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The Indirect Impacts of the Inflation Reduction Act on Pharmaceutical Pipeline and Portfolio Strategy

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Introduction

In August 2022, President Joe Biden signed into law the Inflation Reduction Act (IRA) aimed at reforming federal spending toward lowering healthcare costs, among numerous other aims. Although the future of this legislation is under question, as will be explored toward the end of this discussion, the enactment of the IRA marks the start of an inevitable waterfall of bipartisan policy action and drug pricing reform, which industry stakeholders will need to monitor. At a little more than one year since the passage of this act, it is likely that every drug manufacturer understands the tenets of the IRA and its direct implications for cross-functional decision making. However, this brief publication seeks to build on that understanding, by illustrating the indirect implications of the IRA that manufacturers will need to consider as part of their new product planning and portfolio strategy.

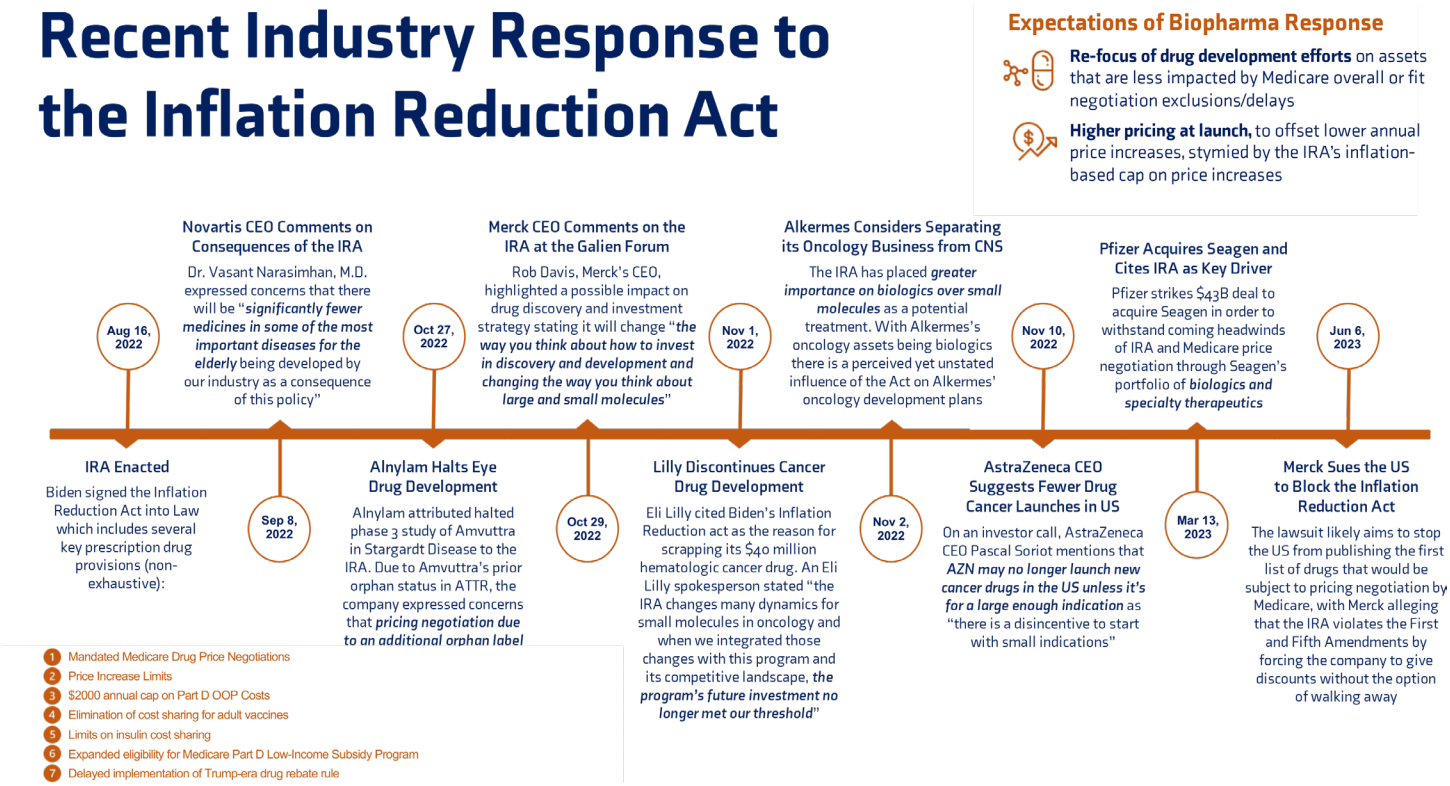
Market Sentiment

Before evaluating indirect IRA implications, it is beneficial to briefly review market sentiment towards the IRA and the changing policy landscape. While IRA-related actions taken by pharmaceutical executives do not seem to have had a negative impact on financial valuation or market capitalization overall, the strategic responses illustrate which provisions of the IRA pharmaceutical manufacturers are most wary of. Examples include:

Price Negotiation: As the shining achievement of the IRA, all manufacturers are wary of the implications of Medicare's ability to negotiate drug prices. With biologics being given a 13-year period prior to being eligible for negotiation, compared to the shorter 9-year period for small molecules, manufacturers may find incentives to pursue assets in the biologic and cell/gene therapy markets, potentially devaluing small molecule programs.	Lilly: In November 2022, Eli Lilly withdrew its Phase I blood cancer small molecule asset due to concerns around the IRA's impact on small molecule oncology assets.
	Alkermes: Also in November 2022, Alkermes announced the spin-off of a pure-play, development-stage, oncology-focused division to capitalize on biologics longer period of exemption from price negotiation.
Price Negotiation: The IRA exempts orphan drugs from the Medicare negotiation process, but only for drugs approved in a singular orphan indication. This may impact how pharma considers portfolio strategy and life cycle planning in the rare/orphan archetype.	Alnylam Pharmaceuticals: In October 2022, Alnylam announced the halt of its Phase III program for Amvuttra in Stargardt disease, given the drug is already approved for rare disease hereditary ATTR amyloidosis and will be limited by the single-orphan exclusion of the IRA.
Part D Redesign: The out-of-pocket (OOP) spending cap for Part D beneficiaries beyond the catastrophic coverage limit will increase fulfilment and adherence for otherwise inaccessible, high-cost, specialty therapies. This may also increase the value attributed to assets in the specialty care, pharmacy benefit archetype (as further outlined in Figure 4, which describes the characteristics a sample of product archetypes most likely to be impacted by the IRA).	Pfizer / Seagen: In March 2023, Pfizer completed its acquisition of Seagen, a manufacturer of numerous specialty assets, citing provisions of the IRA as key drivers for the transaction.

Figure 1.

Recent Industry Response to the Inflation Reduction Act



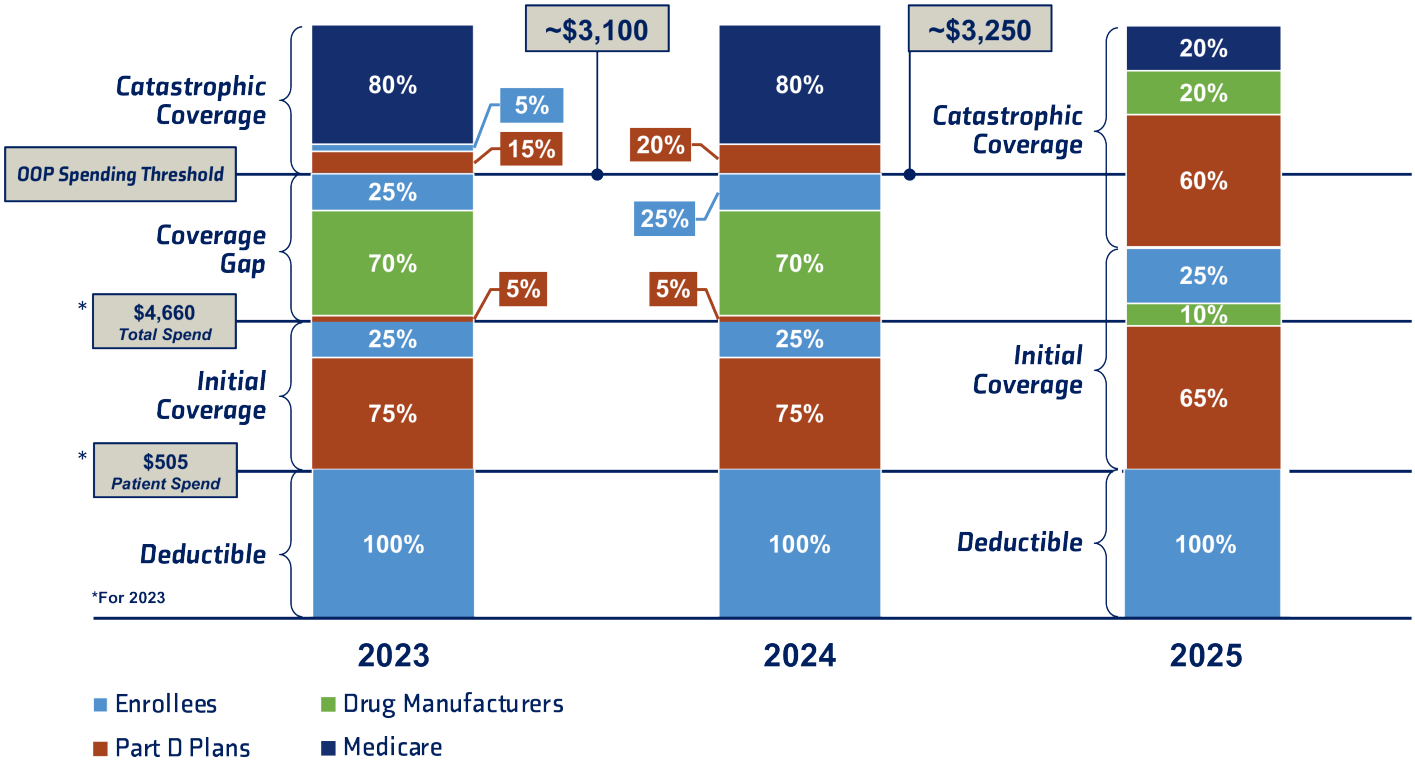
Indirect Impacts of Key Provisions of the IRA

Part D Redesign: IRA Part D Redesign limits patient out-of-pocket costs, removes the "donut hole" or coverage gap, redistributes Medicare cost burden to manufacturers and Part D plans, and reduces the threshold at which catastrophic coverage begins by about ~40%.

Indirect Impact of Part D Redesign - Payer Cost Sharing: Although manufacturers will statutorily be subject to 20% of drug costs in the catastrophic phase under the IRA, this cost burden should be perceived as the 'floor' in the context of the higher cost burden that plans will also be subject to (i.e., 60% in the catastrophic phase in 2025, compared to 20% in 2024). Given the increased exposure that Part D plans will face in the catastrophic phase in 2025 and beyond, payers may push some of that cost burden towards manufacturers in the form of increased demand for rebates, resulting in manufacturers potentially being subject to more than the statutory 20%. This is also more likely to occur in mature and/or competitive markets, such as for assets in certain oncology or cardiometabolic indications, as is further illustrated in Figure 4.

Figure 2.

Pre- and Post-IRA Cost Burden by Channel



Indirect Impact of Part D Redesign – Temporal Considerations of Catastrophic Cost Sharing for Manufacturers: In some indications where patients use multiple therapies, experience comorbidities, or are prescribed high-cost specialty regimens (e.g., oncology), patients are likely to meet the catastrophic limit early in the calendar year. Given that, manufacturers who were previously paying only during the coverage gap in the same indication, would be subject to 20%+ cost-share across the calendar year meaning many companies with branded assets in markets resembling the aforementioned characteristics will see a significant erosion of potential net revenue.

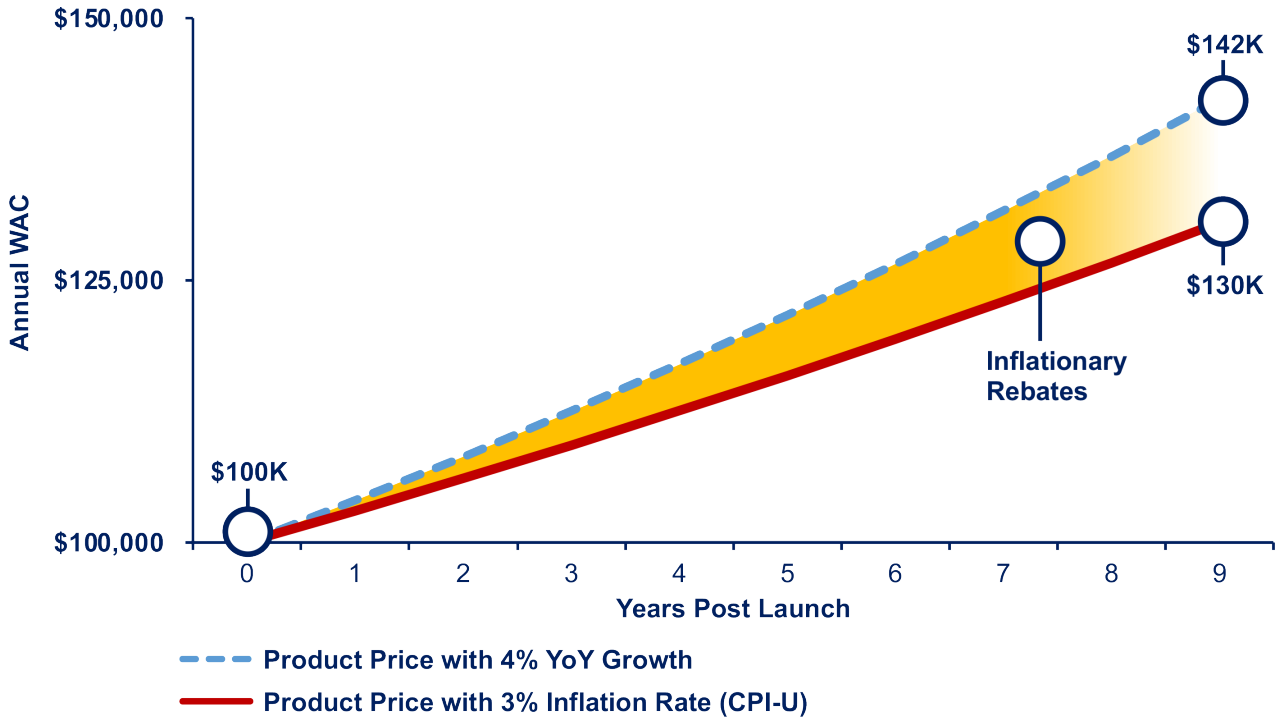
Price Negotiation: As outlined in the IRA, the 50 Part B and Part D Medicare drugs with the highest spend (spread across 2026-2031) may have price controls, or price negotiations, implemented to lower prices and overall spend. Through this "negotiation" process, a maximum fair price (MFP) will be determined, and pricing for products may utilize the negotiated price or contract price, whichever is lower.

Indirect Impact of Price Negotiation – Competitive Negotiations: Even if a manufacturer's product isn't selected for direct CMS negotiations, manufacturers will need to be aware of negotiation activity within the competitive landscape. Drugs that are not selected for price negotiation but are in the same market basket as negotiated assets may face subsequent downward pricing pressure from payers (in both the Medicare and Commercial channels). This is most likely relevant where assets are deemed to be therapeutically interchangeable or provide little differentiation to patients. Additionally, drugs that are not particularly high cost, but are launched or approved in indications with sizeable Medicare patient populations may also be targets for price negotiation given their aggregate cost burden to Medicare, as is alluded to in Figure 4 with cardiometabolic drugs.

Inflation-Based Rebating: Starting in 2022, manufacturers are required to pay a rebate to the federal government if prices for Part B single sourced drugs and biologics or Part D drugs rise faster than the rate of inflation, measured by CPI-U.

Indirect Impact of Inflation-Based Rebating – Commercial Revenue May Outweigh Medicare Costs: Under the IRA, manufacturers are required to pay back, in the form of rebates, the difference between the inflation rate and the price growth rate. For example, if a product's price increased by 4% and CPI-U was 3% for that defined time period, the manufacturer would owe 1% in inflationary rebate penalties to CMS (Figure 3). In many scenarios, revenue in the Commercial channel may offset negative impacts on revenue in Medicare created by inflationary rebates, dependent upon the distribution of commercially insured vs. Medicare lives. Manufacturers may also consider channel-dependent differential price growth strategies in the context of this IRA provision and their portfolio.

Figure 3.



Indirect Impacts of the IRA on Portfolio Strategy

In light of the combined effects of these key provisions of the IRA, drug manufacturers will need to carefully consider their portfolio and new product planning strategies (including launch and LCM pricing). This critical, policy-informed decision-making becomes even more crucial for organizations whose portfolios contain products with characteristics most likely to be impacted directly or indirectly by the IRA.

Figure 4.

		Part D Redesign			Price Negotiation		Inflation-Based Rebating	Other Impacts
		Part D Redesign – Direct Impacts	Payer Cost Sharing	Temporal Catastrophic Cost Sharing	Price Negotiation – Direct Impacts	Competitive Negotiations	Inflation Rebates – Direct Impacts	Other Drug Pricing Reform Impacts
Benefit	Pharmacy Benefit							
	Medical Benefit							
Technology	Small Molecule							
	Biologic							
	Biosimilar							
	Cell/Gene Therapy							
Cost	Specialty							
	Non-Specialty							

Not directly relevant to product characteristic
No/low negative impact expected on manufacturers who have portfolio or pipeline products with this characteristic
Some negative impact expected on manufacturers who have portfolio or pipeline products with this characteristic
Significant negative impact expected on manufacturers who have portfolio or pipeline products with this characteristic

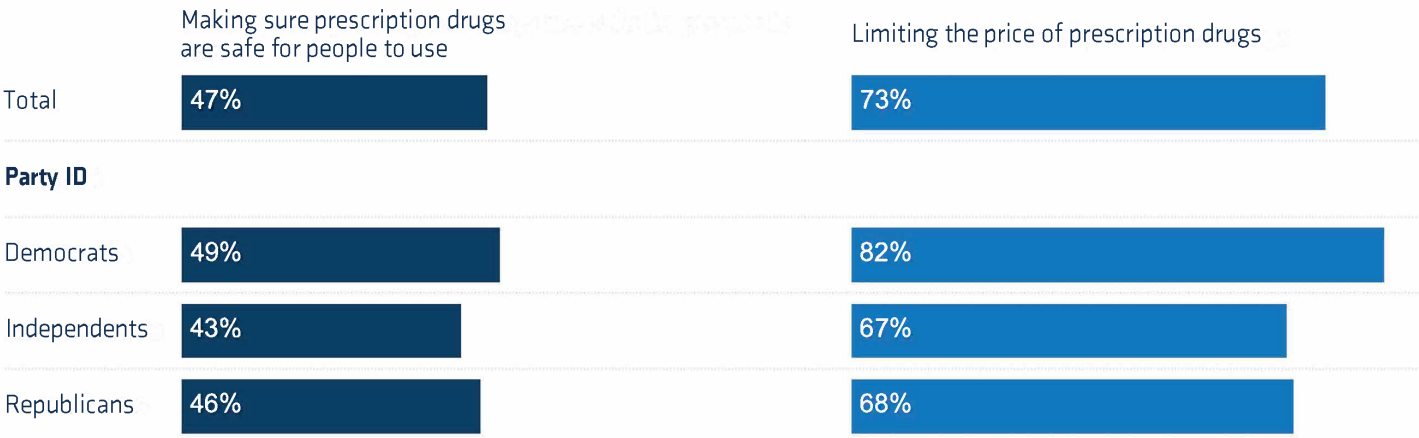
As demonstrated in Figure 4, there is notable complexity in how provisions of the IRA will impact different product characteristics. The heat map visualization in Figure 4 emphasizes the interplay within product portfolios that will influence the strategic considerations of drug manufacturers. In addition to the elements highlighted in Figure 4, further intricacies exist along the axes of specific therapeutic areas, indications, disease prevalences (e.g. single-orphan provision), and other product-specific attributes.

Despite potential uncertainties around the viability of the IRA arising from ongoing lawsuits involving Merck, BMS, BI, and others, it is important to note the strong bipartisan support for drug pricing reform (Figure 5), ongoing initiatives from the Centers for Medicare & Medicaid Innovation (CMMI) (e.g. High-Value Drug List Model, or "$2 generic" model), and various other drug pricing priorities. Taken together, these trends confirm the market's unequivocal shift toward exerting pressure on drug manufacturers and other key stakeholders to reduce drugs costs for Americans. Triangle Insights can support pharmaceutical manufacturers in navigating an ever-evolving policy landscape with respect to drug pricing reform and partnering within the industry to develop and refine portfolio and pipeline strategies that remain adaptable and cogent in the face of change.

Figure 5.

Majorities Across Partisanship Say There Is Not Enough Government Regulation When It Comes To Limiting The Price Of Prescription Drugs

Percent who say there is not as much regulation as there should be when it comes to...



NOTE: See topline or full question wording.

Sources:

Figure 1: Company reports; Kaiser Family Foundation ("Explaining the Prescription Drug Provisions in the Inflation Reduction Act"); Gelman, Max. "Updated: Eli Lilly Blames Biden's IRA for Cancer Drug Discontinuation as the New Pharma Playbook Takes Shape." Endpoints News, Endpoints News, 1 Nov. 2022, https://endpts.com/eli-lilly-rolls-snake-eyes-as-it-axes-two-early-stage-drugs-including-a-40m-cancer-therapy-from-fosun; EndPoints News "IRA impact: AstraZeneca and Merck CEOs warn of oncology drug development shifts" https://endpts.com/ira-impact-astrazeneca-and-merck-ceos-warn-of-oncology-drug-development-shifts/; Usdin, Steve. "Narasimhan: Inflation Reduction Act Forcing Pharmas to Rethink Pipelines." BioCentury, Biocentury, 8 Sept. 2022, https://www.biocentury.com/article/645066/narasimhan-inflation-reduction-act-forcing-pharmas-to-rethink-pipelines

Figure 2: "Explaining the Prescription Drug Provisions in the Inflation Reduction Act." Kaiser Family Foundation, 24 Jan. 2023

"First Anniversary of the Inflation Reduction Act: Millions of Medicare Enrollees Saving on Health Care Costs." U.S. Department of Health & Human Services, 16 Aug. 2023

"Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin." Centers for Medicare & Medicaid Services, 26 Sep. 2022

"Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." Centers for Medicare & Medicaid Services, 30 Jun. 2023

"Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments." Centers for Medicare & Medicaid Services, 15 Mar. 2023

"Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments." Centers for Medicare & Medicaid Services, 9 Feb. 2023

Figure 5: Public Opinion on Prescription Drugs and Their Prices." Kaiser Family Foundation, 21 Aug. 2023