

MEDICARE NEGOTIATING DRUG PRICES: EFFECT ON DRUG COMPANIES



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Introduction

The Inflation Reduction Act (IRA) of 2022 has had a big impact on many areas of the economy, and its impact on the Healthcare sector is about to be even more pronounced. U.S. citizens spend much more on pharmaceuticals than other people around the world, and the IRA is aimed at reducing that discrepancy by giving bargaining power to Medicare. In this piece we will explore the ramifications of this as we get closer to the time frame where drug pricing could be impacted. As always, we view this through the lens of investors and are always thinking of ways these outcomes will impact our portfolios.

US Spending on Drugs

Per capita, the U.S. spends almost twice (\$963) as much, on prescription drugs, as other developed nations (\$466)¹. Higher drug prices is one of the main reasons for this disparity. Prescription drug prices in the U.S. are amongst the highest in the world. A study authorized by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) found that in 2022, U.S. prices for all drugs, branded and generic, were 2.78 times higher than those in OECD (Organization for Economic Co-operation and Development) nations and 3.22 times higher for branded drugs even after adjusting for rebates². Also, drug prices have increased significantly. In fact, total inflation adjusted prescription drug spending has increased 16% over the 2016-2021 period³. Of this, 10% was due to higher utilization and 6% due to drug price increases³.

A major difference between medical insurance in the U.S. and the European union (EU) is that in EU there is universal health coverage provided by the government, whereas in the U.S. health insurance is private. As a result, governments in EU countries have significant negotiating power and extract steep discounts for drugs. In the U.S., each private insurer negotiates drug rebates separately. This reduces their bargaining power. Also, the 2003 Medicare Modernization Act, which created Medicare Part D benefit to help pay for outpatient prescription drug costs, had a noninterference clause which prohibited Medicare from negotiating drug prices with pharmaceutical manufacturers and pharmacies.

The Inflation Reduction Act (IRA) of 2022 allocates federal funding to lower healthcare costs. It does this using the following three provisions:

1. Direct Price Negotiations by Medicare: It allows Medicare to directly negotiate pricing for the top 50 highest expenditure single source drugs for Medicare Part D in 2024 and Part B in 2026 with drug manufacturers⁴. Single source drugs are drugs that do not have a generic equivalent. The law establishes a Maximum Fair Price (MFP), which is an upper limit, for a given drug price. The Centers for Medicare and Medicaid Services (CMS) will negotiate prices of 10 drugs in 2024 and will be effective from January 1, 2026. CMS will then negotiate prices for 15 drugs in 2025 and 2026 each. After that, 20 prices for drugs will be negotiated annually⁵. Drugs that have a generic or biosimilar equivalent, orphan drugs, small biotech drugs, all plasma derived products and small molecule drugs that are less than 9 years from FDA approval and biologics that are less than 13 years from FDA approval are excluded from these negotiations. An excise tax starting at 65% and reaching up to 95% of U.S. sales will be levied against all companies that do not negotiate with Medicare⁶. An alternative is for companies to withdraw all their drugs from Medicare and Medicaid coverage.

2. Medicare Part D Redesign: In addition to price negotiations, as part of the Part D redesign, out of pocket costs for Medicare patients will be capped at \$2000 per year⁷. To do so, financial liability will be shifted from Medicare to commercial payers. Also, in the catastrophic phase, when the patient reaches out of pocket limit, drug manufacturers will provide 20% discount and the payer responsibility will increase from 15% to 60%⁸.

3. Inflation Price Caps: Companies that raise prices of certain Part D and Part B drugs at a faster rate than inflation are required to pay Medicare a rebate. The rebate amount will be calculated by the CMS⁹.

The Congressional Budget Office (CBO) estimates that, by 2031, the average drug price will be 8% lower for Part D and 9% lower for Part B. It also estimates that this will reduce the deficit by \$25B in 2031¹⁰.

Various pharmaceutical companies had filed lawsuits against the IRA to prevent it from implementing the Medicare price negotiations. However, so far, all those appeals have been denied. Also, any future administration would have limited flexibility to make changes without the backing of the U.S. Congress.

Investment Case

Pharmaceutical and biotech companies will be affected in several ways:

1. Revenue growth: In 2024, Medicare has capped out of pocket spending to \$3000 - \$3800 (vs. \$8000) on catastrophic coverage and eliminated coinsurance. Starting in 2025, Medicare will cap out of pocket spending on prescriptions to \$2000 per year⁷. This should have a positive effect on the pharmaceutical sector as lower out of pocket expenditure will increase compliance and result in higher prescription volumes. However, from 2026 onwards, when the negotiated prices become effective, the IRA is expected to have a negative effect on revenue growth. However, this is expected to be muted until 2028, as most Part D drugs are small molecule drugs that are nearing loss of exclusivity. The effect of these negotiations will vary for each company.

The first set of negotiated MFPs were announced on August 19, 2024, and will go into effect in 2026. The price discounts on the list price range from 79% for Januvia™ to 38% for Imbruvica® (Table 1¹¹). The list price is the price set by the pharmaceutical companies for their drugs. However, as these companies always offer significant discounts and rebates, the net price and revenue generated for a given drug is significantly lower than that suggested by its list price. Also, some of the drugs will be close to losing patent protection when the discounts go into effect (Table 1¹¹). For example, Merck’s (MRK) Januvia™, which has had the steepest discount, is expected to lose patent in 2026 and is expected to contribute only 1% of total revenue in 2025¹². Similarly, AbbVie’s (ABBV) Imbruvica® is expected to lose market share in 2026 due to competing drugs and is expected to contribute 3% to total revenue in 2026¹². On the other hand, drugs like Bristol Meyer Squibb’s (BMY) Eliquis®, which is expected to contribute 11% to its total revenue in 2026, will be more affected¹². The MFP for Eliquis reflects a 25% discount to its 2025 net price¹². This implies a 12-13% loss of revenue for Eliquis in 2026¹².

Table 1: Negotiated Prices for Year 2026¹¹

<i>Drug</i>	<i>Company</i>	<i>Percent of Total 2023 Sales</i>	<i>Discount from 2023 list price</i>	<i>Loss of Patent</i>
Eliquis®	BMY	27%	56%	2028
Jardiance®	LLY	8%	66%	2028
Xarelto®	JNJ	2.7%	62%	2027
Farxiga®	AZN	13%	68%	2026
Januvia™	MRK	3.6%	79%	2026
Entresto®	NVS	13%	53%	2025
Stelara®	JNJ	12.7%	66%	2025
Enbrel®	AMGN	13%	67%	2029
Fiasp®	NVO	1%	76%	2024
Imburvica®	ABBV	6%	38%	2032

Negotiations for Medicare Part B drugs are expected to start in 2026 and to be effective from 2028. Drugs covered under Medicare Part B are more specialized and have to be administered in a doctor’s or healthcare provider’s office. These are typically biologics which are higher growth and higher margin products. As a result, slowdown in pharmaceutical revenue growth is expected to be more pronounced from 2028. Some of the possible Part B drugs that may be subject to Medicare price negotiations are shown in Table 2¹³. As with Part D negotiations, the impact of Part B negotiations will vary for each company.

Table 2: Drugs With Exposure to Medicare Part B¹³

<i>Drug</i>	<i>Company</i>	<i>Percent of Total sales in the year prior to discount (estimate)</i>	<i>Potential Price Discount</i>	<i>Loss of Patent</i>
Keytruda®	MRK	46%	2028	2028
Opdivo®	BMY	25%	2028	2028
Biktarvy®	GILD	48%	2028	2032
Mounjaro®	LLY	34%	2032	2036
Rinvoq®	ABBV	15%	2029	2033

Some studies expect the IRA to reduce, on average, industry revenues by about 12% over the 2024-2039 time period¹⁴. However, the effect of the IRA will vary for each company.

2. Drug Development: Drug development is costly and time consuming. By guaranteeing market exclusivity, patent protection allows drug companies to realize profits on their R&D investments. While patent protection is typically granted for 20 years, the time required to bring a drug to market is significant and varies for each drug. Thus, the Effective Patent Life (EPL) for each drug is different. The current average EPL for small molecule drug is about 13 years¹⁵. The IRA will have the most impact on small molecule drugs since it will shorten the Effective Patent Life (EPL) to 9 years. Since the FDA allows 12 years of market exclusivity and IRA allows 13 years of EPL to biologics¹⁶, these will not be affected. As a result, it is possible that drug companies will focus their R&D on biologics rather than small molecule drugs. This may be a positive for the industry since biologics typically generate higher revenue and have higher margins.

Summary

The Inflation Reduction Act (IRA) of 2022 allows, for the first time, Medicare to directly negotiate drug prices with drug manufacturers. The first set of negotiated prices were announced in August 2024 and will go into effect on January 1, 2026. Medicare price discounts are expected to slow down revenue growth for the pharmaceutical and biotech companies. This slowdown is expected to be muted till 2028, as most Part D drugs are small molecule drugs that are nearing loss of exclusivity. Price discounts for Part B drugs, which are on average higher priced, go into effect in 2028. As a result, slowdown in revenue growth may be more pronounced from 2028.

The Inflation Reduction Act (IRA) of 2022 is also expected to affect development of new therapies. Since it is expected to have the most adverse effect on small molecule drugs, companies may focus their R&D on biologics rather than small molecule drugs. This could be a positive for the industry since biologics typically generate higher revenue and have higher margins.

Product portfolio, loss of patents and product pipeline have always been the key to investing in pharmaceutical and biotech companies. This is even more important now as the effect of Medicare price discounts will vary significantly for all companies.

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