

29 Aug 2023 | Analysis

# First Round Of Drugs Up For Medicare Negotiation Gets Soft Landing

*Stock Market Shrugs; Biotechs Rise Slightly*

by Mandy Jackson

Big pharma valuations mostly held steady as CMS released its list of the first 10 drugs subject to Medicare negotiations under the Inflation Reduction Act, which held few surprises and included products nearing the end of their patent lives by the time negotiated pricing takes effect.

For all of the biopharmaceutical industry's concerns that drug pricing provisions in the Inflation Reduction Act will stifle innovation, when the Centers for Medicare and Medicaid Services (CMS) released its list of the first 10 drugs subject to Medicare negotiations under the IRA, the stock market reaction was "meh." Biotechnology stock indices closed up on 29 August and most of the big pharma firms facing Medicare negotiations for the first time in 2026 closed a bit higher as well.

Investors likely were nonplussed because the list was largely in line with expectations, including the anticoagulants Eliquis (apixaban) from [Bristol Myers Squibb Company](#) and Xarelto (rivaroxaban) from [Johnson & Johnson](#) as well as [AbbVie Inc.](#)/J&J's blood cancer medicine Imbruvica (ibrutinib) and [Boehringer Ingelheim GmbH/Eli Lilly and Company](#)'s diabetes drug Jardiance (empagliflozin). (Also see "[Medicare Price Negotiation List Remains A Puzzle, Even For Those That Are \(Probably\) On It](#)" - Scrip, 17 Aug, 2023.)

In addition, all of the listed products will be on their way to reduced revenue regardless of lower Medicare pricing on 1 January 2026 because of generic or biosimilar competition before or within one to three years of that date. Many already are subject to heavy rebating under Medicare Part D plans. (Also see "[Big Rebates Already A Big Factor For Drugs On Medicare Negotiation List](#)" - Scrip, 29 Aug, 2023.)

Pharma companies' primary argument against the IRA price negotiation provisions is that rather than reducing out-of-pocket expenses for patients covered by Medicare, the impact of the negotiation will be reduced biopharma innovation. (Also see "[Industry Looks At IRA Drawbacks And Silver Linings](#)" - Scrip, 20 Jan, 2023.)

The IRA requires Medicare price negotiations to begin nine years after US Food and Drug Administration approval for small molecules and 13 years after approval for biologics, a difference that many in the industry argue makes small molecule drug development less attractive than biologics because of the reduced time in which companies can generate maximum profits. However, for the first 10 drugs subject to lower negotiated prices for Medicare patients in 2026, they will have generic or biosimilar competitors at that time or soon after.

Biosimilars of [Novo Nordisk A/S](#)'s NovoLog (insulin aspart) and its fast-acting version Fiasp already are making their way onto the US market, with the first biosimilar NovoLog launch back in 2020. And while J&J recently was successful in delaying the expected late 2023 launches of biosimilars of its IL-12/IL-23 inhibitor Stelara (ustekinumab), those lower-cost competitors still will reach the market starting 1 January 2025, a full year before the branded product is subject to a lower negotiated Medicare price. (Also see "[J&J Predicts No Stelara Biosimilar Until 2025](#)" - Scrip, 20 Jul, 2023.)

"We await future developments to see if [biosimilar] Stelara manufacturers will be able to petition to have [Medicare price] controls removed," Leerink analyst David Risinger said in a 29 August note.

### Companies Facing Medicare Negotiations

*Stock indices reflecting the values of smaller biotech companies remained in the black, with the Nasdaq Biotechnology Index closing up 0.8% and the XBI fund gaining 0.5% by the end of 29 August. [Company, drug(s) and 29 August stock performance]*

- Bristol Myers Squibb (Eliquis), 2%
- Lilly (Jardiance), 0%
- J&J (Xarelto, Imbruvica and Stelara), 0%
- AbbVie (Imbruvica), 0.1%
- Merck (Januvia), 1%
- AstraZeneca (Farxiga), 0.7%
- Novartis (Entresto), 0.9%
- Amgen (Enbrel), 1.2%
- Novo Nordisk (Fiasp and NovoLog), 1.5%

Risinger pointed out that J&J's Xarelto and [Novartis AG](#)'s heart failure drug Entresto (sacubitril/valsartan) will only be affected by Medicare price negotiations for one year since both are expected to lose patent exclusivity (LOE) in 2027. "If generics are approved for Xarelto or Entresto prior to March 31, 2027, then either would be deselected on January 1, 2028," he said. "[[Merck & Co., Inc.](#)'s] Januvia and [[AstraZeneca PLC](#)'s] Farxiga both have LOEs in 2026, thus minimizing the price control impact of these products given the likelihood of imminent generic entry."

## Medicare Price Negotiations Already Factored Into Projections

BMS senior vice president and general manager of US commercial Catherine Owen said in an interview with *Scrip* that the company loses exclusivity for Eliquis in the US in 2028, and while the two to three years of reduced Medicare pricing have been factored into Bristol's thinking, it does not affect the company's commercial strategy moving forward. BMS has pinned much of its growth for the rest of this decade and beyond on new products expected to make up for drugs losing patent protection. (Also see "[Strong Launches Will Help BMS Win The LOE Battle In 2023 And Beyond](#)" - *Scrip*, 30 Jan, 2023.)

Indeed, while an Evaluate Vantage compilation of analyst consensus estimates shows that Eliquis sales will shrink by more than \$6bn from \$13.46bn in 2026 to \$7.21bn in 2028, Bristol's total pharmaceutical sales are not expected to decline by such a large gap, falling by more than \$2bn from \$47.91bn in 2026 to \$45.57bn in 2028.

"For Eliquis, the inclusion does not come as a surprise, and has already been factored into our estimated sales of Eliquis for 2026 and 2027, however, it remains to be seen what level of discount will be negotiated with CMS over the coming year, and therefore we expect our estimates will likely change," William Blair analyst Matt Phipps explained in a 29 August note.

"Given the drug is shared with Pfizer and patent loss of exclusivity is in 2028, the impact has limited duration on the company's overall revenue in the \$46 billion-\$50 billion range in that timeframe," Phipps added. "Going forward, Bristol Myers will likely experience more impact from the addition of Part B drugs such as Opdivo and Ocrencia in 2028, and therefore puts greater reliance on the acceleration of revenue for new franchises."

Mizuho analyst Salim Syed noted limited impact for [Amgen, Inc.](#) from having Enbrel (etanercept) included in Medicare price negotiations for 2026. "By our math, Enbrel already receives a ~36.5% discount from its list price for its Medicare business. 24% of Enbrel's US payor mix is Medicare," Syed said in a 29 August note. "Hence, the math could potentially look as follows: Enbrel US 2026 consensus revenue of \$2.5bn [with] 24% Medicare US payor mix [and] an additional 23.5% price discount = ~\$150m of revenue impact or <1% of total 2026 consensus revenue."

## Drugs Selected To Reduce Patients' Costs; Industry Skeptical

CMS selected the 10 drugs for Medicare price negotiations for 2026 based on gross Part D spending between June 2022 and May 2023, which does not take into account rebates and other discounts. (Also see "[Big Rebates Already A Big Factor For Drugs On Medicare Negotiation List](#)" - Scrip, 29 Aug, 2023.) Up to 15 Part D drugs will be selected for Medicare negotiations for 2027, with up to 15 Part B and Part D drugs chosen for 2028, and up to 20 drugs selected each year after that.

While the much-anticipated list of the first 10 drugs subject to Medicare negotiations did not cause a big commotion among biopharma investors, there still are more milestones to come as CMS works to implement this portion of the IRA. Pharma companies must choose by 1 October whether they want to negotiate – the alternative being not making their drugs available to Medicare beneficiaries – and by 2 October they must submit manufacturer-specific information for CMS to consider in the negotiations.

“We think it is likely that manufacturers will choose to participate in the process vs. pulling out of Medicare/Medicaid or facing a steep excise tax/other penalties,” Raymond James analyst Chris Meekins said in a 29 August note.

CMS will send initial offers of a maximum fair price to each manufacturer by 1 February 2024 and the negotiation period will end on 1 August 2024, with CMS publishing the final maximum fair prices on 1 September 2024. The prices will go into effect on 1 January 2026.

“It remains to be seen what the negotiated prices will be ... which will serve as a clearer indication of what level of negotiated rates to expect from the program in future years, especially if President Biden wins reelection in 2024,” Meekins said.

## Gross Part D Spend

*Gross Part D spending June 2022-May 2023 and number of Medicare patients treated.*

- Eliquis: \$16.48bn, 3.7 million
- Jardiance: \$7.06bn, 1.57 million
- Xarelto: \$6.03bn, 1.33 million
- Januvia: \$4.09bn, 869,000
- Farxiga: \$3.27bn, 799,000
- Entresto: \$2.88bn, 587,000
- Enbrel: \$2.79bn, 48,000
- Imbruvica: \$2.66bn, 20,000
- Stelara: \$2.24bn, 22,000
- Fiasp/NovoLog: \$2.58bn, 777,000

CMS administrator Chiquita Brooks-LaSure said in the agency's statement about the first 10 drugs that the goal for Medicare price negotiations is "to improve access to some of the costliest drugs for millions of people with Medicare while driving competition and innovation." Medicare enrollees taking the 10 drugs subject to price negotiations for 2026 paid \$3.4bn in out-of-pocket costs for these drugs in 2022.

However, BMS exec Owen noted that the company's main area of concern about the IRA's Medicare price negotiation requirements "is around the disconnect that we believe people might imagine the law might have in terms of the savings that the government is talking about versus how it will actually work."

Owen pointed out that Eliquis is used widely for patients who have atrial fibrillation, and for people who are at risk for deep vein thrombosis (DVT) and pulmonary embolism (PE) or DVT and PE recurrence, because of its potential to prevent strokes and stroke-related events, with about 3 million Medicare-covered seniors prescribed the medicine currently, accounting for more than 50% of the patients taking the drug. It is on the list of drugs first up for Medicare price negotiations, she said, "because it is widely used and adds tremendous value to both patients and the health care systems."

However, Owen added, "the disconnect that we have is that the perception is that the savings that the government are going to develop from these negotiations will be passed on to seniors. And the reality is that the law has been written, so far, to say that there is no obligation for those savings to be passed to patients. And so, right now, we're actually concerned that insurance companies have no obligation to continue to cover Eliquis."

Medicare Part D plan providers could decide to change their cost-sharing parameters for Eliquis or change the drug's position on plan formularies, she said.

"We actively negotiate with all Medicare payers to get access for patients for Eliquis and we do that through rebates, discounts, etc.," Owen explained. "And right now that means that, on average, a patient pays \$55 per month for Eliquis and more than half of patients pay \$45 or less, so it's a relatively low out-of-pocket expense. The way that payers and plans are incentivized in terms of their financials is different and so they might make a decision not to cover a lower-cost product because they don't enjoy the same level of rebates, and so that is why we are concerned that Eliquis may become a higher cost-sharing burden or have different hurdles to access it than patients enjoy right now."

## **Price-Setting Worries, Innovation Impacts**

Novartis echoed Bristol's concerns in a statement it issued after CMS released its list of 10 initial drugs selected for Medicare price negotiations: "More comprehensive changes are required to ensure the IRA's drug price-setting provisions do not result in worse access for patients; that the

law is implemented in the most transparent and patient-centric manner possible; that the process allows for meaningful stakeholder input; and that ongoing innovation is valued equally for small molecules and biologics.” (Also see "[US Pricing Reform Puts Cancer Drug Innovation At Risk, Drug Leaders Warn](#)" - Scrip, 2 Nov, 2022.)

Novo Nordisk said in a statement that while the company supports policies to ensure patients can afford their medicines, including insulin, “unfortunately, we have seen CMS take aggressive steps to carry out unilateral price setting without consideration for the impact on patients living with chronic disease or the overall health care system.”

While Novo Nordisk is not among the big pharma companies that has filed lawsuits attempting to halt certain IRA provisions, Novo said that it “will explore all options that allow us to drive change for people that need it and strive to continue to bring innovative medicines to the market while helping increase access for those that need them. Given our products have been included in today’s list, we will be determining next steps toward addressing those important initiatives.”

Merck, the first company to file suit against the US government over the IRA, said in a 29 August statement that the law’s “price-setting provisions are bad policy that will stifle the US

biopharmaceutical sector’s research and development and have potentially devastating consequences for the millions of patients who need new therapeutic options.” (Also see "[Merck & Co. Files First IRA Suit, Signaling Industry Is Ready To Fight](#)" - Scrip, 6 Jun, 2023.) The company has been an early and outspoken critic of the IRA, particularly in terms of its impact on R&D and dealmaking decisions. (Also see "[IRA Already Impacting Merck & Co. BD Decisions, CEO Davis Says](#)" - Scrip, 5 Jan, 2023.)

In regard to Januvia’s inclusion on the Medicare price negotiation list, Merck said its DPP-4 inhibitor for type 2 diabetes “is a critical innovation” and the company believes “the price of Januvia reflects its value to patients and society and that it is critical that any ‘negotiation’ recognizes that value.”

Boehringer, which recently filed a lawsuit to halt provisions of the IRA, noted in its statement

### ***Piling On: AstraZeneca Files Sixth Manufacturer Lawsuit Against Medicare Negotiation Program***

By **Cathy Kelly**

25 Aug 2023

Firm leans into allegations that the US government violated the Administrative Procedures Act in implementing the program. More legal actions are expected from industry once CMS announces the first list of drugs subject to negotiation. Our lawsuit tracker will keep you apprised.

[\*Read the full article here\*](#)



about Jardiance's inclusion in the initial Medicare price negotiations that "the law is often mischaracterized ... as focusing on the highest-priced drugs, when in reality CMS has selected medicines with the overall highest Medicare spending. We believe that CMS selected Jardiance based on the spend associated with improving health of the millions of patients who rely on the proven outcomes of Jardiance – not based on the already heavily discounted price for the government." (Also see "[\*Industry's Suits Against Medicare Price Negotiation: Consolidation And Expansion\*](#)" - Scrip, 22 Aug, 2023.)

The company said Medicare price negotiations will dampen companies' ongoing R&D spending for their drugs, including after initial approvals, for on follow-on indications. Boehringer's ongoing spending in Jardiance, for instance, has expanded the drug's use to more patients, the company noted, including its approval in June as the first SGLT2 inhibitor indicated for type 2 diabetes patients aged 10 and older.

Despite the industry's objections to the IRA's Medicare price negotiation requirements, pharma companies are moving ahead under the law's requirements even while their lawsuits are pending.

"For right now, we have to assume that the law is going to go into effect," Owen said. "We have an active lawsuit and we believe strongly that that lawsuit has merits based on our first and fifth amendment rights, but we have to comply with the legislation and the law and we are preparing to do that. And we will go with the documentation and all of the requirements that the law currently requires until such time as the legal cases are heard."

Raymond James' Meekins said he is working on the assumption that implementation of Medicare price negotiations will be delayed, however.

"The district court rulings in the negotiation lawsuits will be the first in a long process likely ending up at the Supreme Court, and final resolution from the Supreme Court may not come until the first half of 2026," he wrote. "Whether CMS will be stopped from implementation between now and then remains to be seen. Our base case expects a delay in implementation of the law ... and we also believe there is a chance one or more of the lawsuits could result in the Supreme Court striking down the Medicare negotiation program overall."