Inflation Reduction Act: Assessing the impact for new drug development, launch, Life Cycle Management and Loss of Exclusivity strategy

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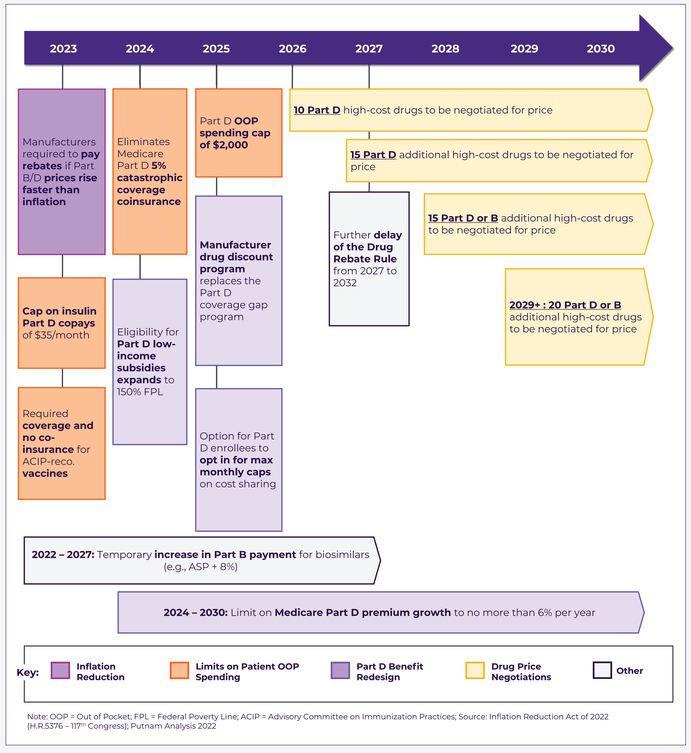
Background and objective

The Inflation Reduction Act (IRA) will have an impact on drug development and commercialization strategy throughout the product lifecycle.

The main provisions of the Inflation Reduction Act will go into effect starting in **2023** and are described in the Figure below:



Note: OOP = Out of Pocket; FPL = Federal Poverty Line; ACIP = Advisory Committee on Immunization Practices; Source: Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress); Putnam Analysis 2022

This study aimed to assess the potential consequences on the different steps of the drug development process.

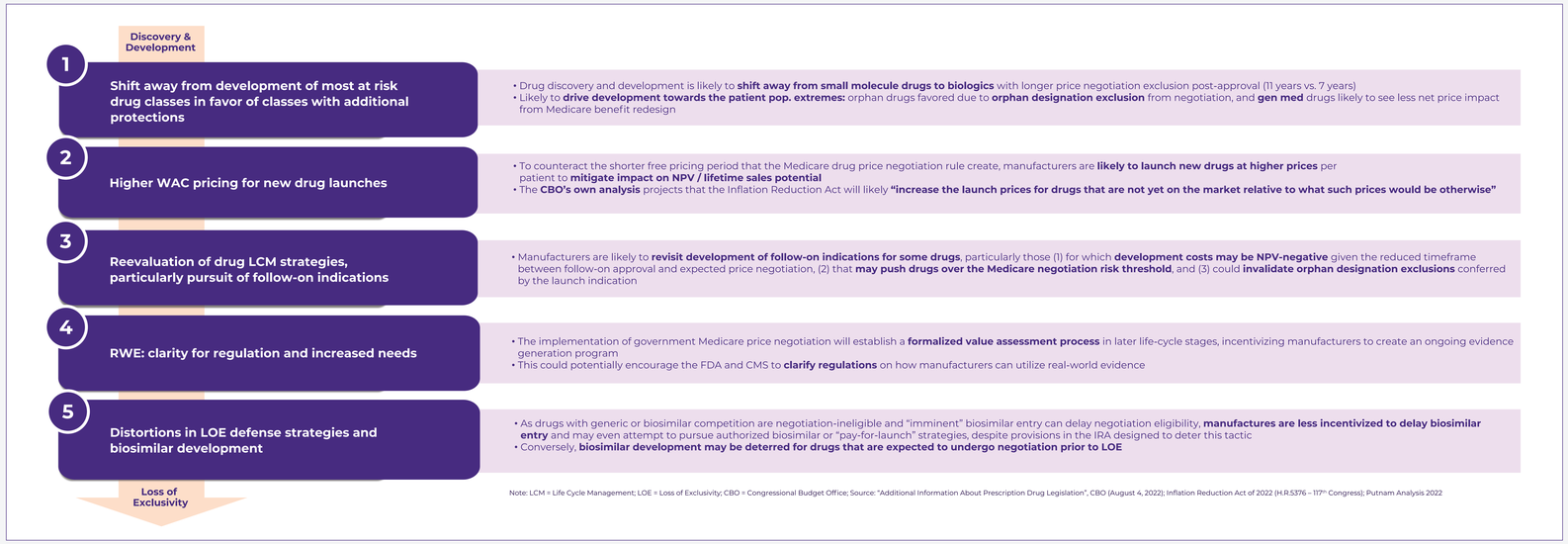
Methods

We analyzed the **preliminary implications of the IRA** for **drug development**, **launch**, Life Cycle Management (**LCM**) and Loss of Exclusivity (**LOE**) strategy 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, pricing, and competitive strategy.

Results

The Figure below summarizes the authors' predictions regarding how the **Inflation Reduction Act of 2022** is likely to impact new drug development, launch, LCM and LOE strategy:



Note: LCM = Life Cycle Management; LOE = Loss of Exclusivity; CBO = Congressional Budget Office; Source: "Additional Information About Prescription Drug Legislation", CBO (August 4, 2022); Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress); Putnam Analysis 2022

1 Drug Discovery and Development
Drug discovery and development emphasis may **shift away from small molecule drugs to biologics** with longer protection from price negotiation (11 years vs. 7 years exclusion post-approval) and **towards the patient population extremes**, as lower cost general medicine drugs are less impacted by the Medicare Part D benefit redesign and higher cost single orphan drugs are excluded from price negotiation.

2 Product Launch and Pricing Strategy
For new drug launches, to counteract the shorter free pricing period that the Medicare drug price negotiation rule creates, manufacturers are expected to launch new drugs or biologics at **higher prices** per patient to **mitigate the overall impact on lifetime sales potential**.[2]

3 Life Cycle Management
When assessing LCM strategies, manufacturers may revisit and ultimately forgot the development of follow-on indications, particularly those:

1. for which development costs may be **NPV-negative** given the reduced timeframe between follow-on approval and expected price negotiation
2. that may **push drugs over the Medicare negotiation risk threshold,**
3. could **invalidate orphan designation exclusions** conferred by the launch indication

In general, we expect that the number of manufacturers pursuing multiple indications for the same molecular entity with a staggered clinical development plan is likely to decline, ultimately **reducing the number of therapeutic options** that patients have available. Manufacturers will also be **less likely to develop novel formulations** (e.g., extended release formulations of oral drugs) of their products, as the sales of all formulations and strengths of drugs composed of the same active moiety and produced by the same primary manufacturer will be combined for the purposes of determining selection for price negotiation, with eligibility assessed on the basis of the FDA approval date for the first formulation.

However, fixed dose combination drugs combining two or more active moieties will be assessed separately for the purposes of determining selection for price negotiation, which may lead to greater interest in development follow-on products that include one or more additional active moieties (e.g., subcutaneous Darzalex Faspro vs. IV Darzalex,).

4 Real World Evidence
The implementation of Medicare price negotiation by the **IRA** will establish a **formalized value assessment process** in later life-cycle stages, requiring manufacturers whose products are selected for price negotiation to submit, among other information, evidence about their product's clinical value relative to alternative treatments (e.g., comparative effectiveness data, prescribing information, and residual unmet need) to the Department of Health and Human Services (HHS). This requirement incentivizes manufacturers to create an **ongoing evidence generation program** that supports the product's entire life cycle and adapts to changing value requirements.
Manufacturers can leverage life-cycle value assessment to capitalize on real-world evidence and address uncertainties that may exist at the time of launch or subsequently arise. This enables them to tackle outstanding questions and improve their product's overall perceived value and negotiating position.
The implementation of **IRA** could **trigger the manufacturers to seek additional clarity from CMS regarding the role (and limitations of) RWE in the price negotiation** process a

5 Loss of exclusivity
Finally, as drugs with generic or biosimilar competition are negotiation-ineligible and "imminent" biosimilar entry can delay negotiation eligibility, **manufacturers may be less incentivized to employ legal tactics to delay biosimilar entry** as the net sales impact of competition from one biosimilar entrant is likely to be less severe than the imposition of a Maximum Fair Price (MFP) following Medicare price negotiation. Conversely**, biosimilar development may be deterred for drugs that are expected to undergo negotiation prior to patent expiry** as the net sales potential for the molecular entity will be significantly reduced.

Conclusion

This qualitative analysis illustrates how the IRA can impact the drug lifecycle from early development to LOE.
Further research will be needed to monitor the consequences of the Act, expected or unexpected, over time.

References:
1. Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress). Retrieved from https://www.congress.gov/bill/117th-congress/house-bill/5376
2. Congressional Budget Office "Additional Information About Prescription Drug Legislation".(2022) Retrieved from https://www.cbo.gov/publication/58355
3. Steve Usdin, Navigating the Inflation Reduction Act. (2022) Retrieved from https://www.biocentury.com/article/646192/navigating-the-inflation-reduction-act

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