such as regulator perceptions of cost or prices beyond the manufacturer's control. $\rho = 0$ is the limiting case in which the regulated price is proportional to the reference-market price. In that case, $1-b$ can be described as a mandatory rebate or discount rate, which is the share by which the regulated price must be set below the reference price.

To understand the incentive that manufacturers face to alter reference prices in response to the regulation, suppose that initially p_f and P_f remain unchanged at p_f^*. If the price regulation (2) binds as a ceiling, the regulated-market price will be below its unregulated profit maximizing price. As a result, raising the regulated price will increase profits earned in the regulated market.

But the manufacturer's only tool for increasing the regulated price is to increase the reference price above p_f^*, which reduces profits earned in the reference market. Thus, greater regulated market profits from the higher regulated price come at the cost of lower profits from the higher price in the reference market.

The tradeoff can be seen in the profit maximizing condition with respect to p_f described by equation (4). Profits are maximized when the marginal loss in profits in the reference market from an increase in p above p_f^* equals the marginal gain in profits in the regulated market from the increase in p_r that is allowed by the increase in p_f. The left-hand side of equation (4) is the marginal gain function (MG). It describes the regulated market's marginal profit from increasing the reference price p_f. The product of the derivative term and T is the marginal increase in profits in the regulated market from an increase in the regulated price p_r. The term b is the regulatory parameter that determines the allowable increase in p_r resulting from each unit increase in p_f. The right-hand side of equation (4) is the marginal loss function (ML). It is the negative of the reference period's marginal profit function. ML is positive for prices above p_f^* because increasing p_f involves moving still further away from the unregulated profit maximizing price.

$$MG \equiv bT\frac{\partial \pi_r}{\partial p_r}\left(p_r, P_{r,}\rho\right) = -\frac{\partial \pi_f}{\partial p_f}\left(p_f, P_f, \rho\right) \equiv ML > 0 \tag{4}$$

Because profits are concave in prices, ML slopes up in p_f. Given the positive regulatory link (2) between p_r and p_f, MG slopes down in p_f.

So far, we have ignored changes in competitor prices P_r and P_f. If competitors have the same calculus and the equilibrium has $P = p$, then each competitor's first-order condition is identical. The industry equilibrium (5) is the firm condition (4) with symmetry imposed:

$$MG = bT\frac{\partial \pi_r}{\partial p_r}(p_r, p_r, \rho) = -\frac{\partial \pi_f}{\partial p_f}\left(p_f, p_f, \rho\right) = ML \tag{5}$$

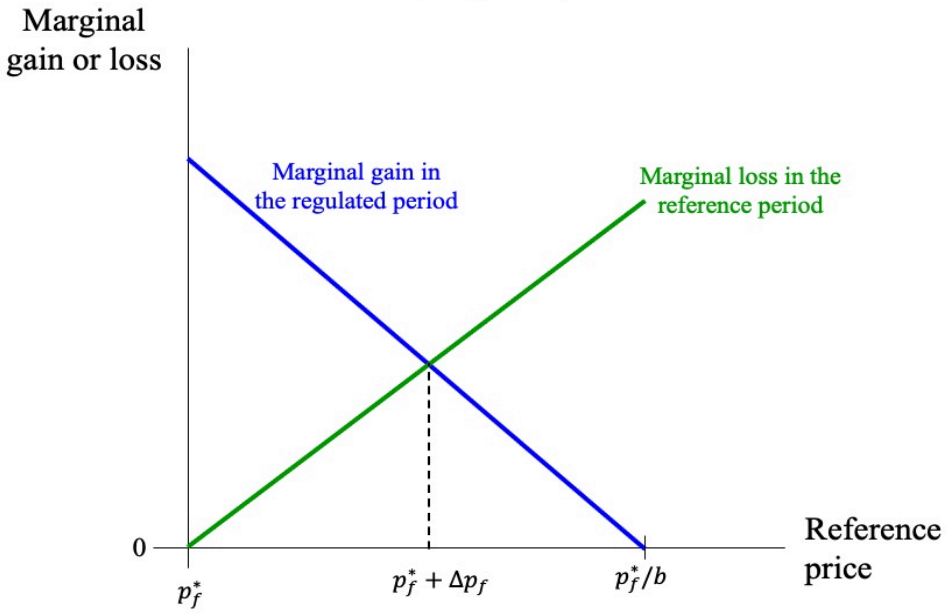
Interpreted as two equations in the "unknowns" p_f and p_r, equations (2) and (5) provide equilibrium comparative statics with respect to the market size parameter T and the regulatory

parameters b and ρ. The expression of those comparative statics is the same regardless of the number of competitors, which affects the quantitative properties of π_f and π_r without affecting the qualitative ones. Importantly, *MG* still slopes down in p_f and *ML* slopes up in both the monopoly (where profits are independent of *P*) and oligopoly cases.[8]

The two functions are graphically depicted in Figure 1 for reference prices above p_f^*. For convenience, we have drawn these functions as linear, as they would be if the underlying demand curves were linear in prices. But, in general, their curvature depends on second derivatives of the underlying demand functions. The vertical axis shows marginal profit losses in the reference market and marginal profit gains in the regulated market. The horizontal axis shows reference prices above p_f^*. The marginal loss function intersects the vertical axis at zero, reflecting the fact that p_f^* is the profit maximizing price in the reference market in the absence of regulation. Its positive slope reflects the fact that reference-market profits decline with p_f above p_f^*.

Figure 1. Marginal gains and losses with reference pricing

Drawn for the case in which the demand curve is, up to scale, the same in regulated and reference markets and the regulatory parameter ρ is zero.



The marginal gain function is positive for all values of p_f from p_f^* to p_f^*/b. In this range, the regulated price is less than the regulated period's profit maximizing price. Profits rise at a

[8] If the oligopoly equilibrium is stable—a one unit change in the competitor price index results in less than one unit change in own price – then $\frac{d\pi_r}{dp_r}\frac{\partial \pi_r}{\partial p_r}\left(p_r, p_r, \rho\right) < 0$.

decreasing rate with increases in the regulated price (p_r) permitted by a higher reference price (p_f). The marginal gain in regulated market profits declines to zero when the reference price reaches p_f^*/b. At this price, the regulated price equals the profit maximizing price; that is $p = p_r^*$. Further increases in the reference price would reduce profits in the regulated period as well as in the reference period.

As Figure 1 shows, a manufacturer has the incentive to increase the reference price so long as the marginal gain in regulation market profits exceeds the marginal loss in reference market profits. The manufacturer would continue to do so until the marginal gain from further increases in the reference price equals the marginal loss from that increase; namely, the condition described by equation (4).

It is often asserted that a manufacturer will raise the reference price of its regulated drug to offset losses in profits on sales at the lower regulated price. Our analysis shows that, on the contrary, a firm does so because the higher reference price, by raising the allowable regulated price, generates higher profits in the regulated market. These higher profits are partially offset by losses in the reference market.

If the reference and regulated markets have, up to scale, the same demand curves, then there are only two differences between the *ML* and *MG* curves in Figure 1. One difference is the scaling factor bT that equation (5) has in the *MG* but not in the *ML*. The other is that, up to the bT factor, *MG* is the mirror of *ML*. This already gives us two comparative statics, one of which is the T parameter moves the equilibrium reference price further away from its unregulated value p_f^* and towards p_f^*/b without changing either of those horizontal-intercept values.

Another comparative static is that changes $d\rho < 0$ in the regulatory parameter ρ to reduce regulated prices result in higher reference prices because the marginal gain curve is shifted out. In other words, even if the regulated price is anchored in factors ρ other than the reference price, that regulatory channel still results in price offsets in the reference market. Our Appendix B extends this setup to allow for a second manufacturer control variable that influences regulators through ρ. There we find even less overall price reduction (measured as $p_f + Tp_r$) than is indicated by our model that only allows manufacturers to react to regulation with their reference price.

Now compare two drugs with the same unregulated price p_f^*, but one being generated by a monopolized market and another by an oligopoly.[9] The same reference-price regulation is imposed on these drugs. Therefore, the price intercepts in Figure 1 would be the same for the two drugs. The *ML* function might be steeper for the oligopolist than for the monopolist due to the additional effect working through competitor prices, but then the *MG* function must also be steeper for the oligopolist. The two may well intersect at the same regulated-equilibrium price regardless of market structure, as they do in the linear demand case that follows.[10]

Another comparison is between two monopoly drugs with different price elasticities of demand. They have different unregulated prices p_f^*, but they still have the same proportional gap between the two intercepts in Figure 1. The more price-sensitive drug has steeper *MG* and *ML* curves. Nevertheless, the two may well intersect at the same regulated-equilibrium price, up to the proportional factor p_f^*. This is the case with linear demand, where the reference-price impact of regulation is, as a proportion, independent of price sensitivity.

An increase in *T* increases the magnitude of the manufacturers' price response to the regulation. This can be verified by inspecting equation (5), where *T* appears as a scalar in the marginal gain function. In Figure 1, an increase in *T* is shown by a clockwise rotation of the marginal gain function. The marginal loss function is unchanged. With a higher *T*, the marginal gain function intersects the marginal loss function at a higher reference price. Thus, the larger the regulated period relative to the reference period, the greater the incentive for manufacturers to raise the reference price. Intuitively, the larger the regulated period, the greater the gain in that period's profits from an increase in the regulated price permitted by a higher reference price.[11] Another important implication is that since *T* differs among drugs, a uniform rebate across all drugs will, in general, result in changes in relative reference prices among drugs as well has an increase in reference prices of all drugs. This introduces an additional distortion into pharmaceutical markets.

The impact of an increase in the regulatory parameter *b* on the manufacturer's incentive to raise the reference price is, perhaps surprisingly, ambiguous. A larger value for *b* moves the

[9] That is, we are holding constant the price elasticity of demand facing an individual seller.
[10] Appendix A obtains the same linear-demand result without restricting the regulated and reference markets to be equally price sensitive.
[11] Equation 5 formalizes a result relied upon by Duggan and Scott Morton (2006) to estimate the impact of the Medicaid program's rebate policy.

MG intercept to the left in Figure 1 and rotates it clockwise. Depending on the demand function parameters, the reference price may increase as the regulatory parameter rises, eventually reaching a peak, and then decline with further increases in the discount. This occurs because the intercept-shift effect, which reduces the equilibrium reference price, is most potent for small b. If the MG rotation effect, which increases the reference price, is to dominate, it tends to be for large b. The relationship is explored in Appendix A and is discussed further when we turn to the case of linear demand curves in the next section.[12]

Our remaining results are shown most easily by normalizing the marginal cost of the drug to one and assuming a linear market-demand system. Equivalently, we could require the profit-function derivative $\frac{\partial \pi_r}{\partial p_r}(p, P, \rho)$ to be linear in p. Either way, we have profits quadratic in the equilibrium price.

For regulations that only slightly distort prices, the linear approximation would be quite accurate. Larger distortions involve moving further up the demand curve during the reference period, which are parts of the curve unlikely to have been observed in the historical record. In that sense, our exercise shares some of the analytical uncertainty of valuing new goods which involves assessing valuations for inframarginal consumers.

2.2 Linear Demand

The demand function can be parameterized as $D(p,P;\varepsilon,\eta)$:[13]

$$D(p, P; \varepsilon, \eta) \equiv \frac{(\varepsilon + 1)[\varepsilon\, p + (\eta - \varepsilon)P] + (1 - \eta)\varepsilon}{\eta + \varepsilon} \tag{6}$$

where the constants η and ε satisfy $\varepsilon \leq \eta < 0$ and $\varepsilon < -1$. Note that this oligopoly model has monopoly as the special case $\varepsilon = \eta$ in which the market demand curve coincides with the

[12] We note here that in the special case of constant elasticity demand curves, the reference price increase has no peak and rises monotonically with respect to the discount.

[13] We assume the prices are below the choke prices, so that nonnegativity constraints on demand do not bind. Mulligan (2022) shows how this demand function can be derived from a quadratic-form utility function. Note that the same results could be derived with the alternative notation $D(p,P) = a_0 - a_1\, p + a_2\, P$ with the constants a_0, a_1, and a_2. However, this approach has a less transparent connection to the elasticities that are central to the economics of competition and to the sign conditions required to guarantee stability and interior solutions. It is also opaque regarding what is held constant when comparing a monopolist to an oligopolist.

producer's demand curve. The unregulated symmetric oligopoly equilibrium price under this demand system is $p^* = \varepsilon/(1+\varepsilon) > 1$. Although ε and η are slopes, they coincide with the firm- and industry-level point elasticities of demand, respectively, at prices $p = P = p^*$. This parameterization normalizes quantities to one at $D(1,1;\varepsilon,\eta)$.

To focus our analysis on the impact of a rebate rule, we assume that $\rho = 0$. The quantities sold in the reference and regulated markets are $D(p_f,P_f;\varepsilon,\eta)$ and $TD(p_r, P_r;\varepsilon,\eta)$, respectively. Up to the scale factor T, the profit in a market is $(p-1)D(p,P;\varepsilon,\eta)$, evaluated at the corresponding prices and demand parameters. Substituting this profit function, the regulation formula (2), with $\rho = 0$ into the equilibrium condition (5) results in a single equation that can be solved for the equilibrium reference-market price:

$$p_f = \frac{\varepsilon}{1+\varepsilon}\,\frac{1+bT}{1+b^2T} = p_f^*\,\frac{1+bT}{1+b^2T} \tag{7}$$

The first ratio is the price that would be set by a manufacturer in the absence of regulation. For $T > 0$, the second ratio exceeds one as long as the regulatory parameter b does not push the regulated price below marginal cost.

Equation (7) can be rewritten in terms of the proportional impact on price:

$$\frac{\Delta p_f}{p^*} = \frac{1-b}{1+Tb^2}Tb \tag{8}$$

Conveniently for our empirical purposes, the proportion in equation (8) by which manufacturers raise price in response to the regulation is independent of the parameters of the demand curve and cost curves. It depends solely on b, the regulatory parameter that expresses the regulated price as a fraction of the reference price, and T, the size of the regulated market relative to the reference market. This result relies on reference and regulatory demand curves that are linear and have common "choke" points, and marginal costs curves in the two markets that are equal and constant. Under these conditions, determining the price response to reference price regulation does not require any further knowledge about the shape or location of the demand and cost curves.

As is evident from the absence of the market demand parameters from equation (8), the proportional price response in equation (8) holds regardless of whether the market is monopolistic, oligopolistic or consists of several drugs that are imperfect substitutes for one another. Market structure may be related to the firm level demand elasticity (ε) and therefore the levels of unregulated prices. But the proportional gap between the price-intercepts in Figure 1 depends only on the regulatory parameter b. The firm-level elasticity ε makes both the *MG* and *ML* functions steeper without (up to scale p_f^*) affecting the price where the two intersect.[14]

The equilibrium proportional price response from a higher T is given by:

$$\frac{\partial p_f}{\partial T} 1/p_f^* = \frac{b - b^2}{(1 + Tb^2)^2} \tag{9}$$

Because equation (9) is positive for all possible values of b and T, the price response will be larger the greater the value of T. One implication of Equation (9) is that price responses will tend to be larger for Part D drugs than for Part B drugs. Negotiations between manufacturers and payors over net prices of drugs sold in the Part D program are separate and distinct from negotiations over commercial prices. As a result, net Part D prices are largely independent of commercial market prices. For this reason, changes in the price of a drug sold in the Part D program do not necessarily affect the price charged for the same drug in the commercial market. Thus, the reference and regulated markets for Part D drugs are limited to the Part D market, and T is determined by the size of these two markets. The price Medicare Part B pays for a drug is, in contrast, statutorily tied to its average sales price (ASP) in the commercial market. Thus, a manufacturer seeking to raise a drug's price in the Part B program must necessarily increase its commercial price. Any such price increase will reduce profits on both Part B and commercial sales during the reference period. For Part B drugs, therefore, T is determined by the size of the regulated market compared to the combined size of both the Part B and commercial markets during the reference period.

[14] The degree of competition may differ between the reference and regulated markets. A late entrant drug may, during its drug's reference period, have a competitor drug that is already subject to price regulation. Such a late entrant's price increase would be constrained by regulated price. Also, if the market consists of several competitor drugs with different regulated period market shares (*T*s), the reference price increase would be limited by the firm with the smallest market share.

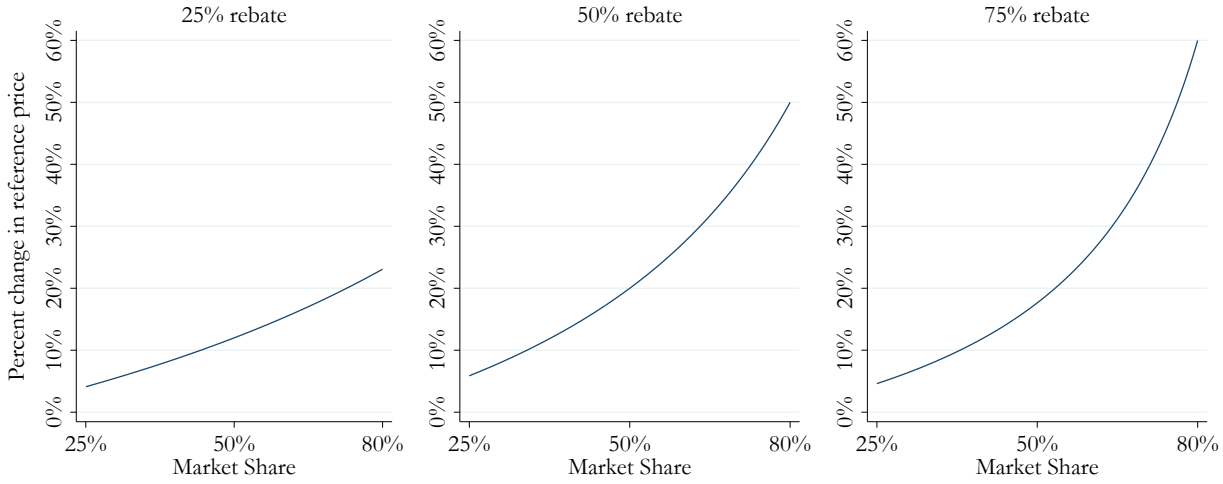
Equation 9 has an important policy implication. The term *T* is a function of, among other things, the number of years a drug is expected to be on the market before its price is subject to regulation. The fewer the years, the larger the *T*. Thus, a regulatory or statutory reduction in the number of years will produce an even higher increase in reference prices. This issue is discussed more fully in the next section.

As equation (9) shows, a manufacturer's price response is a function of *T*, *b*, and the interaction between them. Figure 2 shows the price response to the market shares for three alternative rebate levels: 25 percent, 50 percent, and 75 percent. For expository convenience, we have converted *T* into a drug's regulated period market share, which is defined as a drug's expected regulated period profits (discounted for the future) as a share of discounted profits that would have been earned in both the reference and regulated markets in the absence of the IRA policy. The conversion is given by the formula

$$Market\ Share = \frac{T}{1+T}$$

As shown in Figure 2, the price response is positive and highly sensitive to market share regardless of the rebate level. With a 25 percent rebate, the price response is almost a linear function of market share. At higher rebate levels, the price response rises more rapidly with increases in market share. With a 50 percent rebate, the price response increases from 12 percent to nearly 37 percent as the market share increases from 35 percent to 70 percent. With a 75 percent rebate, the price response rises from 10 percent to nearly 40 percent over the same market share range.

Figure 2. Percent change in reference price by regulated period market share

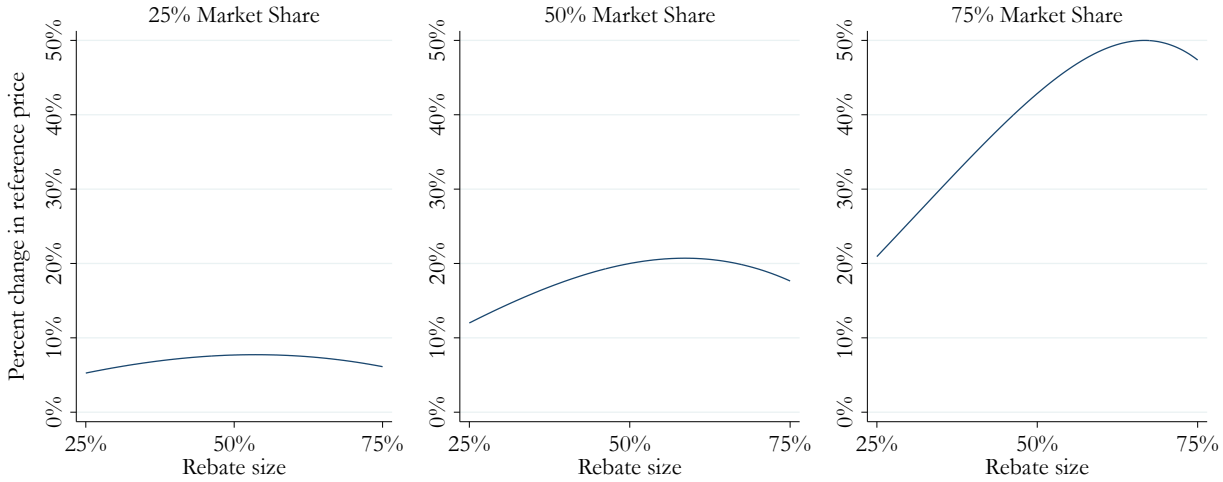


As noted earlier, the impact of a change in the regulatory parameter b on the size of the manufacturer's reference price response is ambiguous. With a linear demand curve, the impact is a complex function of T and b and given by:

$$\frac{\partial p_f}{\partial b} 1/p_f^* = -\frac{T(Tb^2 + 2b - 1)}{(1 + Tb^2)^2} \tag{10}$$

Figure 3 traces the price responses to a range of rebate levels for three regulated period market shares: 25 percent, 50 percent, and 75 percent. Across all market shares, the price response is an inverted U-shaped function. The sensitivity of price responses to rebate levels increases with the size of the regulated market share. The price response rises from 5 percent to a peak of 8 percent with a market share of 25 percent (left-panel), 12–21 percent with a market share of 50 percent (middle panel), and 20–50 percent with a market share of 75 percent (right panel).

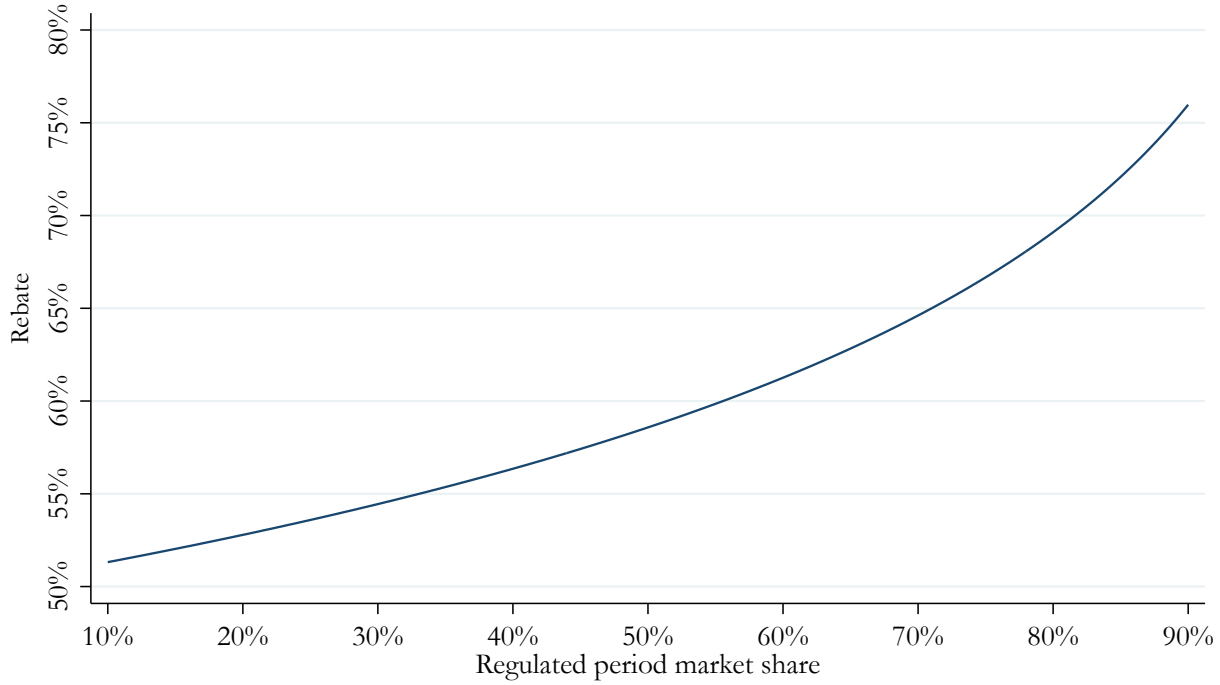
Figure 3. Percent change in reference price by rebate size



The rebate that generates the maximum reference period price response is a monotonically rising function of the regulated period market share. Intuitively, the larger the market share, the greater the revenue gained in the regulated period from increasing the reference price. Figure 4 plots the relationship between the rebate that generates the maximum price response and the market share. For any given regulated period market share, the rebate which produces the largest price response exceeds 50 percent. The maximum price response occurs at rebates of 54 percent and 59 percent for the 25 and 50 percent market shares, respectively. The maximum price for a drug with a 75 percent market share occurs at a somewhat higher 67 percent rebate level. Up to a market share of 62 percent, the maximum price response occurs with rebates in the 50 to 60 percent range. This result is particularly noteworthy since while the eventual outcome of price negotiations is unclear, CBO's preliminary analysis assumes that negotiated prices will be about 50 percent below the manufacturer's net price.[15]

[15] See page 10 in CBO (February 2023).

Figure 4. Rebate yielding maximum price response by regulated period market share



3 Price Changes After the IRA

This section applies the reference pricing model to actual market share data to obtain estimates of likely manufacturers' long-run price responses, government savings, and reductions in Medicare enrollee premiums and cost sharing. As discussed above, under certain simplifying assumptions regarding the drug market's demand and cost functions, manufacturers' price responses to the IRA's price negotiation policy depend only on two pieces of information:

1. The size of the negotiated rebate, measured from a drug's price net of privately negotiated discounts, i.e., its net price.

2. The drug's anticipated pre-IRA policy profits from sales during the regulated period as a share of profits earned over the drug's life cycle, where the drug's lifecycle is defined as the reference period plus the regulated period.[16] Profits are measured in present value terms. For expository convenience, when we refer to sales or revenues during the reference and regulated market periods, we are referring to sales and revenues that would be expected in the absence of the IRA pricing policy.

[16] As we noted earlier, the IRA specifies that the regulated period ends when the drug faces or is about to face generic entry. Our analysis assumes that generic competition reduces economic profits to zero.

To move from our theoretical model to empirical estimates, we make four simplifying assumptions. First, consistent with the two-period model, we treat the reference market as a single period, measuring its prices and quantities as simple averages.[17] Second, we assume that manufacturers respond only by changing a drug's price during the reference period. This rules out changes in prices and utilization due to shifts in marketing or in the timing of launches for new indications. Third, as is commonplace in the literature on pharmaceutical markets, we assume that revenues serve as an adequate proxy for firm profits.[18] Fourth, and most important, we assume that a newly marketed drug has no therapeutic equivalent drug whose price is currently subject to price regulation. The existence of such an equivalent would limit a manufacturer's ability to raise its drug's launch price to the level implied by our analysis.

3.1 Estimating Regulated Period Market Shares

In this section, we develop a range of regulated period market shares using historical revenue data for Part B and D drugs. Regulated market share depends on the length of its exclusivity period and the life cycle pattern of a drug's revenue stream that would be affected by the regulation. Specifically, we define a drug's regulated period market share as:

$$MS = \frac{\sum_{i=n}^{k} \frac{\pi_i}{(1+r)^i}}{\sum_{i=1}^{k} \frac{\pi_i}{(1+r)^i}} \tag{11}$$

Where π_i is affected revenue i years after approval, r is the discount rate, k is the number of years prior to generic competition, and n is the number of years from the approval year to the regulated period. We use a 10 percent discount rate to calculate market shares.[19]

[17] A more complicated model would allow for different prices over a drug's lifecycle and a benchmark price that is based upon prices close to the year in which the drug is selected for regulation. This complexity may be a more accurate characterization of the drug market, but it adds little to our basic findings.
[18] As noted in the theoretical section, the price and revenue results are not a function of a firm's cost so long as marginal cost is constant. Nevertheless, the effect on profits will affect innovation rates and other related firm behavior.
[19] A review of corporate filings finds pharmaceutical companies use discount rates from 10 to 13 percent for "in-process research and development assets." The median for biotech companies was 10 percent (Stasior, Machinist, and Esposito 2018).

As noted previously, because Part D prices and commercial prices are determined independently of one another, the regulated period market share is revenue from Part D drug sales during the regulated period as a share of revenue from Part D drugs sales over the drug's lifecycle. On the other hand, because Part B prices are legislatively tied to commercial prices, the regulated period market share is revenue from Part B drug sales during the regulated period as a share of both commercial and Part B revenues over the drug's lifecycle.

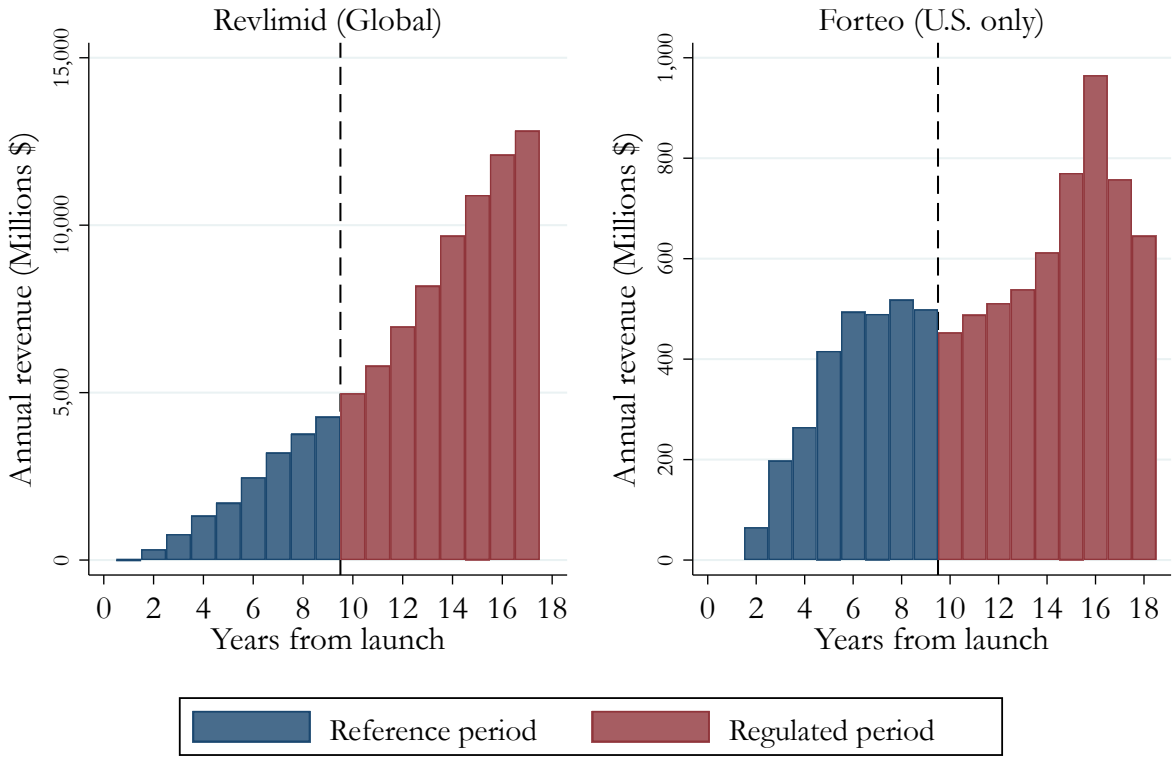
3.1.1 Part D Market Shares

The Part D regulated market share can vary widely by drug. Figure 5 illustrates this variation by displaying the lifecycle revenue paths of two drugs which have recently faced generic competition: Revlimid and Forteo. Neither drug was subject to IRA price regulation. The lifecycle paths are derived from company financial reports and have the desirable attribute that they are net, as opposed to gross, revenue paths. However, these revenues have a drawback because they include both commercial and Medicare revenues.

If Celgene and BMS, the manufacturers of Revlimid and Eli Lilly, the manufacturer of Forteo, correctly forecast each drug's future revenues at the time of launch, these lifecycle revenue paths would measure what each drug's expected regulated market share would have been in the absence of the regulation.[20] The blue-colored area in Figure 5 depicts revenue during the drug's first 9 years on the market. The red depicts revenues during the drug's 10th year on the market to the year of generic entry.

[20] Revenue data are based on manufacturers' financial reports. Due to reporting limitations, Revlimid's lifecycle pattern is based on global revenue data; Forteo's is based on U.S.-only revenue.

Figure 5. Revenue lifecycles for selected Part D drugs



Notes: We use reported revenue from regulatory filings. Where available we use U.S. revenue only; otherwise we use global revenue. Figures are in nominal dollars.

Revlimid was first approved in 2005 for the treatment of multiple myeloma. It lost its market exclusivity to generic entry in 2021. Aided by label expansions, its annual revenues increased steadily to $12 billion at the end of its market exclusivity period. As a result of its long patent life and rising revenue path, 80 percent of its revenues would have been earned during the regulated period. Its regulated period market share, assuming a 10 percent discount rate, would have been 67 percent.

Forteo was first approved for the treatment of osteoporosis in late 2002 and first faced generic entry in 2019. In contrast to Revlimid, the drug experienced an initial spurt of strong revenue growth during its initial years on the market. Its annual U.S. sales rose to $265 million in its 4th year on the market and plateaued thereafter before declining toward the end of its market exclusivity period. Despite its relatively long patent life, 66 percent of its revenue would have been earned during the regulated period. Its regulated market share would have been 48 percent.

To estimate the likely regulated period market share for a typical Part D drug, we use Medicare Part D gross expenditure data on all single-source drugs to construct a composite

revenue life cycle. The use of gross Part D expenditures may overstate the growth in the typical drug's revenue, hence its regulated market share, because rebates tend to rise the longer a drug has been on the market.

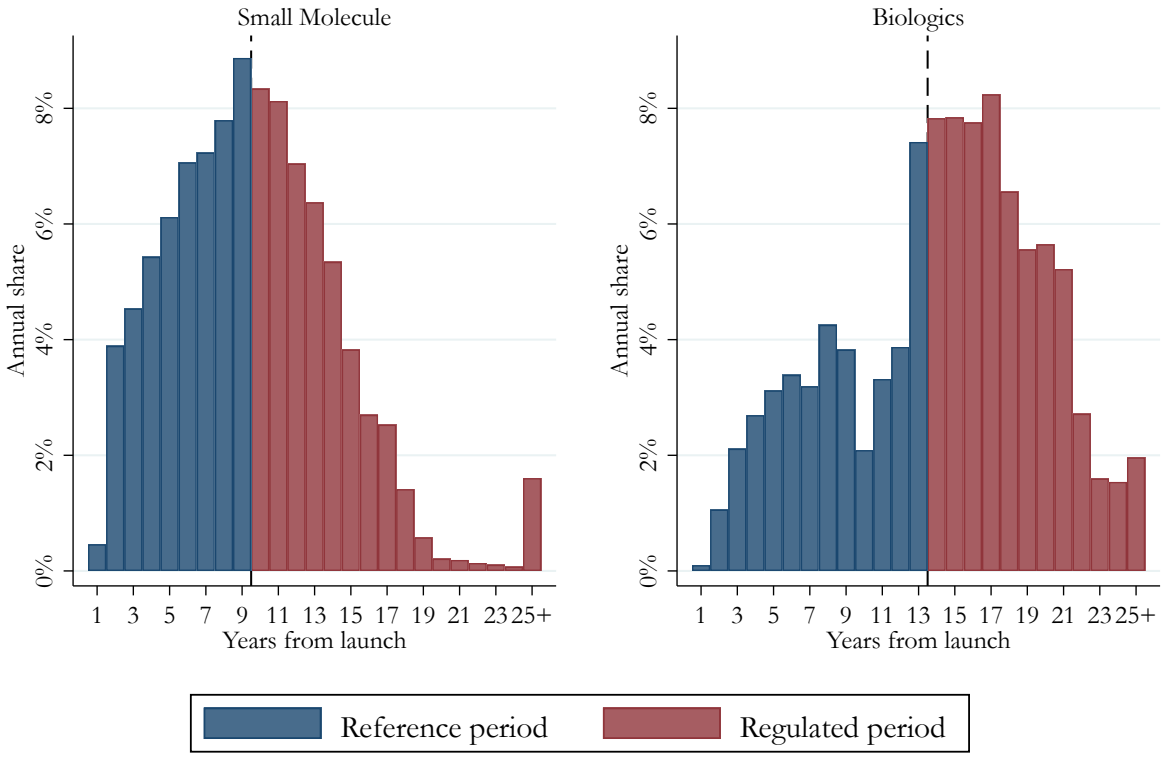
Medicare Part D gross expenditure data are publicly available from 2012 to 2022. To construct our synthetic revenue lifecycle, for each year from 2012 to 2022, we compute the percentage of the year's total expenditures on single-source drugs by years on the market.[21] We calculate annual market shares for small molecules and biologics separately and estimate a combined expenditure-weighted average of the two. We smooth the results by calculating the arithmetic average across the 11 years of data.

Figure 6 shows the stylized lifecycle revenue stream generated by these data for small molecules and biologics averaged over the 11 years. The fact that gross expenditures on small molecules happen to peak after 9 years is just coincidental. For small molecules, 49 percent of the lifecycle revenues occur in the regulated period. This rises to 60 percent for biologics. Using our assumed 10 percent discount rate, the regulated market share is 33 percent for small molecules and 39 percent for biologics.[22] The expenditure-weighted market share for all Part D drugs is 34 percent. The market share estimate is sensitive to the assumed discount rate. A 5 percent discount rate produces a market share of 42 percent, while a 15 percent discount rate produces a market share of 27 percent.

[21] To determine whether a drug is single-source, we limit the CMS sample to drugs that have only one manufacturer in the CMS drug expenditure database.

[22] Philipson, Ling, and Chang (2023) effectively calculate a market share estimate for 92 small molecule drugs that are likely to face the price regulations in the future. Their estimates suggest a regulated market share for these drugs of up to 26.6 percent.

Figure 6. Share of Part D gross expenditures by years from launch

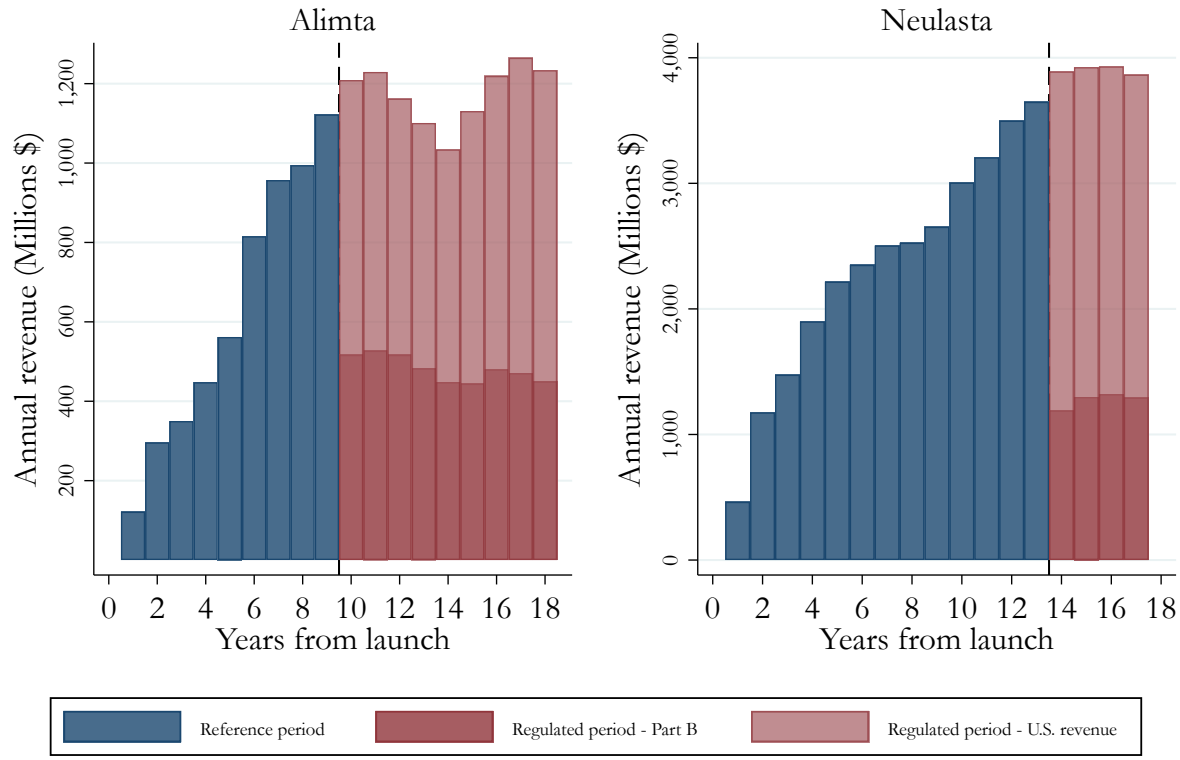


Notes: Data are based on CMS expenditure data (2012–2022) for single-source drugs.

3.1.2 Part B Market Shares

Figure 7 shows the lifecycle revenue paths of two Part B drugs that have recently faced generic competition: Neulasta and Alimta. Revenues are U.S. sales and are obtained from manufacturers' financial reports. The blue-colored area depicts revenue from commercial and Part B sales during Alimta's first 9 years on the market and Neulasta's first 13 years on the market. The dark red area depicts Part B revenues that would have been subject to the IRA policy if it had been in effect for each drug. The lighter red area shows revenues from U.S. commercial sales.

Figure 7. Revenue lifecycles for selected Part B drugs



Notes: We use reported revenue from regulatory filings. Figures are in nominal dollars.

Neulasta first entered the market in 2004 to prevent infections in cancer patients arising from chemotherapy. As a biologic, it would have been granted 13 years, until 2015, before it was subject to price regulation. Three years later, in mid-2018, Neulasta lost its market exclusivity. Its annual revenues from total commercial and Part B sales during its reference period averaged around $2.4 billion. Neulasta's yearly Part B sales during the regulated period averaged a healthy $1.3 billion. But because of its relatively short regulated period, only 14 percent of its revenues would have been earned from Part B during the regulated period. After discounting, its regulated period market share would have been only 7 percent.

Alimta was first approved for the treatment of mesothelioma in 2004. Four years later its indication was expanded to include non-small cell lung cancer. As a chemical agent, it would have been granted 9 years before it was subject to price regulation. Alimta first faced generic competition in 2022. Annual total U.S. sales grew steadily to over $1 billion in 2012, the last year of what would have been its nine-year reference period had the IRA been in effect. Subsequently, its annual sales leveled off at about $1.2 billion until it faced generic competition

in 2022. Alimta's annual Part B sales during what would have been its regulated period averaged about $500 million. Forty-three percent of its revenues were earned during the regulated period. After discounting, Alimta's regulated period market share would have been 27 percent.

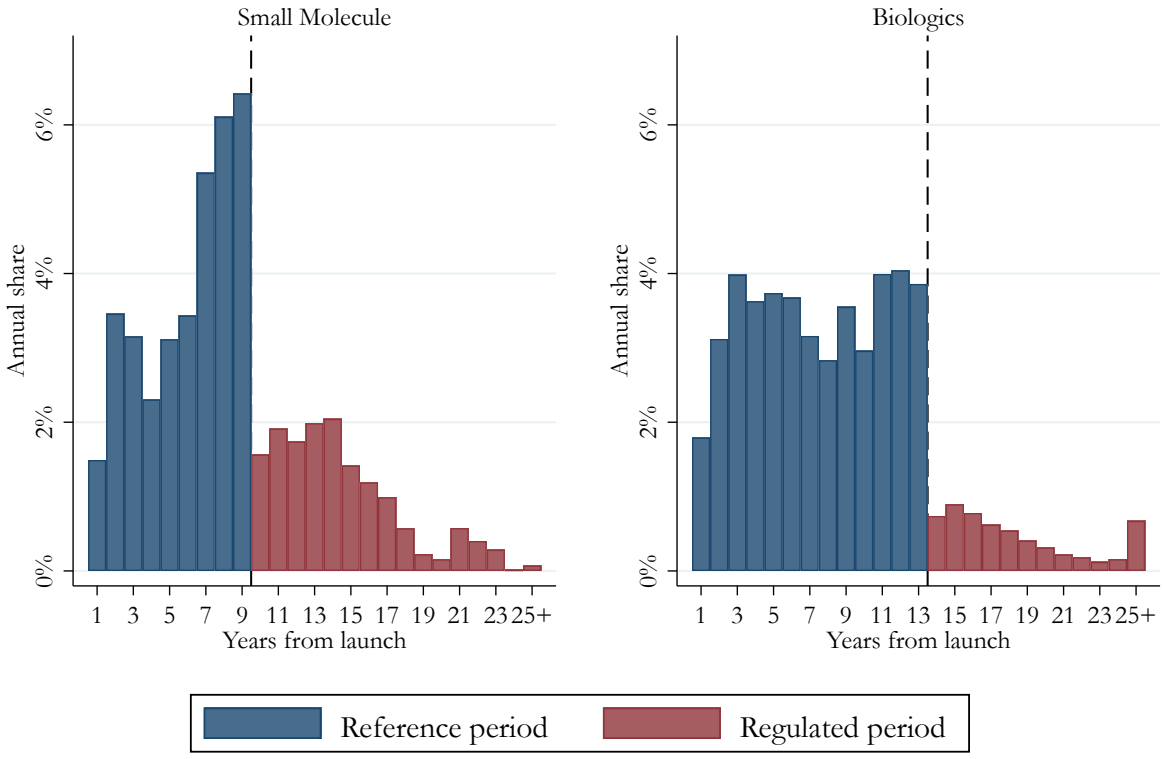
Calculating the regulated period market share for a typical Part B drug requires data on total revenues from sales in both the commercial and Part B markets. Total revenues for all Part B drugs from 2012 to 2022 were obtained from SSR Health, a proprietary data set containing individual drug revenues derived from SEC reports.[23] Medicare Part B revenues for the same period were taken from publicly available CMS Part B expenditure data for the same years. Unlike Medicare CMS's Part D expenditures, the agency's reported Part B expenditures are net, as opposed to gross, expenditures.

Annual SSR Health net sales on individual drugs were matched to their corresponding Part B expenditures in the CMS dataset for each year.[24] SSR Health data do not include all Part B drugs, but the sub-sample of matched drugs accounts for 90 percent of all Part B drug expenditures during the 11-year period.[25] Using this matched data set, we followed the same procedure used in computing the typical Part D drugs regulated market share.

Figure 8 shows the stylized Part B revenue stream for biologics and small molecules. The proportion of life cycle revenues earned during the regulated period is 30 percent for small molecules and 11 percent for biologics. For the two drug types combined, the overall expenditure-weighted proportion is 14 percent.[26] This percentage is markedly lower than the 54 percent estimated for the typical Part D drug. Using our assumed 10 percent discount rate, the expenditure-weighted regulated market share is 6 percent. A 5 percent discount rate produces a market share of 4 percent, while a 15 percent discount rate produces a market share of 9 percent.

[23] For a description of these data, see https://www.ssrhealth.com. For a discussion of its limitations see, Ippolito and Levy (2022).
[24] See https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug.
[25] There were several instances where the SSR Health data for a particular year are missing. As a sensitivity check, we recalculated market shares excluding these drugs from the sample; market shares changed by less than 1 percentage point.
[26] The expenditure-weighted share uses annual drug expenditures within Part B for biologics and small molecules.

Figure 8. Share of Part B gross expenditures by years from launch



Notes: Data are based on CMS expenditure data (2012–2022) for single-source drugs.

3.2 Price Responses for Part B and Part D Drugs

This section uses the market shares calculated above to estimate the long-term price effects of the IRA price regulations on Medicare drugs. To add a degree of concreteness to our analysis, we also analyze how the IRA would have affected the pricing decision and revenues of the four drugs considered individually in the previous section.

As we noted in the preceding section, while rebates are ultimately subject to a negotiated outcome, CBO (February 2023) estimated that rebates will average around 50 percent of drugs' net prices. We assume this rebate for our analysis. Table 1 shows the optimal reference price responses under various regulated period market shares. The price responses, shown in column 2, are highly sensitive to market shares (column 1). The synthetic revenue path constructed from all Part D drugs results in an 11 percent price increase during the reference period. The Forteo price increase is marginally higher at 19 percent. The 33 percent price response for Revlimid reflects its significantly larger regulated period market share. The synthetic revenue path for Part B drugs produces a 2 percent price increase during the reference period. Likewise, since Alimta and

Neulasta have significantly lower market shares than the two Part D drugs in the table, their estimated price responses are accordingly smaller. Alimta's price would have increased by 9 percent, while Neulasta's price would have risen by 2 percent.

The estimated 11.3 percent Part D and 1.7 percent Part B reference price responses can be compared to the price response that is implied by Duggan and Scott Morton's (2006) empirical analysis of the Medicaid rebate policy only under certain conditions. They estimated that each 10 percentage point increase in a drug's regulated market share increases its reference price by between 7 and 10 percent. This estimate is conditional on the 15.1 percent rebate that prevailed at the time of their writing.[27] But as equation 9 shows, the impact of an increase in the regulated market share depends on the rebate's size. In particular, the larger the rebate, the smaller the market share's impact on the reference price. Thus, their estimate can only be applied to the IRA policy if the rebate is 15.1 percent. Applying it to rebates above 15.1 percent will overstate the price response.[28]

Table 1. Price effects of reference pricing for selected drugs with 50 percent rebate

	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%
Selected Drugs		
Revlimid (Part D)	67%	33.4%
Forteo (Part D)	48%	18.6%
Alimta (Part B)	27%	8.6%
Neulasta (Part B)	7%	2.0%

Notes: The regulated period begins 9 years after approval for small molecule drugs and 13 years for biologics. A 10 percent discount rate is used to calculate the market share. Combined market shares for small molecules and biologics are weighted by the share of CMS expenditures for each drug type.

[27] It is also conditional upon the fact that in the Medicaid policy, the regulatory and reference markets are contemporaneous.

[28] Applying theoretical model to the Duggan-Scott Morton (2006) data results in a lower estimate of the price response to the Medicaid rebate policy. At the Duggan-Scott Morton's sample mean regulated market share of 16.5 percent, their parameter estimates imply a price response of between 12 percent and 17 percent. At this market share and a 15.1 percent rebate, our model (equation 8) yields a price response of 2.2 percent

4 Impact on Medicare Expenditures and Enrollee Savings

The theoretical model can be used to derive estimates of a fully phased-in IRA policy's impact on Medicare drug expenditures after accounting for the manufacturers' pricing responses. Equation 12 shows the percentage change in manufacturer revenues from drugs sold in the reference and regulated markets:

$$\frac{\Delta TR}{TR^*} = \frac{1+Tb}{1+Tb^2}\,\frac{1+Tb}{1+T} - 1 \tag{12}$$

where the asterisk denotes the unregulated value. As with the manufacturer's price response, with linear demand and cost functions, the percentage change in revenues from drugs sold in the reference and regulated markets is independent of the functions' parameters.

Since the reference and regulated markets for Part D drugs include only revenues from drugs sold in the Medicare program, the percentage change in manufacturer revenues equals the percentage change in Medicare Part D expenditures. However, changes in revenues for Part B drugs sold in the reference market include commercial revenues as well as revenues from drugs sold in the Part B program. We adjust equation 11 to eliminate these commercial revenues and, thereby, obtain estimates of changes in Medicare Part B drug expenditures.[29]

Table 2 reports estimated changes in Medicare expenditures after accounting for the manufacturers' pricing response and compares them to changes under a static assumption. The static changes assume that manufacturers do not alter reference prices and hold the quantity of drugs sold in the reference and regulated markets constant. The first two rows show the effect on branded drugs, i.e., those drugs that are subject to the IRA policy. Accounting for the price response reduces the static estimates of Medicare Part B and Part D savings on branded drugs by slightly more than half. The third row, which combines Part B and Part D branded drugs, reports a static estimate of savings of 14.6 percent and 6.6 percent after accounting for the price response.

Table 2. Effects of reference pricing on Medicare drug **e**xpenditures with 50 percent rebate

[29] The adjusted equation is $\frac{(1+Tb)[1+T^2b^3-w+Tb(1+w)+Tb^2(1-2w)]}{(1+Tb^2)^2(1+T-w)} - 1$, where *w* is the share of revenue in the reference period from sales in the commercial market. Using SSR Health and CMS data, we estimate *w* is 29.4 percent.

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

Notes: Regulatory period begins 9 years after approval for small molecule drugs and 13 years for biologics. A 10 percent discount rate is used to calculate the market share. The change in expenditures without reference pricing assumes no quantity changes.

Medicare expenditures on branded drugs account for approximately 80 percent of total Medicare drug expenditures, with generic drugs accounting for the remainder.[30] As shown in row 4, after accounting for the price response, a fully phased-in IRA policy is estimated to reduce total Medicare drug expenditures by 5.3 percent. Measured in dollars, the total reduction in Medicare Part B and D spending in 2023 would be $10.9 billion after accounting for the price response and $24.1 billion without it. As a percentage of total Medicare expenditures, the savings are only 2.3 percent under the static assumption and only 1.1 percent after accounting for manufacturers' pricing responses.

The Medicare expenditure reductions from the IRA's drug price negotiation policy would reduce Medicare premiums and cost sharing among enrollees. To estimate these effects for Part D, we use the 2021 Medical Expenditure Panel Survey Household Component (MEPS-HC). The survey contains data on income, Part D enrollment, and retail prescription drug spending for 2021. This allows for a distributional analysis. Since MEPS does not include household spending on non-retail Part B drugs, which account for a large portion of total Part B expenditures, our Part B analysis is limited to the IRA policy's impact on Part B premiums and the average cost sharing for traditional fee-for-service Medicare recipients.

We estimate that, in contrast to the IRA pricing policy's potential health costs and consistent with its relatively small federal budget savings, the reduction in drug costs to both Part D and B enrollees would be small. The revenue effects reported in Table 2 show that a 50 percent rebate results in a 16.9 percent reduction in Medicare Part D brand name revenue without

[30] United States Department of Health and Human Services (2022) finds branded drugs account for about 80 percent of retail and non-retail drug purchases.

including the price response and a 7.5 percent reduction after including it. After accounting for the share of drug expenditures on brand name drugs, benchmark Medicare premium and Part D-covered drug expenditures would decline by 13.5 percent without reference pricing and 6.0 percent with reference pricing. That would result in 2023 Part D premiums falling by $40 annually and cost sharing falling by $28 per enrollee. After accounting for the price response, annual premiums would fall by $18 and cost sharing would fall by $12 per enrollee in 2023 dollars.

Without accounting for the price response, the IRA policy would lower Part B drug expenditures by 9.4 percent and 4.5 percent after accounting for it. Nevertheless, drug purchases only account for about 10 percent of Part B expenditures so the effects on Part B premiums would be small. Without incorporating the price response, the 2023 basic Part B premium would fall by about $19 per year. The average cost sharing amount would fall by a similar amount. After accounting for the price response, premiums and mean cost sharing would each fall by $9 annually.[31]

To calculate the distributional impact of the IRA pricing policy on Part D recipients, we make several simplifying assumptions. First, we assume that the basic premium declines by the same proportion as total Part D expenditures. Second, to estimate cost sharing savings, we assume that drug expenditures by, or on behalf, of enrollees (i.e., insurance plus out-of-pocket payments) also decline in proportion to total Part D expenditures. Third, we assume all enrollees choose a basic Part D plan rather than an "enhanced alternative" plan with higher premiums and lower cost-sharing requirements. Fourth, all prescription drug expenditures in MEPS-HC among Part D enrollees are assumed to be covered under a Part D drug plan. Fifth, we assume all individuals with family incomes less than 150 percent of the federal poverty guidelines are enrolled in LIS and that their cost sharing or premium payments are covered by Medicare.[32] Finally, we assume all other IRA provisions affecting premiums or cost sharing amounts are fully implemented; this includes changes to the Low-Income Subsidy program (LIS) and new

[31] This excludes dual eligibles. We assume Part B enrollees are enrolled in traditional fee-for-service with no supplemental coverage, i.e., they face a coinsurance rate of 20 percent for all Part B expenditures.
[32] This assumption will understate the effects on premiums and cost sharing as not all LIS-eligible individuals enroll in the subsidy. In addition, LIS recipients do have small copayment requirements that are not included in our calculation.

out-of-pocket maximums.[33] We then apply Medicare Part D post-IRA benchmark deductible, coinsurance rate, and out-of-pocket limits to compute each enrollee's cost sharing payments.

Table 3 shows the distributional effects of the Part D enrollee expenditure savings after accounting for the manufacturer's price response. The savings are small for all income groups. Enrollee households in the lowest quintile of the U.S. household income distribution would see the smallest reductions. Most of these households qualify for LIS or Medicaid and thus face no premiums and minimal cost sharing requirements. Enrollee households in the middle- and highest income 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 $51 per year. For households in the upper-income quintile, it amounts to $65. These households are more likely to pay large premiums due to the Income-Related Monthly Adjustment Amount (IRMAA). In addition, higher-income households are disproportionately married and thus are more likely to have two Part D enrollees.

The Part D savings, expressed as a percentage of income, are similarly very small for all income groups. The savings approach 0.1 percent of household income for enrollee households in the middle-income quintile and are smaller for the highest and lowest income quintiles. These small savings to enrollees 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.

Table 3. Effects on Part D recipient households

	Percent change			Total savings
	Premium	Cost-sharing	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.

5 Innovation Effects

Economists have long stressed the negative consequences of government-administered prices, either in the form of strict price controls, reference pricing, or mandatory price

[33] Specifically, we assume that the 2025 cost sharing rules were in place in 2021, with the thresholds deflated by the CPI-U (using the Congressional Budget Office's economic projections to estimate the change in prices from 2021 to 2025).

negotiations on drug development. Such price restrictions, by lowering the return on investment, lead to less research and development. Eventually, this leads to fewer drug discoveries, new therapies, and less availability of valuable medicines. Ultimately, the result is poorer health outcomes and higher non-drug health care costs. Thus, while price controls may reduce the cost to patients and the government in the short run, they come at a long-run cost to society. As research on the European experience has shown, the more restrictive the price regulation, the higher the long-run cost.[34]

A long line of empirical research has been used to estimate the role of pharmaceutical industry R&D expenditures on innovation. In this research, changes in revenue—a proxy for a drug's profitability—drive current spending on research and development and, in turn, innovation.[35] Recently, Philipson and Durie (2021) and Philipson, Ling, and Chang (2023) apply this methodology to the IRA's various drug pricing policy changes including the prescription drug price negotiation program. They found that the policy changes, like European price regulations, will reduce manufacturer R&D expenditures, leading to fewer new drugs and significant societal costs.

Following the approach taken by earlier analyses, we assume that changes in manufacturers' revenues are the driver behind drug innovation. The change in manufacturer revenue can be calculated by multiplying the revenue change estimated in equation 11 by the share of total revenue that is affected by the regulation. Based on National Health Expenditure (NHE) data for 2023, revenues from Medicare Part D sales account for 22 percent of total US branded drug sales.[36] For Part B, affected revenues are those from Part B drug sales plus commercial sales in the reference period. Using our synthetic market share estimates, we estimate that these revenues account for 29 percent of the US branded drug sales. Table 4 shows the results of applying these shares. A fully phased-in IRA would reduce US branded drug

[34] See for example surveys by Hassett (2004) and Kessler (2004). Also see the seminal work of Jensen (1987) and studies of European price controls and their implications for the U.S by Brouwer, Silverstein, and Wolff (2004), Danzon (1997), Danzon and Furukawa (2003), Danzon and Ketcham (2003), Kyle (2003), Brouwers, Silverstein, Brower, and Wolff (2004), Danzon, Wang and Wang (2005), Santerre, and Vernon (2006), Giacotto, Santerre, and Vernon (2005), and Golec and Vernon (2010).
[35] See Acemoglu and Linn (2004) and Blume-Kohout and Sood (2013).
[36] NHE data only include retail sources for brand name and generic drugs. We impute a non-retail share using estimates from Roehrig and Turner (2022). MedPac (2023) reports that drug purchases accounted for 10 percent of total Part B expenditures. The Medicare share includes cost sharing and premiums by enrollees. For Part B, we assume cost sharing is 20 percent of estimated drug expenditures, For Part D, we use cost sharing estimates by CMS (United States Department of Health and Human Services 2023).

revenues by 2.1 percent after accounting for the price response and 4.6 percent before accounting for it. In dollar terms, the reduction in 2023 would have been from $11 billion to $24 billion.

Table 4. Change in US brand name drug revenue

	With Price Response	Without Price Response
Percent change	-2.1%	-4.6%
2023 dollars (dillions)	-$10.9	-$24.1

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

We apply these estimated revenue reductions to calculate the social cost of the foregone drugs using two different methodologies. One is by Mulligan (2022), the other follows the work of Philipson and Durie (2021) and Philipson, Ling, and Chang (2023).

The method developed by Mulligan estimates deadweight cost from redistributing new drug surpluses from manufacturers to consumers. The deadweight cost is equal to $(1/s - 1)r$, where r is the share of manufacturers' revenue spent on R&D and s is the share of social surplus of a new drug captured by manufacturers. Consistent with previous estimates, Mulligan assumes manufacturers spend 15 percent of their revenue on R&D. Mulligan estimates that firms capture 26.6 percent of total surplus. The deadweight loss is a net cost in that it counts the savings from withdrawing resources from drug research and development. It includes the value of reduced life years and any other surplus that consumers would have obtained from the drugs that would have been brought to markets for various therapies.

The Philipson and Durie (2021) and Philipson, Ling, and Chang (2023) approach first estimates the number of life years lost by applying Lichtenberg's (2002) estimate of the R&D cost of saving a life year to their estimate reduction in R&D spending due to the price regulation. They assign a value to these years using a range of value of statistical life years.[37] For comparability to Mulligan's approach, we use our estimated R&D reduction as the starting point,

[37] The Mulligan approach assumes an elasticity of R&D with respect to revenues of 1. Philipson and Durie (2021) and Philipson, Ling, and Chang (2023) use a larger elasticity of 1.54 and, implicitly, a lesser manufacturer share of social surplus. Our update of Lichtenberg's estimate is $2,278 compared to their $2,000. The upper and lower bounds for the value of statistical life year used in Philipson, Ling, and Chang (2023) are $100,000 and $490,000. To account for the lagged effects of new drugs on lives saved, we have discounted the value of life years lost to the present year. The choices of the key variables used to discount future flows is somewhat arbitrary due to the large degree of heterogeneity among drugs. We have opted for simplicity in our calculations. We have assumed a two-period world in which R&D costs are incurred in a present period and the drug's benefits are spread over a 24-year future period. The value of years of life lost is discounted to the present period by the midpoint of the future period, 12 years. We use a discount rate of 3 percent.

update Lichtenberg's estimate to 2023, and apply the midpoint of the Philipson and Durie (2021) range of per year values. The results are shown along with Mulligan's in Table 7.

Table 5 shows the estimates of annual net costs to society due to the loss of innovation with and without accounting for the manufacturers' price response. The difference between the estimates provided by the two approaches is substantial, from $5 billion to $196 billion with the price response. The large differences reflect, to some degree, the considerable uncertainty that surrounds the value of the particular medicines and drug therapies that will not become available due to the loss of innovation. The manufacturers' price response reduces these costs by slightly more than one-half. But these estimates bolster the conclusion reached by Philipson, Ling, and Chang (2023) that the IRA's cost to society are substantial and likely far outweigh any benefits from the policy.

Table 5. The net opportunity cost of reduced drug innovation, by manufacturers' share of social surplus of new drugs (billions)

Method	With Price Response	Without Price Response
Philipson and Durie/Philipson, Ling, and Chang Method	-$196.3	$433.4
Mulligan (2022)	-$4.5	$10.0

Notes: We assume R&D expenditures as a share of manufacturer's revenue are 15 percent.

The calculations provide a unique perspective on the pharmaceutical company pricing responses. From the perspective of a governmental agency seeking to reduce Medicare expenditures and premium payments, the pricing response by pharmaceutical companies is viewed negatively because it partially offsets the anticipated reduction in Medicare savings and premiums. The price increases may even cause the government to impose a second round of larger rebates, as it has in the Medicaid program. From an innovation perspective, however, the pharmaceutical companies' price responses have the desirable effect of increasing the return on developing new drugs. From this perspective, further increases in rebates would worsen the adverse innovation impact of the policy.

Reduced innovation will only be partially reflected in metrics such as the number of molecules or expenditures designated as "research and development." For example, once a negotiated price is imposed on a particular molecule, that price applies to the molecule's use in the treatment of all diseases. The provision effectively reduces the length of time additional

indications for an existing drug remain free from price regulation. A new indication for a previously approved drug that has been on the market for six years may be subject to price regulations within three years. With fewer years to recoup investments to expand the drug's usage, there will be fewer expansions. Examples of such responses have already been cited.[38]

The harmful consequences for research and development of cancer drugs are likely to be especially severe. Typically, in the development of cancer drugs, pharmaceutical companies seek initial approval for a drug's use in treating one particular type of cancer. Subsequent clinical research and knowledge about a drug's risks and benefits gained from its real-world use often leads to its treatment in other cancer types and/or its use in combination with other drugs to provide a more efficacious treatment regime.

In some instances, pharmaceutical companies will respond by canceling research and development programs focused on additional indications and combination therapies. In other instances, firms may respond by altering their research and drug development programs to develop more than one indication or fixed dose combination simultaneously. This will inevitably result in launch delays. It is entirely likely that innovation losses from the policy's impact on additional indications and combination therapies are as large or larger than its impact on new molecules. But measuring the magnitude of these effects is beyond the paper's scope.

6 Effect of Shortening the Reference Period

The Biden Administration proposed to shorten the number of years that a drug has been on the market before its price is subject to negotiations. The Trump Administration has not taken a position either on the current policy or the Biden Administration's proposal. Any shortening of the reference period will necessarily increase the regulated period market share and therefore the price response. This section quantifies the impact of such a policy on the price response on Medicare drug expenditures and Medicare enrollee savings.

The Biden proposal did not specify how much the reference period would be shortened. We consider two alternatives: shortening the reference period by 2 or 4 years from the current law's 9 years for small molecules and 13 years for biologics. We apply these policy

[38] For example, see Philipson, Ling, and Chang (2023).

specifications to our hypothetical lifecycle Part B and Part D revenue paths shown in Figures 8 and 10 and assume a rebate of 50 percent.

Table 6 reports the results. Shortening the reference period would increase the regulated period market share for both Part B and Part D drugs significantly. Reducing the reference period by 2 years would increase the regulated period market share for Part D drugs by 47 percent. Reducing the reference period by 4 years would double the share. The proportionate increases in regulated period market shares for Part B drugs would be larger. As a result, the price responses would be substantial. The price increase for Part D drugs would nearly double with a two-year reduction in the reference period and would nearly triple with a four-year reduction. The price increases for Part B drugs, though they would remain small in absolute terms, would be similarly large in proportionate terms. In contrast, reducing the reference period by two or four years would reduce Medicare expenditures by relatively small amounts.

Table 6. Effects of shortening reference periods on Part B & D drugs

Part D Drugs			
	Baseline	Two-Year Reduction	Four-Year Reduction
Market Share	33.8%	49.7%	65.1%
Price Response	11.3%	19.8%	31.8%
Part D Expenditure Effect	-7.5%	-10.0%	-11.1%
Manufacturer Revenue Effect	-1.6%	-2.2%	-2.4%
Part B Drugs			
	Baseline	Two-Year Reduction	Four-Year Reduction
Market Share	6.3%	11.4%	19.1%
Price Response	1.7%	3.1%	5.6%
Part D Expenditure Effect	-4.5%	-6.9%	-9.4%
Manufacturer Revenue Effect	-0.5%	-0.8%	-1.3%

Notes: Market share calculations assume 10 percent discount rate. Manufacturer revenue effects are weighted by the share of brand name drugs affected by regulation.

The small additional savings in Medicare expenditures would result in similarly small reductions in Part D premium and copayments and Part B premiums. Reducing the reference period by four years would raise annual Part D savings for middle-income enrollee households by only 0.04 percent of household income or $25 in 2023. Similarly, annual Part B premiums would fall by only $10.

7 Conclusions

This paper develops a simple model of the direction and magnitude of drug-price effects of the IRA's drug price negotiation policy. The result 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. The predicted price response is substantial. Part D prices are estimated to increase by an average of 11 percent and Part B prices by an average of 2 percent during the time before they or any therapeutic competitor drug is subject to price regulation. These price responses offset just over half of the manufacturer revenue loss from the price regulation. Correspondingly, Medicare Part D budget savings will be reduced by over half. The effects on expected Part B budget savings are slightly smaller since Part B drug prices and commercial market prices are legislatively tied together.

The reference price response shifts some of the regulatory distortions away from long-term harm to innovation from price and utilization distortions over time. But the innovation harm remains substantial. In our long-run analysis, when virtually all Medicare drug prices will be subject to regulation, for each dollar of federal budget savings, up to $24.60 of patient welfare is lost from poorer health outcomes due to the decline in innovation.

In contrast, the savings to Medicare enrollees are negligible. Dual eligibles receive no financial benefit. The same is true for the poorest 25 percent of enrollees who participate in the Part D Low-Income Subsidy program. Part D basic plan enrollees with the median senior household income are estimated to save $51 annually from lower premiums and copayments. Lower Part B premiums are estimated to save enrollees paying the basic premium by about $9 annually. When combined, these savings are 0.1 percent of the median household income of seniors enrolled in Medicare.

Our analysis has several limitations. Our estimates of the price response for Part D drugs are based upon gross, as opposed to net, Part D expenditures. If privately negotiated rebates rise over a drug's lifecycle, our estimates will overstate regulated market shares and, therefore, the magnitude of manufacturers' price increases. Our theory applies to drugs that have a monopoly and those that have therapeutic competitors that are yet to be subject to price regulation. Price increases may be more limited for drugs facing competition from therapeutic alternatives that are

already subject to price regulation. As a result of these limitations, our estimated price increases may overstate their true magnitude and may understate the true harm to innovation.[39]

Our analysis does not account for other effects of the IRA drug price negotiation policy that are likely to significantly affect drug prices and innovation. For example, the IRA imposes a larger financial penalty on follow-on drugs than originator drugs and on new indications for previously approved drugs. These higher penalties discourage innovation and competition, leading to fewer drugs and potentially higher prices.[40] The regulated price may also be linked to other factors besides the reference price, such as R&D and production and distribution costs. To this extent, the impact on reference prices may be reduced, but it would be accompanied by reduced manufacturer incentives to control costs.[41]

Manufacturers are likely to respond to the IRA in ways other than by raising prices during the reference period. Manufacturers may, for example, bundle regulated products with unregulated products 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. During the IRA phase-in period, manufacturers may seek to avoid or delay selection of their drugs for price regulation by lowering gross Medicare expenditures on these drugs. Our theoretical framework 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.

Finally, our analysis does not incorporate the impact of other IRA provisions on drug prices and innovation, such as the inflation rebates and changes in benefit design, in particular, the distribution of catastrophic drug expenses among manufacturers, payors, and Medicare enrollees.

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[39] Similarly, the IRA requirement that Medicare plans include regulated drugs on its formulary limits competition is likely to exacerbate this effect.

[40] For example, manufacturers may forgo drug trials that would show effectiveness for new indications, due to the additional sales that would result from a successful trial (see WSJ Editorial Board, November 2, 2023).

[41] See Joskow and Rose (1989) for a general treatment of the incentive effects. In our model, the cost variable can be represented as ρ, with determinants of ρ also entering the profit function. Incorporating any of these pricing responses reduces, or even reverses, the likely impact of the IRA on innovation and on short-term benefits to Medicare enrollees.

Appendix A. The impact of allowing different price elasticities of demand

The quantities sold in the reference and regulated markets are $D(p_f,P_f;\varepsilon,\eta)$ and $TD(p_r,P_r;\theta\varepsilon,\theta\eta)$, respectively. The parameter $\theta > 0$ allows for the two markets to have different price elasticities. The unregulated equilibrium with the demand system $TD(p_r,P_r;\theta\varepsilon,\theta\eta)$ is $\theta\varepsilon/(1+\theta\varepsilon) > 1$.

Up to the scale factor T, the profit in a market is $(p-1)D(p,P;\varepsilon,\eta)$, evaluated at the corresponding prices and demand parameters. Substituting this profit function, the regulation formula (2), and $\rho = 0$ into the equilibrium condition (5) results in a single equation that can be solved for the equilibrium reference-market price:

$$p_f = \frac{\varepsilon}{1+\varepsilon}\frac{1+\theta bT}{1+\frac{1+\theta\varepsilon}{1+\varepsilon}b^2T} \tag{10}$$

The first ratio is the price that would be set by a manufacturer with $T = 0$. For $T > 0$, the second ratio exceeds one as long as the regulatory parameter b does not push the regulated price below marginal cost, which is one. The reference price can increase with T even if the regulated market were more price elastic ($\theta > 1$).

Holding constant the firm level demand elasticity ε, the market-level demand elasticity η is irrelevant for prices in the reference market, both in the baseline and under regulation. That is, equation (7) applies just as well to the monopoly case as to oligopoly.

The degree of competition may differ between the reference and regulated periods. A late entrant may, during his reference period, find his competitors already subject to price regulation and thereby pricing lower than we have modeled. Meanwhile, the early entrant has less competition during his reference period and thereby setting p_f higher than in our model.

Let the baseline be the values of p_f and p_r that maximize their corresponding profit functions. The relative effect of the regulation (2)-(3) on the two prices is:

$$\frac{\Delta p_f}{-\Delta p_r} = bT\frac{1+\theta\varepsilon}{1+\varepsilon} \tag{11}$$

The ratio on the RHS reflects differences in price sensitivity between the two markets, if any. It is less than one if and only if the regulated market is less price sensitive, which is a force encouraging manufacturers to tolerate the price ceiling. The reference price is increased more when the regulated price is sensitive to the reference price or the regulated market is relatively large.

Appendix B. Additional margins of manufacturer response

Manufacturers are likely to respond to the IRA in ways other than increased reference prices. Manufacturers may, for example, bundle regulated products with unregulated products and use tie-in sales to mitigate the impact of the price regulation during the regulation period. In this appendix, we model possibilities of this type by letting the manufacturing influence ρ. At some addition cost $p_x c(\rho)$, the manufacturer can charge higher prices in the regulated market without necessarily changing the price in the reference market. $p_x > 0$ denotes the price of those actions, which we treat as a parameter to see how manufacturers respond when these alternative choices are more effective. $c()$ is nonnegative, increasing and strictly convex.

The manufacturer choice variables are p_f and ρ, subject to the regulatory constraint (2). The manufacturer's objective now includes the cost of influencing ρ:

$$\pi_f(p_f, P_f) + T[\pi_r(p_r, P_r) - p_x c(\rho)] \tag{B.1}$$

The first-order condition with respect to ρ is (B.2)

$$\frac{\partial \pi_r(p_r, P_r)}{\partial p_r} = p_x c'(\rho) \tag{B.2}$$

The first order condition with respect to p_f is still equation (4). As before, we consider a stable symmetric equilibrium. Near to the unregulated outcome, the equilibrium comparative statics with respect to p_x include:

$$\frac{d\rho}{dp_x} < \frac{dp_r}{dp_x} < 0 < \frac{dp_r}{dp_x} \tag{B.3}$$

$$\frac{d}{dp_x}(p_f + Tp_r) < 0 \tag{B.4}$$

Making it easier for manufacturers to influence the price through ρ, $dp_x < 0$, increases the regulated price and reduces the reference price relative to the case when influencing ρ is more expensive. The net result is to increase prices.

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