Strategic Implications for Biopharmaceuticals: Navigating the Medicare Price Negotiation Provisions of the Inflation Reduction Act

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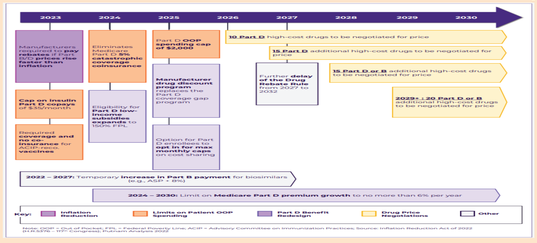
Background

- The Inflation Reduction Act (IRA) of 2022 introduced a landmark Medicare Price Negotiation provision in the United States[1].
- The main provisions of the Inflation Reduction Act will be phased in over the next several years and are described in the Figure 1

Figure 1: Main Provisions of the Inflation Reduction Act (IRA)



Objective

Our objective was to evaluate and predict the implications of the IRA, with a focus on drug development, portfolio planning, evidence requisites, launch and lifecycle management (LCM) strategy.

Methods

- Implications of IRA were drawn using the Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress)[1], the Congressional Budget Office's "Additional Information About Prescription Drug Legislation" Report[2] and relevant secondary desk research.
- Many of the conclusions drawn are predictions based on the financial incentives implicit in the Inflation Reduction Act of 2022 and rely on the experience of the authors in advising pharmaceutical manufacturers on drug development, data evidence requisites, pricing and market access strategy, and competitive differentiation strategy.
- Putnam's proprietary Medicare Price Negotiation Database – which predicts drugs that are most likely to be selected for negotiation in future rounds based on a combination of CMS data, drug-specific analyst revenue projections, and a detailed review of all relevant inclusion and exclusion criteria – was also used to inform our conclusions.[3]
- An in-depth review of the provisions within the IRA was conducted, particularly related to the criteria for Medicare Price Negotiation in years 2026-28 with a focus on key areas:
  - Impact on pharmaceutical manufacturer investment priorities
  - Development, launch and LCM strategies across various drug classes and therapeutic areas
  - Implications on data evidentiary needs to build a robust value proposition and support the pricing negotiation process.

Table 1: Implications related to IRA on Investment Priorities, Life Cycle Strategy & Evidence Generation

Focus Area	Potential Implications
Investment Priorities	• Potential shift in strategic focus within the biopharmaceutical industry. • Differential eligibility timelines for price negotiation post-FDA approval for biologics compared to small molecules gives biologics a longer pre-negotiation runway to realize a return on their substantial development costs, likely yielding a more favorable Net Present Value (NPV) calculation at the time of investment vs. small molecule drugs targeting the same indication. • The Act could influence investment directions, potentially favoring therapeutic areas and technological modalities with additional protections from IRA-imposed risks, including plasma derived therapies, vaccines, gene therapies, and orphan drugs. • Therapies targeting indications in pediatric or young adult populations which historically have been subject to underinvestment due to their high Medicaid exposure may be perceived as relatively more attractive going forward. • Given the increase in manufacturer liability in the Medicare Part D catastrophic coverage phase (20% in 2025 vs. 0% in 2023 due to Part D redesign), products with a lower per patient cost but with a large population size will be more attractive. • Products that would have historically faced cost-based abandonment issues might be less risky to pursue given the introduction of Out-of-Pocket (OOP) cost limits under Medicare Part D. • The Act also affords temporary protection (until 2029) to "small biotech" companies that derive most of their revenue from one drug, which in the near term may make certain co-commercialization partnership models between these small biotech and larger manufacturers potentially more attractive than direct acquisitions.
Launch and Life Cycle Strategy	• Drug manufacturers have typically followed a "land and expand" model for indication sequencing, starting first with smaller, less costly trials of novel molecules in a narrow or heavily pretreated population to de-risk the asset and subsequently pursuing indications for larger populations. • In a post-IRA world where a first approval starts the Medicare negotiation clock, the older pattern of indication building over 10 or more years is unlikely to be viable. Manufacturers may feel compelled to pursue larger indications first and the smaller indications subsequently. • A strategic shift towards conducting clinical trials and seeking regulatory approval for different indications in parallel instead of sequentially could be observed.
Evidence Requisites	• A comprehensive evidence generation strategy focusing on patient subgroups of interest (including elderly patient population) would need to be an essential component of LCM going forward. • Robust data evidence post-FDA approval on clinical, humanistic/patient reported and economic outcomes in the elderly (≥65 years) population treated with the selected drugs could play a significant role in assessing and/or establishing value and could be leveraged as part of pricing negotiation. • Additional comparative analyses in the elderly population versus standard of care/more recent drugs approved for same indications could also provide added leverage for some of the selected products at the time of negotiation.

Results

- Even though the first round of Medicare price negotiations began in early 2024, uncertainty remains regarding the implementation of the program and its ultimate effect on near-term revenue potential for certain drug categories.
- With impending threats to vital revenue streams, drug developers will have to think critically about pipeline development and launch strategy to optimize risk benefit for all key stakeholders including patients, while continuing to address key clinical unmet needs.
- A deep understanding of negotiation eligibility criteria, potential exemptions, and the therapeutic areas most likely to be impacted over time can help manufacturers mitigate these risks.
- The therapeutic classes most impacted by Medicare price negotiation are likely to differ substantially in future rounds.
- While the first round of selections disproportionately affected cardiovascular and diabetes treatments (with 7 of the 10 selected drugs carrying primary indications in these areas[4]), the 2027 and 2028 selections are likely to see greater impact in oncology, respiratory, and metabolic indications.
- The threshold for drug selection is likely to decline as HHS works its way down the list of mega-blockbusters.
- **Table 1** summarizes the authors' predictions regarding how the Inflation Reduction Act of 2022 is likely to impact investment priorities, launch and life cycle management strategies and evidentiary needs.

Conclusion

- The Medicare Price Negotiation provision of the IRA could lead to significant strategic shifts in the biopharmaceutical industry.
- The industry will need to balance fulfilling responsibilities to shareholders to generate a return on investment with continuing to address unmet clinical needs, which will require increased emphasis on robust evidence generation in the elderly patient population to support Medicare price negotiations.

References

1. Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress). https://www.congress.gov/bill/117th-congress/house-bill/5376.
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4. https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/

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