Signal From Noise

September 28, 2023

Upcoming Medicare Drug-Price Negotiations: An Investment Perspective

Many countries, among them Canada, Japan, the United Kingdom, Germany, and France, negotiate directly with pharmaceutical companies to set prices of vital prescription medications on behalf of their respective residents. Although each country uses a different system and methodology to negotiate, for many years, all have successfully obtained lower prices by using the bargaining power represented by the collective potential markets of their entire respective populations.

On October 1, 2023, the United States will attempt to do something similar, albeit on a far more limited scale initially. This marks a significant break from policy set in 2003 with the creation of Medicare Part D, which allowed Medicare to offer prescription-drug benefits to plan participants (primarily comprised of elderly Americans). Part D contracts with private-sector pharmacy benefits managers (PBMs) to deliver these benefits.

The PBMs, in turn, negotiate with pharmaceutical companies to determine the prices they and plan participants will collectively pay for the medications. The federal legislation that created Medicare Part D included a "non-interference" clause prohibiting Medicare and the Secretary of Health and Human Services (HHS), under whose aegis Medicare is administered, from getting involved with these price negotiations.

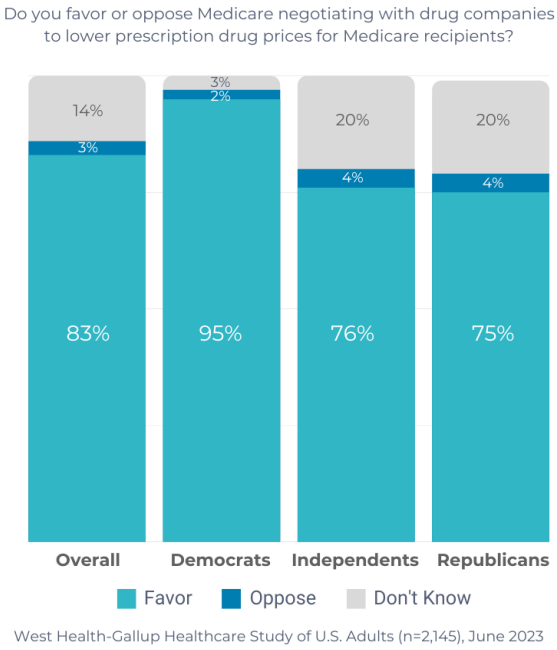
This clause has long been criticized by activists and some policymakers, who argue that this has resulted in Americans (and the federal government) paying more for prescription medications than necessary. The critics have pointed out that in the countries that negotiate directly with drugmakers, prescription-medication per-capita costs are far lower. Despite opposition from pharmaceutical companies which argue that an analogous practice in the US would inhibit innovation and result in fewer options being made available to patients, a number of polls show that a bipartisan majority of Americans agree on this issue. For example:

One Year After the Passage of the Inflation Reduction Act

83%

of Americans Still Support Allowing Medicare to Negotiate Drug Prices for Medicare Recipients

westhealth GALLUP



West Health-Gallup Healthcare Study of U.S. Adults (n=2,145), June 2023

Large Majorities Across Partisans Say Many Health Care Issues Are Important Priorities For Congress To Work On

Percent who say each of the following should be a **top priority or important** for Congress:

	Democrats	Independents	Republicans
Allowing the federal government to negotiate with drug companies to get a lower price on prescription drugs for people with Medicare	96%	87%	84%
Increasing government funding for access to mental health services and training for mental health providers	95%	87%	78%
Placing a limit on out-of-pocket health care costs for seniors, such as co-pays for prescription drugs	94%	91%	91%
Limiting how much drug companies can increase the price for prescription drugs each year to no more than the rate of inflation	93%	90%	90%
Expanding government health insurance coverage for lower-income people in states that have not expanded their Medicaid program	92%	80%	62%
Taking federal action to improve the safety and quality of care in nursing homes	91%	86%	87%
Capping out-of-pocket costs for insulin at $35 a month	90%	88%	86%
Providing more funding to continue the COVID-19 pandemic response	85%	61%	41%
Making permanent the additional financial help from the COVID-19 relief bill for people who buy their own insurance	78%	62%	42%

NOTE: See topline for full question wording.
SOURCE: KFF Health Tracking Poll (March 15-22, 2022). • PNG

KFF

President Biden's Inflation Act of 2022, which passed along partisan lines, included a mandate for Medicare drug-price negotiation. On August 29, 2023, the Department of Health and Human Services announced that it had selected the first 10 drugs that would be subject to price negotiation with their respective manufacturers. They were selected by looking at which medications Medicare Part D spends the most, then prioritizing those that are single-source drugs – brand-name medications for which there are no generic or biosimilar competitors, and for which there is a low likelihood of one becoming available soon.

The HHS said that the first 10 drugs chosen collectively accounted for $50.5 billion in gross covered prescription-drug costs, roughly 20%, between the June 1, 2022 – May 31, 2023 assessment period. Unsurprisingly, many treat chronic conditions that often appear later in life including diabetes, arthritis, and heart failure.

The first negotiations will involve:

- **Eliquis** – This is the brand name for Apixaban, from Bristol-Myers Squibb ($BMY) and Pfizer ($PFE). It is an anticoagulant used to help prevent clots, strokes, and heart attacks in people with atrial fibrillation. It is also prescribed to help prevent deep vein thrombosis and pulmonary embolism in certain circumstances. The Centers for Medicare and Medicaid Services (CMS) reported that during the assessment period, it accounted for $16.5 billion in Medicare Part D costs, prescribed to 3.7 million patients.
- **Jardiance** (Empagliflozin) – Marketed by Eli Lilly ($LLY) and made by Boehringer Ingelheim, this medication helps those with Type 2 diabetes control their blood glucose levels. The drug works by inhibiting the action of sodium glucose co-transporter-2 and thus increasing sugar loss through urine. As a side benefit, this sometimes results in a moderate decrease in blood pressure and weight. ($7.1B, 1.6 million patients, per CMS data.)
- **Xarelto** (Rivaroxaban) – Developed by Bayer and marketed by Johnson & Johnson ($JNJ), Xarelto is an anticoagulant with similar indications as Eliquis. It is used to help prevent clots, strokes, and heart attacks in people with atrial fibrillation, and to prevent deep vein thrombosis and pulmonary embolism in certain circumstances. ($6.0B, 1.3 million patients.)

- **Januvia** (Sitagliptin) – Sold by Merck ($MRK), Januvia is an oral treatment for Type 2 diabetes in adults. It works by increasing insulin secretion and by suppressing glucagon release by the pancreas, thus helping to regulate blood glucose levels. Because this effect moderates as blood glucose levels moderate to acceptable levels, the overshooting and consequent low blood sugar associated with other diabetes treatment does not occur. It is available in multiple generic formats. ($4.1B, 869,000 patients)
- **Farxiga** (Dapagliflozin) – Marketed by AstraZeneca ($AZN), Farxiga is used to help treat Type 2 Diabetes, and also to treat adults with heart failure and chronic kidney disease (both diabetic and non-diabetic). Farxiga and its generic variants work by inhibiting sodium glucose transport proteins and thus increasing sugar loss through urine. ($3.3 billion 799,000 patients)
- **Entresto** (a combination medication of Sacubitril and Valsartan) – Sold by Novartis ($NVS), Entresto is used to treat heart failure, primarily by increasing blood-vessel dilation and extracellular fluid volume. It is often used as an alternative to ACE inhibitors and Angiotensin II receptor blockers. $2.9B, 587,000 patients)
- **Enbrel** (Etanercept) – Sold by Amgen ($AMGN), Enbrel is a biologic treatment prescribed to patients with several types of arthritis or with autoimmune conditions such as plaque psoriasis. The medication works by inhibiting TNF ("tumor necrosis factor"), an immune-system protein that plays a key role in controlling the body's inflammatory response. ($2.8B, 48,000 patients)
- **Imbruvica** (Ibrutinib) – This medication inhibits the so-called B-Cell receptor pathway. The aberrant behavior of this pathway is associated with a number of cancers, including mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), Waldenström's macroglobulinemia (WM), and marginal zone lymphoma (MZL). It is jointly marketed by AbbVie ($ABBV) and Johnson & Johnson ($JNJ). ($2.7B, 20,000 patients)
- **Stelara** (Ustekinumab) – Developed by Johnson & Johnson ($JNJ), Stelara and its generic equivalents are used to treat various autoimmune and inflammatory disorders including Crohn's disease, ulcerative colitis, plaque psoriasis, and psoriatic arthritis. It is a biologic medication that works by suppressing certain cytokines and thus the body's inflammatory response. ($2.6B, 22,000 patients.)

- **Novolog FlexPen/Fiasp** (insulin aspart) – A modified, fast-acting form of human insulin manufactured by Novo Nordisk ($NVO) that allows diabetics to inject right before a meal, instead of timing their injections for 30-60 minutes beforehand. ($2.6 billion, 777,000 patients)

Manufacturers must decide by October 1, 2023 whether to take part in the negotiations. The CMS will then begin evaluating data and make initial price offers to companies in February 2024, at which point responses and counteroffering can begin. The results of the negotiations will be announced September 1, 2024, and the negotiated prices scheduled to go into effect on January 1, 2026.

Pharmaceutical companies that decline to participate can opt withdraw their drugs from Medicare and Medicaid participants or accept the priced deemed appropriate by the CMS. If not, they will be charged a 65% excise tax on US revenues from sales of the medication in question for the first quarter. That percentage will increase by 10% every quarter until it reaches 95%.

As a baseline, the maximum price for any of the drugs will be capped at the current price Medicare plans currently pay after discounts. For each medication, the CMS will then consider:

- **Research and development costs**, including how much of those costs have been recouped, and how much of those costs were funded by the federal government.
- **Production and distribution costs**.
- **Exclusivity period**, including any pending applications for additional applications or indications.
- **Effectiveness**, including effectiveness as compared to alternatives and effectiveness on specific populations such as those with disabilities, the elderly, children, etc.
- The extent to which the drug addresses an otherwise **unmet need**.

Going forward, the CMS will select 15 more drugs for similar price negotiations to take effect in 2027, 15 more for 2028, and then 20 more for each year afterward.

Although the knee-jerk expectation is that this will hurt pharmaceutical companies' revenues, a closer look suggests that any negative impact could be limited. This is partly because some of the drugs selected for the first round are close enough to the end of their respective exclusivity periods that by the time the negotiated prices take effect, generics will soon be approved and arriving on the market, driving prices down anyway.

Some companies also might actually find the negotiations helping their revenues, as they expand access to – and thus, utilization by – more Medicare participants. Not all pharmacy benefits managers currently offer Stelara and Novolog/Fiasp to their Part D beneficiaries, for example, but after the negotiated prices take effect, they will all be required to do so.

The more immediate impact might be on PBMs, the private-sector companies contracted to provide prescription-medication benefits to Medicare participants. The current practice has been for each PBM to negotiate with manufacturers independently. One study by the National Bureau of Economic Research (NBER) found that the larger PBMs have typically been able to use their buying power to negotiate bigger rebates and lower prices. Specifically, the NBER found that "enrolling 100,000 additional members is associated with a 2.5 percent decrease in drug prices."

This suggests that if the negotiations do succeed in lowering prices paid by PBMs, some – the smaller ones – will benefit more than the larger ones, we believe. For reference, the biggest PBMs, in order of market share according to *Becker's Hospital Review*, are

- **CVS** Health ($CVS) / Caremark: 33 percent
- **Cigna** ($CI) / Evernorth / Express Scripts: 24 percent
- **UnitedHealth** ($UNH) / OptumRx: 22 percent
- **Humana** Pharmacy Solutions ($HUM): 8 percent
- Prime Therapeutics / Magellan Rx: 5 percent
- MedImpact Healthcare Systems: 4 percent

A final note

As of this writing, only four of the manufacturers of the 10 drugs on the CMS list have publicly disclosed plans to participate in the negotiation process. Yet all four – Merck, AstraZeneca, Bristol Myers Squibb, and Boehringer Ingelheim – have also filed lawsuits to halt the negotiation process. So has Mercik, so has the US Chamber of Commerce, and so has the Pharmaceutical Research and Manufacturers of America (PhRMA), the primary lobbying group for the pharmaceutical industry.

Key to the legal arguments against the price-negotiation law are the First, Fifth and Eighth Constitutional Amendments. Specifically, opponents argue that the law violates the Fifth Amendment ban on "private property [being] taken for public use, without just compensation," the Eighth Amendment ban on excessive fines, and the First Amendment's free speech protections by "compelling" the companies to echo the government's "political messages." Plaintiffs have also argued that because there is no judicial review provided for in the negotiations, the law deprives companies of property in violation of their due process rights.

Legal analysis of these arguments and their likelihood of succeeding are beyond the scope of this publication. Nevertheless, the possibility that the negotiations will be halted seems to be real.

For this and other reasons, the information in this piece should not be used as the basis for taking a position in any of the companies named above, but rather as a starting point for further investigation into how this policy might affect investors.

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