The Impact of Price Controls on Longterm Prescription Drug Prices

Tomas J. Philipson

Deyu Zhang

Noah Fisher

Cyrus Seyrafi

The Initiative on Enabling Choice and Competition in Health Care
The University of Chicago

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Abstract

This paper analyzes the long-run impact of government price controls on prescription drug prices and finds that they may raise prices rather than lower them. While price controls lower the prices of brand medicines, they may also reduce the expected returns that attract generic and biosimilar entrants. Because generic and biosimilar competition is the primary driver of long-run price reductions following loss of exclusivity (LOE), reduced entry can erode competition, leading to higher generic and biosimilar prices. Given generics account for roughly 9 out of 10 prescriptions filled, these competitive effects can have a large influence on long-run average drug prices. The net effect of price controls therefore depends on the offsetting impacts between lower brand prices and higher generic and biosimilar prices resulting from reduced generic and biosimilar competition. We develop a quantitative framework to evaluate these competing effects to assess whether price controls on branded drugs ultimately reduce or increase long-run average prescription drug prices.

We estimate the impact of Inflation Reduction Act (IRA) price setting on average lifetime drug prices, defined as the 35-year period beginning when that price setting takes effect. We compare lifetime prices under two scenarios 35 years after price controls start: 1) one in which the government-set Maximum Fair Prices (MFPs) apply during the exclusivity period and subsequently lead to higher generic and biosimilar prices afterwards, 2) a counterfactual scenario without IRA price setting in which branded prices remain unchanged and generic or biosimilar market competition develops as it would in the marketplace. We calibrate the framework using empirical relationships between branded revenues, post-loss-of-exclusivity generic or biosimilar entry, and generic and biosimilar prices, together with Medicare spending, estimated pre-IRA privately negotiated rebates, and published MFPs for the 25 drugs selected in the first two rounds of IRA price setting.

We find that across the 25 IRA-selected drugs, MFPs reduce branded net prices by an average of 37%. This reduction is estimated to decrease generic and biosimilar entry by 37%, raising post-exclusivity generic and biosimilar prices by 45% on average. Consequently, average lifetime drug prices increase by 19%, indicating that the long-run effects of reduced generic or biosimilar competition more than offset the short-run savings from branded price controls.

Section 1: Introduction

The U.S. pharmaceutical market has historically relied on a two-part system established by the Hatch-Waxman Act of 1984. The Act provides innovators with a period of market exclusivity to recover and earn revenues on research and development investments while facilitating generic entry through abbreviated approval pathways. This market design seeks to balance dynamic incentives for innovation with long-run affordability through generic competition. As a result, generic drugs now account for roughly nine out of ten prescriptions filled in the United States and constitute the primary source of prescription drug utilization for most patients.

The Biologics Price Competition and Innovation Act (BPCIA) was enacted in 2010. Like the Hatch-Waxman Act, it established a balanced system by providing innovators with 12 years of data protection following the first licensure of innovative biologics while facilitating biosimilar entry with the establishment of an abbreviated approval pathway. While the first biosimilar was not approved until 2015, since that time, 88 biosimilars have been approved, and 67 have launched in the U.S. (Cencora, 2025). These biosimilars have generated $56.2 billion in cumulative savings since 2015 (Association for Accessible Medicines, 2025).

Recent policy reforms have begun to alter this market structure. The Inflation Reduction Act (IRA) authorizes the government to set maximum fair prices (MFPs) for selected high-spending drugs in Medicare, while other proposals, such as international reference pricing, similarly seek to lower branded drug prices through government intervention. Existing analyses have primarily focused on the effects of such policies on pharmaceutical innovation by reducing expected returns to research and development. However, branded revenues also affect post-exclusivity competition because prospective generic and biosimilar manufacturers make market entry decisions based on expected profitability. Industry organizations such as the Association for Accessible Medicines (AAM) have argued that government price setting may discourage or delay generic and biosimilar entry by reducing the expected returns to these investments, thereby weakening one of the primary market-based mechanisms through which drug prices decline after loss of exclusivity (Association for Accessible Medicines, 2025). Similarly, Brill and Robinson (2025) argue that government price setting may substitute for, rather than complement, competitive entry by introducing uncertainty into generic and biosimilar development decisions. Additionally, Jeon et al. (2026) found that when accounting for generic and biosimilar entry, IRA price setting yields smaller savings than the government projected, with competition alone saving $2.4B — $100M more than price setting alone.

Economic evidence suggests that these concerns may be particularly relevant for high-spending drugs. Using data from 1995 to 2019, Whittington (2026), drawing on evidence from Grabowski et al. (2021), estimates that every additional $140 million in branded sales in the year prior to generic entry is associated with approximately one additional generic entrant. Larger branded markets therefore attract more competitors and generate stronger post-exclusivity price competition. The IRA, however, specifically targets the highest-spending branded drugs for government price setting. Yet these are also the products for which generic and biosimilar competition is expected to be most intense after exclusivity expires.

This raises a fundamental question: can government price setting achieve larger reductions than the highly competitive post-exclusivity markets that would otherwise emerge for these products? The concern may be especially important for biologics, where biosimilar development is more costly and therefore favors even larger brand markets to reduce investment uncertainty. According to IQVIA, although approximately 300 biologics have been approved in the United States and roughly 150 have lost exclusivity, only about 35 biosimilars have entered the market or remain in development. Among biologics that had already lost exclusivity by the end of 2024, most still faced no biosimilar competition. Moreover, IQVIA estimates that approximately 90% of biologics expected to lose exclusivity during the next decade currently have no biosimilars in development, suggesting a substantial "biosimilar void" in future competition (IQVIA, 2025; Jeremias, 2025). These findings suggest that biosimilar competition is far from automatic and may be particularly sensitive to changes in expected market returns.

This paper analyzes the impact of price controls on lifetime prescription drug prices through their effects on generic and biosimilar competition. We develop a quantitative framework linking branded revenues to post-loss-of-exclusivity generic or biosimilar entry and post-loss-of-exclusivity entry to generic or biosimilar prices. Using this framework, we estimate the average lifetime price of a medicine over a 35-year horizon beginning when the IRA's maximum fair prices (MFPs) take effect. We then compare lifetime prices under two scenarios: 1) one in which the MFPs apply during the exclusivity period and subsequently lead to higher generic and biosimilar prices afterwards, 2) a counterfactual scenario without IRA price setting in which branded prices remain unchanged and generic or biosimilar market competition develops as it would in the marketplace. The average lifetime price measure is calculated by averaging estimated prices in each year during the time before and after loss of exclusivity – assuming MFPs and generic and biosimilar prices impacted by MFPs under scenario 1 and branded or generic and biosimilar market-based prices under scenario 2. The framework is calibrated using empirical relationships between branded revenues, expected generic or biosimilar entry, and post-loss-of-exclusivity generic or biosimilar prices. For each product selected for IRA price setting, we approximate annual U.S. branded net revenue using Medicare spending adjusted for estimated pre-IRA rebates, estimate the number of expected generic or biosimilar entrants from branded revenues, and map the resulting reduction in competition into post-loss-of-exclusivity generic or biosimilar prices. The framework then combines MFPs during exclusivity with post-loss-of-exclusivity generic or biosimilar prices to estimate the change in the 35-year average lifetime price relative to a counterfactual without price setting under the IRA.

Applying the framework to the 25 drugs selected in the first two rounds of IRA price setting, we estimate that MFPs reduce pre-IRA net branded prices by an average of 37%, leading to a 37% decline in expected generic or biosimilar entry and a 45% increase in post-loss-of-exclusivity or generic and biosimilar prices. After combining MFPs during exclusivity with higher projected generic or biosimilar prices following loss of exclusivity, we estimate that the average lifetime price across the 25 selected drugs increases by 19% over the 35-year horizon. These findings suggest that the long-run effects of reduced generic and biosimilar competition more than offset the initial savings from government price controls for branded drugs.

Section 2: The Relationship Between Market Size and Generic and Biosimilar Entry

This section develops a framework for evaluating how branded price controls affect average lifetime drug prices. The central mechanism is that price controls generate immediate savings during the remaining exclusivity period but also reduce expected branded revenues prior to loss of exclusivity, thereby discouraging generic or biosimilar entry and increasing post-exclusivity prices. The overall lifetime effect therefore depends on the offsetting effects of these opposing forces.

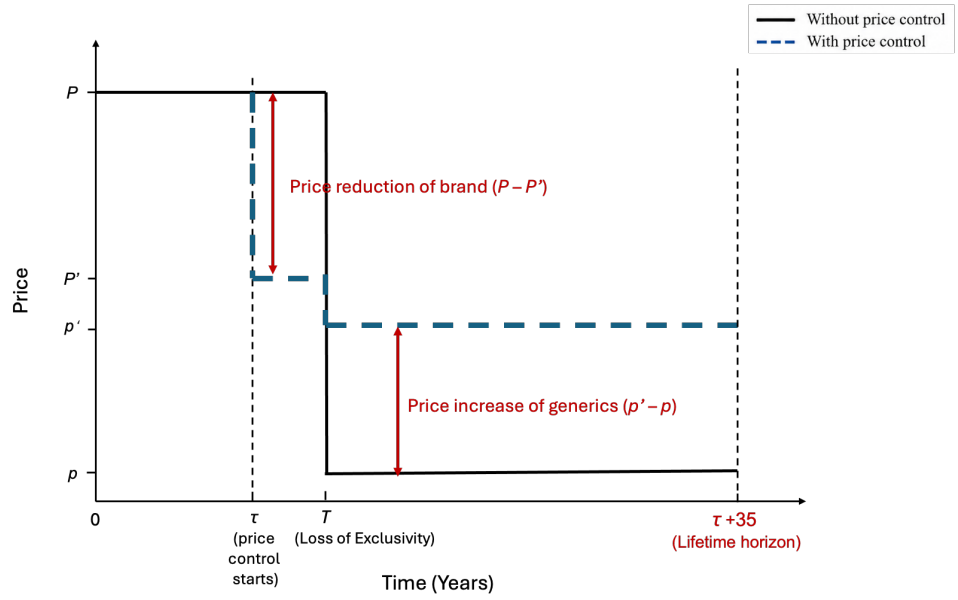
The average price of prescription drugs in the overall market is given by

$$A = w \cdot p + (1 - w) \cdot P,$$

where P is the average brand price, p is the average generic price, and w is the generic volume share, and thus 1-w is the branded volume share. This directly implies that in the overall market, when the market share of generics is much larger than for brands, a given price reduction of brands is offset by a much smaller price increase for generics. For example, if the generic market share is 90%, then a $100 reduction in brand prices is offset by an $11 increase in generic prices.

Since the overall market comprises many different drugs with varying exclusivity periods, we analyze pricing for molecules whose exclusivity period is cut short by government price controls under the IRA. This is illustrated in Figure 1 below, where the x-axis represents time since the imposition of a price control, such as 9 or 13 years after the approval of drugs or biologics under the IRA. Without price controls, the solid lines represent the price moving from a larger branded price P to a smaller generic price p upon loss of exclusivity. With the price controls, the dashed line represents the branded price being controlled at a lower level than before, denoted P', after which the generic price may rise to a higher level than before, denoted p'.

Figure 1. Brand and Generic Price Paths for a Molecule with and without a Price Control.



Average lifetime prices are calculated over a common 35-year horizon beginning when Medicare price setting takes effect under the IRA. Let $\boldsymbol{\tau}$ denote the year in which the MFP becomes effective and $\boldsymbol{T}$ denote the year of loss of exclusivity. The period from price setting to loss of exclusivity therefore lasts $\boldsymbol{T} - \boldsymbol{\tau}$ years, while the remaining post-exclusivity period lasts $\boldsymbol{\tau} + 35 - \boldsymbol{T}$ years. Average lifetime prices without and with Medicare price setting are respectively given by

$$\bar{P} = \frac{(T-\tau)P+(\tau+35-T)p}{35},$$

and

$$\bar{P'} = \frac{(T-\tau)P\prime+(\tau+35-T)p\prime}{35}.$$

The effect of Medicare price setting on the average lifetime price is measured by

$$\frac{\bar{P}\prime}{\bar{P}} - 1.$$

The first component captures the remaining branded-price period following Medicare price setting, while the second captures the post-exclusivity period during which reduced generic or biosimilar competition may increase prices. Average lifetime prices therefore reflect the tradeoff between immediate branded-price reductions and subsequent increases in post-exclusivity prices.

Previous literature has established two robust relationships regarding how generic markets behave after the loss of exclusivity of brands. The first is a negative relationship between the average generic price and the number of generic entrants *p(N)*. The second is a positive relationship between the revenue of the brand and the number of generic entrants *N(R)*. Therefore, the total effect of brand revenue on generic prices *p(N(R))* is negative:

$$\frac{dp}{dR} = \frac{dp}{dN} \cdot \frac{dN}{dR} < 0.$$

Accordingly, any policy that reduces branded revenues before loss of exclusivity decreases expected generic or biosimilar entry and increases post-exclusivity prices. The following sections estimate these two empirical relationships and integrate them into the average lifetime price framework.

Under the assumption that combined brand and generic volume for a drug remains approximately constant before and after loss of exclusivity, proportional changes in branded revenues closely approximate proportional changes in branded prices because spending equals price multiplied by quantity. Prior research has documented that utilization changes relatively little following loss of exclusivity (Lakdawalla and Philipson, 2012). This stability reflects two offsetting forces. On the one hand, generic entry lowers prices and tends to increase utilization. On the other hand, loss of

exclusivity tends to decrease utilization. These opposing effects largely offset one another, allowing changes in branded revenues to serve as a close approximation for changes in branded prices within our framework.

Section 3: Empirical Relationships and Average Lifetime Price Analysis

3.1 Empirical Relationships

3.1.1 Generic Entry and Generic Price

Following loss of exclusivity, greater generic competition is consistently associated with lower generic prices. To characterize this relationship, we draw on three recent studies using different datasets: Conrad and Lutter (2019), which uses IQVIA National Sales Perspective invoice-based prices; Nguyen et al. (2022), which analyzes Medicare Part D data from 2007–2018; and the updated ASPE (2025) analysis using Medicare Part D data through 2022. Despite differences in data sources and estimation methods, all three studies report a similar monotonic relationship between the number of generic manufacturers and the generic-to-brand price ratio, with prices declining substantially as additional manufacturers enter the market.

To obtain a single benchmark relationship for subsequent analysis, we calculate the average generic-to-brand price ratio across the three studies for each level of generic competition, as reported in Table 1. We denote this baseline generic-to-brand price ratio by p, which represents the expected post-loss-of-exclusivity generic price relative to the branded price under the observed level of generic competition.

Table 1. Baseline Generic-to-Brand Price Ratios by Number of Generic Entrants

Number of Generic Entrants	Generic-to-Brand Price Ratios			
	Conrad and Lutter (2019)	Nguyen (2022)	ASPE (2025)	Average
1	0.614	0.86	0.9	0.79
2	0.465	0.82	0.87	0.72
3	0.322	0.78	0.797	0.63
4	0.212	0.74	0.75	0.57
5	0.1444	0.65	0.673	0.49
6	0.061	0.59	0.62	0.42
7	0.04	0.54	0.57	0.38
8	0.049	0.4	0.47	0.31
9	0.012	0.35	0.413	0.26
10	0.01	0.2	0.27	0.16
10+	0.01	0.2	0.27	0.16

Further, to translate changes in expected generic entry into changes in generic prices, we adopt the elasticity estimate reported by Berndt et al. (2017), who estimate the elasticity of generic price with respect to the number of manufacturers to be approximately −0.75. Accordingly,

$$\Delta \ln p = -0.75 \Delta \ln N.$$

Exponentiating both sides yields

$$\frac{p\prime}{p} = (\frac{N\prime}{N})^{-0.75},$$

or equivalently,

$$g = (\frac{N\prime}{N})^{-0.75} - 1,$$

where N and N' denote the expected numbers of generic manufacturers before and after IRA price setting, and g denotes the percentage increase in generic price resulting from fewer entrants. The post-IRA generic-to-brand price ratio is therefore

$$p' = p(1 + g).$$

This relationship enables us to convert reductions in expected generic entry into higher post-loss-of-exclusivity generic prices, which are then incorporated into the lifetime price calculations.

3.1.2 Branded Revenue and Expected Generic Entry

Following Whittington (2026), we approximate the relationship between branded revenues prior to loss of exclusivity and expected generic entry. The analysis suggests that each additional $140 million in annual branded revenue prior to loss of exclusivity supports approximately one additional generic entrant. This relationship reflects the economic incentive for generic manufacturers to enter markets with greater expected post-entry revenues.

Accordingly, the reduction in expected generic entry associated with lower branded revenues can be expressed as

$$\Delta N = \frac{\Delta R}{140},$$

where ΔR denotes the reduction in annual branded revenue (million USD); ΔN denotes the corresponding reduction in the expected number of generic entrants. For each of the 25 selected drugs, expected generic entry prior to IRA price setting is approximated as

$$N = \frac{R}{140},$$

where R is the estimated annual U.S. branded revenue before IRA price setting (million USD). Expected entry after IRA price setting is then calculated as

$$N' = N - \Delta N.$$

These estimates of expected generic entry are subsequently combined with the generic price elasticity described in Section 3.1.1 to estimate the increase in post-loss-of-exclusivity generic prices resulting from reduced competition.

3.1.3 Biosimilar Entry and Biosimilar Price

Evidence on the relationship between biosimilar entry and biosimilar prices is more limited than the corresponding evidence for generic drugs. We therefore calibrate this relationship using observed pricing in the U.S. Humira biosimilar market. Humira currently faces approximately 10 biosimilar competitors. Among biosimilars marketed using lower-list-price strategies, wholesale acquisition costs are generally approximately 80% below Humira's WAC (Fein, 2025). High-WAC versions offered alongside lower-WAC alternatives are excluded from the calibration because these products have experienced limited uptake. We therefore use a biosimilar-to-reference-product price ratio of approximately 0.20 at 10 entrants as the empirical benchmark.

To translate changes in expected biosimilar entry into changes in biosimilar prices, we specify a constant-elasticity relationship between the biosimilar-to-reference-product price ratio and the number of biosimilar entrants:

$$\frac{p}{P} = N^{-\beta},$$

where p denotes the biosimilar price, P denotes the reference biologic price, N denotes the number of biosimilar entrants, and β is the elasticity parameter. We normalize the biosimilar-to-reference-product price ratio to 1 when there is one entrant and calibrate the relationship such that the price ratio equals 0.20 when there are 10 entrants. Accordingly,

$$0.20 = 10^{-\beta}.$$

Taking natural logarithms of both sides yields

$$\ln(0.20) = -\beta \ln(10),$$

and therefore

$$\beta = -\frac{\ln(0.20)}{\ln(10)} \approx 0.70.$$

This calibration implies an elasticity of biosimilar price with respect to the number of entrants of approximately −0.70. Accordingly

$$\Delta \ln p = -0.70 \Delta lnN.$$

Exponentiating both sides yields

$$\frac{p\prime}{p} = \left(\frac{N\prime}{N}\right)^{-0.70},$$

or equivalently,

$$g = \left(\frac{N'}{N}\right)^{-0.70} - 1,$$

where N and N' denote the expected numbers of biosimilar entrants before and after IRA price setting, respectively, and g denotes the percentage increase in biosimilar prices resulting from fewer entrants. The post-IRA biosimilar-to-reference-product price ratio is therefore

$$p' = p(1 + g).$$

This relationship enables us to convert reductions in expected biosimilar entry into higher post-loss-of-exclusivity biosimilar prices, which are then incorporated into the lifetime price calculations.

3.1.4 Branded Revenue and Expected Biosimilar Entry

Empirical evidence linking branded revenues to subsequent biosimilar entry is also limited. Unlike generic markets, relatively few biologics have experienced mature biosimilar competition, limiting the availability of large-sample studies relating pre-loss-of-exclusivity revenues to biosimilar entry. We therefore calibrate this relationship using two biologics that have experienced substantial biosimilar competition: adalimumab and ustekinumab.[1] Calibrating this relationship based on these top revenue-generating biologics presumes similar market dynamics and price competition emerges for biologics with high Medicare spending levels that were selected for government price setting.

Humira generated approximately $20.6 billion in global revenue in 2021, its final full year before meaningful biosimilar competition emerged, while Stelara generated approximately $10.9 billion in global revenue in 2023, its final full year before widespread loss of exclusivity pressures. Because our framework models incentives for entry in the U.S. market, we approximate U.S. branded revenues by applying the U.S. share of prescription drug sales reported by RAND (62.4%) to these global revenues. This yields estimated U.S. annual revenues of approximately $12.9 billion for Humira and $6.8 billion for Stelara.

Humira currently has approximately 10 marketed biosimilars, while Stelara has approximately 8 marketed biosimilars. These observed markets therefore imply approximately $1.29 billion and $0.85 billion in annual U.S. branded revenue per biosimilar entrant, respectively. Averaging across the two markets yields an estimated relationship of approximately $1.07 billion in annual branded revenue for each expected biosimilar entrant. Accordingly, expected biosimilar entry is approximated as

[1] Calibrating this relationship based on these top revenue generating biologics presumes similar market dynamics and price competition emerges for biologics with high Medicare spending levels selected for government price setting.

$$N = \frac{R}{1{,}070},$$

where R denotes annual U.S. branded revenue (million USD) prior to loss of exclusivity, and N denotes the expected number of biosimilar entrants.

3.2 Mapping Relationships into the Average Lifetime Price Framework

We combine the empirical relationships described in Section 3.1 to estimate the effect of government price setting on the average lifetime prices of the 25 drugs selected in the first two rounds of the IRA. The analysis is conducted over a 35-year horizon beginning when the government-set MFPs take effect.

We estimate that the average time from FDA approval to loss of exclusivity is 13.5 years for small molecules (Grabowski et al., 2021) and 14.5 years for biologics approved after establishment of the biosimilar pathway (authors' calculation). Since MFPs become effective 9 years after FDA approval for small molecules and 13 years after approval for biologics, government-set branded prices therefore apply for 4.5 years (13.5 − 9) for small molecules and 1.5 years (14.5 − 13) for biologics before generic or biosimilar competition begins.

For each selected drug, we first approximate annual U.S. branded revenue by multiplying annual Medicare spending by one minus the estimated rebate percentage privately negotiated between manufacturers and Part D plan sponsors prior to the IRA. For small-molecule drugs, dividing the resulting annual branded revenue by $140 million yields the expected number of generic entrants prior to IRA price setting according to the relationship described in Section 3.1.2. We use this pre-IRA number of generic entrants to determine the pre-IRA generic price based on Table 1. For biologics, dividing annual branded revenue by approximately $1.07 billion yields the expected number of biosimilar entrants according to the relationship described in Section 3.1.4. The corresponding pre-IRA biosimilar price is determined using the biosimilar entry-price relationship calibrated in Section 3.1.3.

The MFP discounts published by CMS are reported relative to branded list prices, whereas manufacturer revenues are determined by net prices after accounting for privately negotiated rebates. We therefore convert the published list-price discount into the corresponding reduction from the pre-IRA market-based net price. Specifically, if P denotes the original branded list price, P’ the MFP, and r the pre-IRA rebate rate, the MFP reduction is calculated as

$$\tau = 1 - \frac{P\prime}{P(1-r)},$$

where τ denotes the percentage reduction from the pre-IRA net price to the MFP.

Assuming utilization remains constant, annual branded revenue after IRA price setting is approximated as

$$R' = (1 - \tau)R.$$

The reduction in annual branded revenue determines the reduction in expected post-loss-of-exclusivity entry. For small molecules, the decline in expected generic entry is calculated using the relationship in Section 3.1.2 and mapped into generic price changes using the elasticity presented in Section 3.1.1. For biologics, the decline in expected biosimilar entry is calculated using the relationship in Section 3.1.4 and mapped into biosimilar price changes using the separately calibrated elasticity presented in Section 3.1.3. These relationships yield the percentage increase in post-loss-of-exclusivity generic or biosimilar prices, g, and the corresponding post-IRA price ratio

$$p' = p(1 + g).$$

The average lifetime price is then calculated by combining MFPs during the pre-LOE period with generic or biosimilar prices after loss of exclusivity. In the calculation, we normalize the branded net price before IRA price control as 1.

For small molecules,

$$\bar{P} = \frac{4.5+30.5p}{35},$$

$$\bar{P}' = \frac{4.5(1-\tau)+30.5p'}{35},$$

For biologics,

$$\bar{P} = \frac{1.5+33.5p}{35},$$

$$\bar{P}' = \frac{1.5(1-\tau)+33.5p'}{35}.$$

Finally, the percentage change in the average lifetime price is calculated as

$$\frac{\bar{P}'}{\bar{P}} - 1.$$

3.3 Results of Lifetime Price Analysis

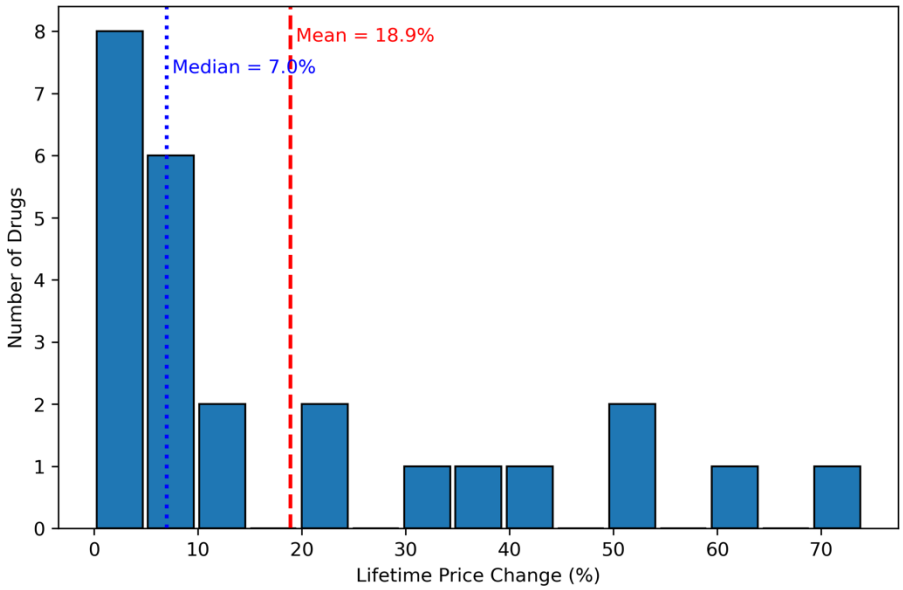
Across the 25 drugs selected in the first two rounds of Medicare price setting, the estimated average pre-IRA rebate is 40%, while the average published IRA list-price discount is 62%, corresponding to an average 37% reduction in pre-IRA net prices. This reduction is associated with a 37% decline in expected generic or biosimilar entry and a 45% increase in post-loss-of-exclusivity generic or biosimilar prices. After combining government-set MFPs during the remaining exclusivity period with higher post-exclusivity prices over the 35-year horizon, the average lifetime price increases

by 19% across the full sample. Average lifetime prices increase for all 25 selected drugs under IRA price setting relative to the market-based counterfactual.[2]

The estimated effects differ somewhat between small molecules and biologics. For small molecules, the average pre-IRA rebate is 39% and the average IRA list-price discount is 61%, corresponding to a 37% reduction in pre-IRA net prices. This is associated with a 37% reduction in expected generic entry, a 46% increase in generic prices, and a 16% increase in average lifetime prices. For biologics, the average pre-IRA rebate is 49% and the average IRA list-price discount is 70%, corresponding to a 39% reduction in pre-IRA net prices. This reduction is associated with a 39% decline in expected biosimilar entry, a 42% increase in biosimilar prices, and a 38% increase in average lifetime prices.

Figure 2 illustrates the distribution of estimated lifetime price changes. Estimated effects vary substantially across products, but all indicate an increase in average lifetime prices. The distribution is right-skewed, with a median lifetime price increase of 7.0% and a mean increase of 18.9%, indicating that a relatively small number of drugs experience particularly large post-exclusivity price increases. Nevertheless, even excluding these extreme observations, all selected drugs continue to exhibit higher average lifetime prices under the IRA than under market-based competition.

Figure 2. Distribution of Average Lifetime Price Effects across IRA Negotiated Drugs



Overall, these findings suggest that once the effects of MFPs on future generic and/or biosimilar competition are taken into account, IRA price setting frequently raises rather than lowers average lifetime drug prices. Although MFPs reduce branded prices during the pre-LOE period, these

[2] Individual drug-level estimates are available from the authors upon request.

savings are fully offset by higher post-loss-of-exclusivity generic and biosimilar prices resulting from reduced generic and biosimilar entry. Consequently, for all drugs in our sample, the estimated average lifetime price under the IRA exceeds that under market competition.

Section 4: Conclusion

This paper examines how price setting for brand drugs under the IRA affects lifetime prescription drug prices by accounting for their effects on post-loss-of-exclusivity generic and biosimilar competition. While government-set prices may lower branded prices during the exclusivity period, they also reduce branded revenues that encourage generic and biosimilar entry. Reduced entry subsequently weakens post-loss-of-exclusivity competition and raises generic or biosimilar prices, partially or fully offsetting the initial savings. To evaluate this tradeoff, we develop a quantitative framework linking branded revenues to post-loss-of-exclusivity generic and biosimilar entry, post-loss-of-exclusivity entry to generic and biosimilar prices, and the average lifetime price of medicines over a 35-year horizon beginning when government-set prices take effect. The framework estimates average lifetime price by accounting for either market-based or government-set prices during the remaining period of market exclusivity along with generic or biosimilar prices after loss of exclusivity to quantify the overall change in average lifetime prices resulting from government price setting under the IRA.

Applying the framework to the 25 drugs selected in the first two rounds of IRA price setting, we estimate that MFPs reduce pre-IRA net branded prices by an average of 37%, leading to a 37% decline in expected generic or biosimilar entry and a 45% increase in post-loss-of-exclusivity generic and biosimilar prices. After accounting for both MFPs during exclusivity and higher post-loss-of-exclusivity generic and biosimilar prices afterward, the average lifetime price across the 25 negotiated drugs increases by 19% over the 35-year horizon. These findings suggest that the increase in post-loss-of-exclusivity generic and biosimilar prices more than offsets the savings from government price setting.

The quantitative results reported in this paper should not be interpreted as universal constants. Rather, they reflect the empirical relationships linking branded revenues, post-exclusivity entry, and generic or biosimilar prices used in our calibration. As additional evidence on these relationships becomes available across therapeutic areas and market settings, the framework can be readily recalibrated while preserving the underlying economic mechanism.

More broadly, our findings contribute to an ongoing policy debate regarding the long-run effects of government price setting on pharmaceutical competition. Industry organizations such as the Association for Accessible Medicines have argued that Medicare price setting may discourage or delay generic and biosimilar entry by reducing the expected returns to post-exclusivity competition (Association for Accessible Medicines, 2025). Similarly, Brill and Robinson (2025) argue that government price setting may substitute for, rather than complement, market-based competition by reducing incentives for generic and biosimilar development. The framework developed in this paper provides a quantitative approach for evaluating these concerns. More fundamentally, it also helps explain why reductions in branded revenues can affect long-run generic prices despite the eventual expiration of patent protection.

One possible debate is that generic and biosimilar markets may ultimately converge to marginal-cost pricing regardless of pre-LOE branded revenues. This argument may be valid for mature generic markets with a sufficiently large number of competitors. Consistent with previous evidence, generic prices continue to decline as additional manufacturers enter the market and, in markets with approximately ten or more competitors, prices typically fall by 70–80% relative to the pre-entry branded price within several years after generic entry (Office of the Assistant Secretary for Planning and Evaluation, 2025). However, reaching this competitive outcome is not automatic. Reiffen and Ward (2005) find that generic drug prices fall with the number of competitors but remain above long-run marginal cost until approximately eight or more competitors are present. More importantly, generic and biosimilar entry requires substantial sunk investments in product development, manufacturing capacity, regulatory approval, and frequently patent litigation before firms know when they will obtain regulatory approval or how many competing manufacturers will ultimately enter the market (Reiffen & Ward, 2005). Consequently, manufacturers make forward-looking entry decisions based on expected profitability, which depends on anticipated revenues, development and manufacturing costs, scientific uncertainty regarding successful product development, and legal barriers (Scott Morton, 1999, 2000; Vokinger et al., 2017). Equilibrium entry is therefore determined by whether expected post-entry profits justify these sunk investments rather than by an automatic tendency toward marginal-cost pricing, implying that pre-LOE branded revenues can influence the intensity of post-LOE competition.

This perspective also explains why reductions in branded revenues can influence long-run generic and biosimilar prices. Generic and biosimilar competition is inherently dynamic: each additional entrant not only lowers market prices for consumers but also reduces the expected profitability of subsequent entrants. As competition intensifies, declining margins make further entry progressively less attractive, causing the market to converge to an equilibrium number of competitors rather than unlimited entry. Reiffen and Ward (2005) show that more firms enter, and enter more quickly, in markets with greater expected rents, and that the number of firms, revenues, and rents are strongly affected by expected market size. Policies that reduce branded revenues before loss of exclusivity therefore shift this equilibrium by lowering the expected returns available to prospective entrants. Under the IRA, government-set prices apply before generic or biosimilar competition would typically emerge, reducing the revenue base upon which entry decisions are formed. As a result, fewer manufacturers may find entry economically worthwhile, leading to less post-LOE competition and higher long-run generic and biosimilar prices. Our framework formalizes this relationship by linking pre-LOE branded revenues to equilibrium generic and biosimilar entry and, ultimately, to post-LOE prices over the product life cycle. These findings suggest that evaluations of pharmaceutical price regulation should account not only for the immediate effects of lower branded prices but also for their consequences for equilibrium competition and long-run drug affordability.

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