EXECUTIVE INSIGHTS

Understanding the Inflation Reduction Act Negotiation Prices After the Dust Has Settled

Nearly one year after announcing the 10 drugs for negotiation under the Inflation Reduction Act (IRA),[1] the Centers for Medicare & Medicaid Services (CMS) announced on August 15[2] that the negotiated prices would have saved approximately $6B in net covered prescription drug costs, resulting in about 22% lower net spend in aggregate. Most drugs will now be sold at a discount of 65%-80% off list price. But what does all this mean for biopharmas and for patients?

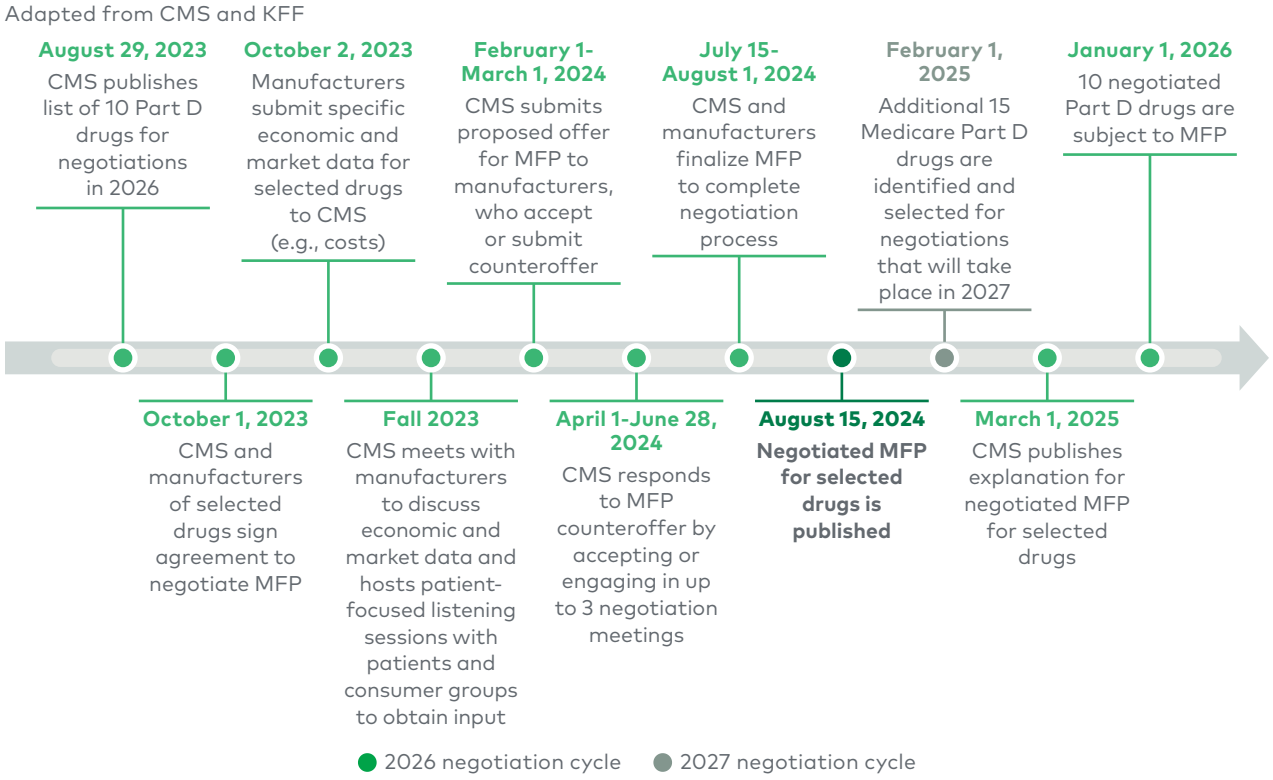
Though highly anticipated across the industry, this announcement leaves many questions unanswered. Details on the negotiation process are not expected until March 2025 (see Figure 1), and the full aftermath will not truly be clear until several years after the negotiated prices go into effect in 2026.

In this edition of *Executive Insights*, L.E.K. Consulting discusses the announcement and breaks down both what was clarified and what remains uncertain.

CMS estimate of $6B savings is likely overstated

While CMS has reported that these discounts — if in effect last year — would have saved CMS $6B, the actual impact by the time of implementation in 2026 is likely to be much smaller. Most of the negotiated drugs were already near the end of their lifecycle.[3] Several small molecules (e.g., Entresto, Farxiga, Januvia, Xarelto) are likely to face generics before 2026 or soon thereafter, which will likely have greater impact than the negotiation. In the same timeframe, Stelara likely faces competition from biosimilars.

Figure 1
Timeline of key negotiation events leading up to initial price applicability in year 2026



Note: CMS=Centers for Medicare & Medicaid Services; KFF=Kaiser Family Foundation; MFP=maximum fair price
Source: L.E.K. research and analysis; CMS; KFF

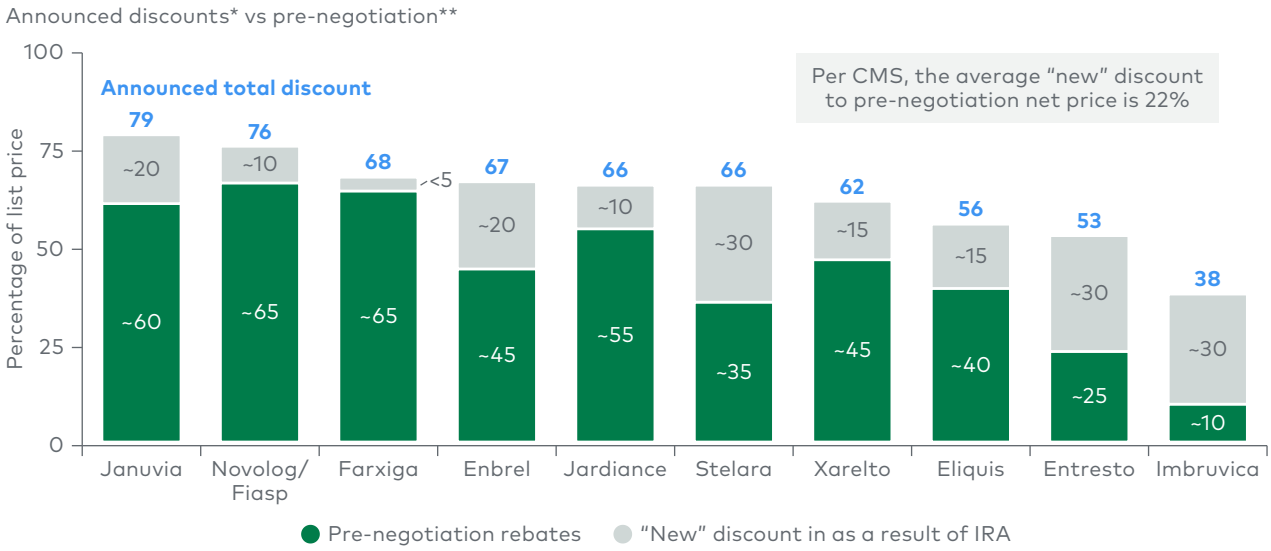
While reported discounts are eye-popping, CMS appears to have been conservative in pushing for additional discounts

As part of the IRA, CMS was given significant discretionary power to negotiate a maximum fair price (MFP) for each of the 10 selected drugs based on a wide range of factors, including cost of therapeutic alternatives, quality of efficacy, and safety data and R&D costs. The IRA did specify a "ceiling" for that MFP at the lower of either (1) the drug's enrollment-weighted negotiated net price for a Part D drug (ASP for Part B), or (2) a percentage of the drug's average non-federal average manufacturer price (non-FAMP), with increasingly steep discounts depending on the number of years on the market.[4] For drug prices below this mandated ceiling, CMS was empowered to pursue substantial discounts at its discretion. The IRA did not specify any equivalent "floor" for MFPs, putting manufacturers in a precarious negotiating position with very limited recourse to contest those prices proposed by CMS in negotiations.

However, despite this substantial and nearly "check-less" negotiating power provided to CMS, the overall impact on net pricing appears to be moderate and in line with expectations. While the reported discounts from list prices range from 40% to 80%, with most landing between 65% and 80%, the true discount from pre-negotiation rebates is far less significant. CMS reported that the discount from current net prices paid by Part D plans is roughly 22% across all products and that no individual product appears to face a >30pp discount to its current pre-negotiation rebates (see Figure 2).

Figure 2^

CMS' announced discounts are substantial, but impact on net prices is more muted



^Exact net pricing paid by Part D plans is confidential and not disclosed but has been credibly estimated by third parties. The "pre-negotiation rebates" shown aim to isolate the commercial discounts negotiated between manufacturers and payers by estimating the difference between gross and net sales, then subtracting discounts to Medicaid, 340B and the Medicare Part D coverage drug program.[5]

*Discounts are shown from list price (i.e., 79% discount indicates a price of 21% of list)
**Pre-negotiation rebates represents the net price relevant to the negotiation (i.e., removes discounts to Medicaid, 340B and the Medicare Part D coverage drug program) and does not represent the pharmaceutical manufacturer's total gross-to-net discount; based on Hernandez et al. (JMCP) estimates
Note: IRA=Inflation Reduction Act; JMCP=definition; CMS=Centers for Medicare & Medicaid Services
Source: L.E.K. research and analysis; CMS; JMCP

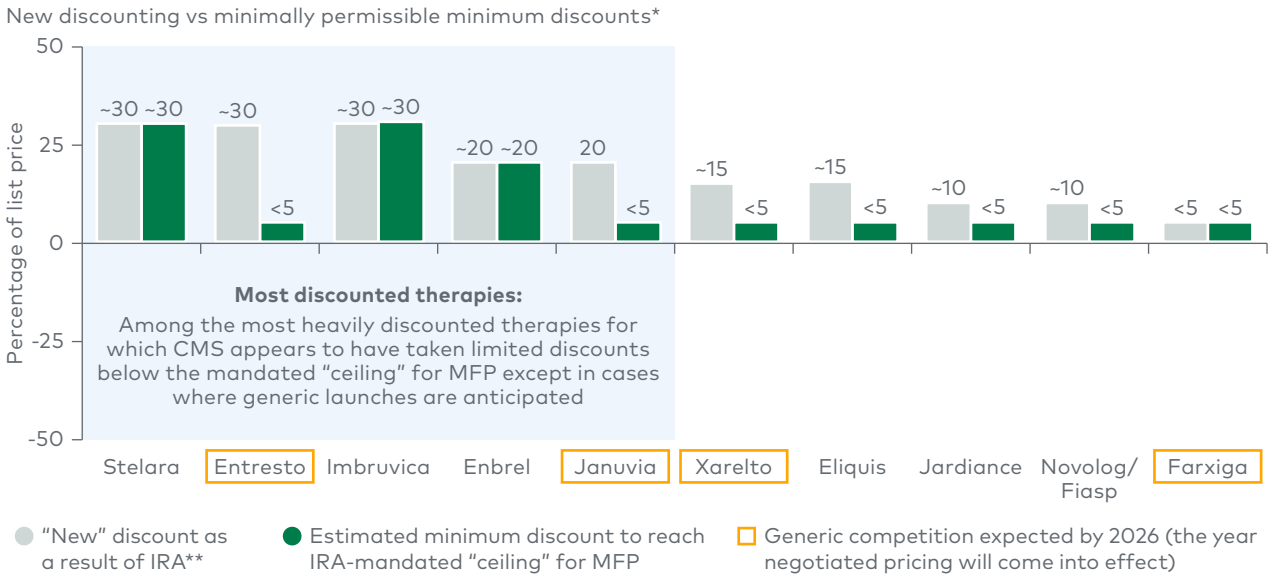
The announced discounts can be somewhat misleading when reconciled with the pre-negotiation rebates. For instance, it might seem as though cancer drug Imbruvica fared the best of the 10 products, having received the most modest discount to list price (38%); yet because it had the lowest pre-negotiation rebates (about 10%), it was actually among the most significantly impacted.

Despite having broad discretion to negotiate prices below the IRA-mandated ceiling, CMS appears to have typically been far more conservative. Regarding the products with the

steepest discounts to pre-negotiation rebates, CMS appears to have taken no significant discount below that ceiling (see Figure 3) except where generic competition is anticipated by 2026, the year negotiated products will take effect.

Figure 3

CMS appears to have taken limited additional discounts below the mandated "ceiling" in many cases



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With CMS largely deferring to the mandated ceiling rather than pushing for greater discounts, the response from the market was minimal. Across affected companies, stock prices remained flat following the announcement.

While this negotiation suggests the impact of IRA negotiations may be muted for many products, substantial risks remain

The announcement suggests that the impact of the IRA may be relatively muted for products with already high rebates. And if CMS continues to discount to the statutory minimum, future rounds may be even less burdensome. This first round of product negotiations included more agents on the market for over 16 years, which have a lower mandated ceiling for MFP than more recently launched drugs do. In the future, this number should decline, potentially leading to lower overall discounts from pre-negotiation net prices.

Still, there are ongoing risks for future negotiated products. In particular, Imbruvica's result may signal that oncology products may feel the greatest sting in future negotiations. Oncology products typically have relatively low rebating pre-negotiation, so the IRA's mandated MFP ceiling is expected to impact these products more substantially. While the next set of 15 products to be negotiated has not been confirmed, L.E.K. predicts that oncology will be two to three times more represented in the next list of products than it is in these first 10.[6]

Additionally, it is unclear how the negotiated products' competitors will be impacted, if at all. Access to these negotiated drugs, and changes in access for competitors, may be less straightforward than one would expect. Negotiated drugs may be less profitable for Part D plans, given fewer rebates and exemption from new cost-sharing requirements.[7] CMS understands that the negotiation will disrupt drug channel incentives, and intends to monitor Part D plans to make sure they remain preferred.[8]

Perhaps most important, with so much negotiating power at the discretion of CMS, pharma is not guaranteed that the relatively conservative discounting from this round of negotiation will hold fast in the future. Changes in CMS leadership and strategy may drive a significantly more aggressive posture in future negotiations — and deeper discounts. The coming of a new U.S. presidential administration in 2025 only adds greater uncertainty as to whether the result of this negotiation round will be predictive of future negotiations.

What is certain is that the IRA negotiations are having a continuing impact on pharma R&D decision-making. Some companies have publicly discontinued programs, some have shifted away from small molecules (given the shorter pre-negotiation window), some are avoiding orphan indication expansions and some are investing in next-generation products to restart the negotiation clock.[9,10] Uncertainty around negotiation selection and impact may also deter biosimilar development.[11] The prices announced in August will be in effect by 2026, but the repercussions of this action will be felt for much longer.

Our firm's Biopharma practice works with clients across a range of strategic issues, including preparing for the impact of IRA negotiations on R&D, commercial and business development strategies. If you and your organization are interested in discussing the implications of the IRA on your future opportunities, as well as optimal strategies to prepare, please reach out to us at **healthcare@lekinsights.com**.

Endnotes

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[11]PHRMA.org, "Biosimilars drive savings, but the IRA undermines their development." https://phrma.org/Blog/Biosimilars-drive-savings-but-the-IRA-undermines-their-development

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