



# Long-Term Effects of Medicare Price Negotiations on Drug Competition

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# Executive Summary

This paper examines the potential long-term impact that the federal government's role as a price setter could have on drug competition. The Inflation Reduction Act (IRA) of 2022 granted the Department of Health and Human Services the authority to select and negotiate certain drug prices in the Medicare program. Negotiated prices for the first 10 drugs will go into effect January 1, 2026. In 2027 and 2028, 15 more drugs each year will be subject to negotiated prices, with 20 more drugs added annually thereafter.

Despite claims to the contrary, the government's involvement will likely be a substitute for, instead of a complement to, existing market-based methods of price competition—namely, the entry of generic drugs and biosimilars.

Generic drug manufacturers have an incentive, established by law, to challenge brand drug patents. But if a brand drug's price could be set by the government prior to generic entry, generic drugmakers' incentives to undertake the risk and expense associated with these challenges will be reduced. Biosimilars have a different regulatory pathway, but the risk and cost associated with bringing biosimilars to market is even greater than for small-molecule drugs given the complexity of developing these products, and increased uncertainty will also discourage biosimilar manufacturers.

Price setting by the government will result in delayed competition and fewer competitors. This will result in higher overall average prices and spending, which will mitigate and potentially negate the government's negotiated savings. To illustrate the magnitude of this impact, we develop a framework for estimating lost savings that could result from fewer generic and biosimilar entrants.

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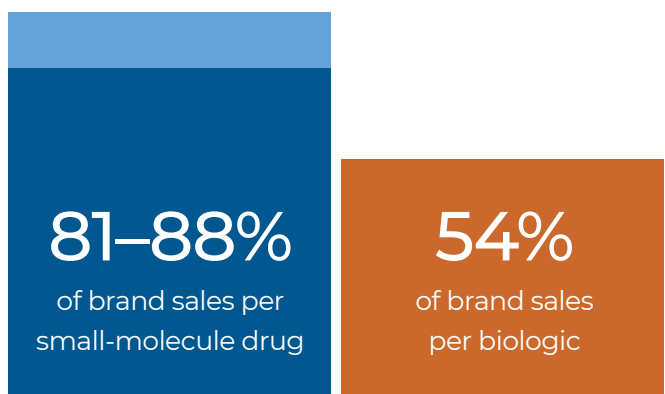
**Government price negotiations risk creating a less competitive pharmaceutical marketplace, with a quantifiable negative impact on the US healthcare system and higher costs for patients.**

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We estimate unrealized annual savings of 81–88 percent of brand sales per affected small-molecule drug and 54 percent of brand sales per affected biologic. These lost savings could be expected to persist for years and could total billions of dollars, depending on the number of drugs that are ultimately affected.

As our analysis demonstrates, government price negotiations risk creating a less competitive pharmaceutical marketplace, with a quantifiable negative impact on the US healthcare system and higher costs for patients.

## Annual Lost Savings



# Introduction

Beginning in 2026, 10 prescription drugs in Medicare will for the first time be sold at prices that manufacturers were required to negotiate with the federal government. Granted authority by the Inflation Reduction Act (IRA) of 2022 to negotiate certain drug prices in the Medicare program, the Department of Health and Human Services will negotiate additional drug prices in successive years.<sup>1</sup>

Health policy experts have already pointed to various unintended negative consequences of this new policy.<sup>2</sup> In this paper, we examine the long-term impact that the government's entry into the market as a price setter could have on drug competition and drug spending.

Despite claims to the contrary, the government's involvement will likely be a substitute for, instead of a complement to, existing market-based methods of price competition—namely, the entry

of generics and biosimilars. Price setting by the government will introduce uncertainty into generic and biosimilar manufacturers' decision-making, resulting in delayed competition and fewer competitors. This in turn will result in higher overall average prices and spending, which will mitigate and potentially negate the government's negotiated savings.

To understand the magnitude of the chilling effect of the government's price negotiation policy on generic and biosimilar entry, we develop a framework for estimating the associated lost savings.

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## How Market Uncertainty Reduces Drug Competition

As generic drug and biosimilar manufacturers make decisions about which markets to pursue, the chance that the drugs they may select will become subject to price negotiation will influence their decision. In addition to the other uncertainties a generic or biosimilar manufacturer must consider, there is now the possibility that a brand drug's revenue will be reduced by the government before a generic or biosimilar can enter the market, thus lowering the expected sales a competitor could expect.

While there are important exceptions,<sup>3</sup> robust and effective market-based means for driving drug competition exist. For traditional small-molecule drugs, generics have been meaningfully lowering drug prices for four decades. In a highly competitive market, generic drugs can offer prices up to 97 percent lower than their brand counterparts (*Conrad and Lutter, 2019*).

<sup>1</sup> *Negotiated prices for the first 10 drugs will go into effect January 1, 2026. In 2027 and 2028, 15 more drugs each year will be subject to negotiated prices, with 20 more drugs added in 2029 and each subsequent year.*

<sup>2</sup> *See, for example, Axelsen (2024) and Cline et al. (2024).*

<sup>3</sup> *For example, patent thickets and other anticompetitive strategies can impede or delay drug competition in some instances. See Brill and Robinson (2023) for a fuller discussion.*

The law that created the modern generic drug industry (known as Hatch-Waxman) established an incentive for generic manufacturers to challenge brand drug patents through a process known as a paragraph IV challenge. These challenges are costly and risky for generic firms to pursue, but the company with the first successful paragraph IV challenge is awarded 180 days of market exclusivity before other generics are permitted to enter. If a brand drug could become subject to price negotiation, generic firms may not be willing to undertake this risk and expense as the reward intended by the 180-day exclusivity period will be diminished.

Competition for biologic drugs is more recent, with the first US biosimilar receiving Food and Drug Administration (FDA) approval 10 years ago. But the biosimilar market, despite some remaining barriers (see *Brill and Robinson, 2025*), is pushing prices down by 24–76 percent, depending on the therapeutic area (*Samsung Bioepis, 2024*). The risk and cost associated with bringing biosimilars to market is even

greater than for small-molecule drugs given the complexity of developing these products.

While the IRA included provisions that attempt to mitigate the risk that the government's new authority will supplant existing market-based mechanisms, companies that invest in generic and biosimilar development will likely still be discouraged from doing so because of the threat of price negotiation.<sup>4</sup> Specifically, the incentive to undertake costly drug development and litigation to address patent challenges will be diminished if the government has already greatly reduced a brand drug's price. In the next section, we estimate the magnitude of lost savings that can be expected from delaying the launch of a small-molecule generic or biosimilar.

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## Analysis

As we described in the previous section, the threat of government price negotiations will factor into generic and biosimilar manufacturers' decisions about if and when to attempt market entry. Manufacturers may be unwilling to take on the risk and expense of a paragraph IV challenge for small-molecule drugs or the risk and expense of development for biosimilars because their ability to recoup their investment could be undercut

by the government selecting a brand drug for negotiation. To quantify the impact of this chilling effect on generic and biosimilar development and entry, we estimate the average per-drug savings that will be lost as a result of a delay in competition. Because market dynamics differ for generic drugs and biosimilars, we analyze these markets separately.

<sup>4</sup> *Biologic manufacturers can avoid price negotiations if a biosimilar is likely to come to market within two years, but this is insufficient given the long lead time associated with biosimilar development.*

It is difficult to say with certainty how many generics and biosimilars will be discouraged or delayed by the threat of price negotiations. If we assume that only first generics that are new molecular entities (NMEs) would be affected by the risk that the government will intervene in the market,<sup>5</sup> up to 22 NME first generics per year on average could be impacted based on data from 2018–2022 (Conrad et al., 2024).

Similarly, if we assume, based on IQVIA (2025), that only higher-sales biologics (those with sales of \$500 million or more) with near-term patent expirations would be affected, up to 37 biologics could be impacted in the next decade.

Some manufacturers may decide that the risk of developing a generic or biosimilar is still worth taking, but these totals hint at the near-term upper limit of potentially affected drugs. For the analytical framework presented here, we look at the lost savings associated with only one generic or biosimilar, but these forgone savings could be much greater depending on the number of drugs that are ultimately affected.

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## GENERIC DRUG LOST SAVINGS

Lost savings from the delay of generic competition can be estimated using evidence of the average price decline and market share for generic drugs. Because the IRA exempts from negotiation any drug with less than \$200 million in Medicare spending, only higher-sales markets will be affected.<sup>6</sup>

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**IRA price negotiations' chilling effect on generic competition would result in unrealized annual savings of 81–88 percent of brand sales per affected small-molecule drug.**

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Research shows that generic competition varies depending on sales of the small-molecule brand drug being referenced. According to Grabowski et al. (2021), generic competitors average 6.4 for brand drugs with annual US sales of \$250 million–\$1 billion and 9.4 for brand drugs with annual US sales of \$1 billion or more. Further, Conrad and Lutter (2019) show that, using invoice-based wholesale prices, the median generic discount is 90.1 percent for drugs with six generic competitors and 97.3 percent for drugs with nine generic competitors. Finally, according to AAM (2024), generic drugs achieve 90 percent market share on average.

<sup>5</sup> NMEs are “first ever generic versions containing those active pharmaceutical ingredients (APIs). . . . [N]on-NME first generics represent generic entry for brand products that contain APIs used in previously approved drugs but that differ from those products in some way, such as a reformulation or novel dosage form” (Conrad et al., 2024).

<sup>6</sup> National Health Expenditures (NHE) data show that Medicare drug spending comprised approximately 32 percent of US drug spending in 2023 (CMS, 2024). By this measure, a drug with \$200 million in annual Medicare sales could be expected to have roughly \$625 million in annual US sales.

Based on these assumptions, we estimate that IRA price negotiations' chilling effect on generic competition would result in unrealized annual savings of 81–88 percent of brand sales per affected small-molecule drug. We have previously calculated that paragraph IV challenges hasten generic entry by an average of 62 months and a median of 50 months (*Brill, 2020*). Therefore, we anticipate that these annual unrealized savings would accumulate for at least four years.

**Generic Lost Savings Example**

To illustrate the impact of price negotiations in the two categories of drug sales—that is, brand drugs with less than \$1 billion in annual sales and those with \$1 billion or more in annual sales—we estimate the lost generic savings associated with a delay in generic entry for a brand drug

**TABLE 1.**  
**LOST GENERIC SAVINGS PER DRUG**

| Drugs with <\$1B in Annual Sales  |               |
|-----------------------------------|---------------|
| Hypothetical annual brand sales   | \$780M        |
| Generic price discount            | 90.1%         |
| Generic market share              | 90%           |
| <b>Annual lost savings</b>        | <b>\$630M</b> |
| <b>Four-year lost savings</b>     | <b>\$2.5B</b> |
| <b>Lost savings as % of sales</b> | <b>81%</b>    |
| Drugs with \$1B+ in Annual Sales  |               |
| Hypothetical annual brand sales   | \$3.4B        |
| Generic price discount            | 97.3%         |
| Generic market share              | 90%           |
| <b>Annual lost savings</b>        | <b>\$3.0B</b> |
| <b>Four-year lost savings</b>     | <b>\$12B</b>  |
| <b>Lost savings as % of sales</b> | <b>88%</b>    |

with \$780 million in annual sales and a brand drug with \$3.4 billion in annual sales.<sup>7</sup>

Our analysis shows that the chilling effect on generic competition would result in unrealized annual savings of \$630 million for the lower-sales drug and \$3 billion for the higher-sales drug (see Table 1). Should the delay persist for four years, as discussed above, lost savings would total \$2.5 billion and \$12 billion per drug, respectively.

**BIOSIMILAR LOST SAVINGS**

As with the small-molecule drug market, to quantify the longer-term impact of IRA price negotiations in the biologic market, we estimate lost savings from reduced biosimilar competition using evidence of the average price decline and market share across biosimilar markets.

For every biosimilar that IRA price negotiations thwart, lost savings will total 54 percent of the reference biologic's annual sales.

According to Samsung Bioepis (2024), in their fifth year on the market, biosimilars achieve 53 percent market share on average and average sales price (ASP) declines of 53 percent compared with the pre-biosimilar reference biologic price. After five years, biosimilar market share continues to increase and ASPs continue to decline. For our analysis, we assume 65 percent biosimilar market share and 65 percent price declines. In addition, after biosimilars enter the market, brand biologics often reduce their prices. We assume that brand biologic discounts average 33 percent (AAM, 2024).

<sup>7</sup> We arrive at these hypothetical sales figures by using prices from 2022 Medicare Part D expenditures (CMS, 2025) for drugs with more than \$200 million in annual Medicare spending and estimating annual US sales based on NHE data mentioned above. The average US sales of drugs with more than \$200 million in Medicare spending and under \$1 billion in US sales is \$780 million, while the average US sales of drugs with US sales of \$1 billion or more is \$3.4 billion.

Based on these assumptions, we estimate that, for every biosimilar that IRA price negotiations thwart, annual lost savings will total 54 percent of the reference biologic’s annual sales. We expect that, unlike with small-molecule drugs, the disincentive to bring a biosimilar to market will not diminish with time. Therefore, we assume that the annual lost savings will persist over years but decline as sales of the reference product eventually decline.

**Biosimilar Lost Savings Example**

To illustrate the impact of price negotiations’ chilling effect on biosimilar competition, we estimate the lost savings associated with a

delay in biosimilar entry for a reference biologic with \$3.5 billion in annual sales.<sup>8</sup> Our analysis finds that the threat of price negotiations would result in unrealized savings of \$1.9 billion annually for a reference biologic of this size (see Table 2).

**TABLE 2.**  
**LOST BIOSIMILAR SAVINGS PER DRUG**

|                                   |               |
|-----------------------------------|---------------|
| <i>Average annual brand sales</i> | \$3.5B        |
| <i>Biosimilar price discount</i>  | 65%           |
| <i>Biosimilar market share</i>    | 65%           |
| <i>Brand price discount</i>       | 33%           |
| <b>Annual lost savings</b>        | <b>\$1.9B</b> |
| <b>Lost savings as % of sales</b> | <b>54%</b>    |

# Conclusion

A significant unintended consequence of Medicare price negotiations will be a chilling effect on the development and launch of new generic small-molecule drugs and new biosimilars. The threat of a brand drug being selected for price negotiation reduces the willingness of these competitors to undertake the significant risk and expense involved in trying to enter the market. As our analysis demonstrates, there is a quantifiable negative impact on the US healthcare system and patients from a less competitive pharmaceutical marketplace. By our estimate, lost savings from Medicare price negotiations could total billions of dollars annually.

While government price negotiations are not an effective means of addressing high drug prices, there is room for meaningful reforms. Reining in anticompetitive behavior by brand drug companies, particularly around patents, and encouraging the further development of the biosimilars market are two examples.

<sup>8</sup> We arrive at this hypothetical sales figure by calculating the weighted average (\$3.5 billion) for high-sales biologics (those with more than \$500 million in US sales) identified in IQVIA (2025).

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