Pharmaceuticals
2025 Preview

CAPSTONE

Prescription for Risk: Drug Price Cuts Loom, Little Recourse for Insurers

THE BOTTOM LINE

Capstone believes the healthcare impacts of Biden's Inflation Reduction Act will be felt in 2025, posing underappreciated risk and little recourse for payors, manufacturers, and pharmacies. The Trump Administration will revisit the Most Favored Nations (MFN) pricing model, which would significantly disrupt the pharmaceutical supply chain. However, concerns about the BIOSECURE Act's impact are overstated, and the bill is unlikely to pass.

Outlook at a Glance

- IRA UNLIKELY TO BE ROLLED BACK, NEGOTIATIONS POSES RISK OF MFN RETURN, A RISK TO PHARMA
- MEDICARE PART D REDESIGN POSES UNAPPRECIATED HEADWINDS WITH LITTLE RELIEF FOR INDUSTRY
- BIOSECURE CONCERNS STILL INFLATED, ELEVATION OF SEN. PAUL FURTHER PROTECTS WUXI

IRA Unlikely to be Rolled Back, Negotiations Poses Risk of MFN Return, a Risk to Pharma

Winners	None
Losers	Pharmaceutical Manufacturers selected for Medicare Price Negotiations, including Novo Nordisk A/S (CPH: NOVO-B), Pfizer Inc. (PFE), and others

While the Republican party has opposed the Inflation Reduction Act (IRA), Capstone believes the pharmaceutical provisions within the broader law are unlikely to be rolled back. This is because of the logistical difficulties of implementing a repeal and undoing the IRA's drug pricing provisions, which would lead to an increase in federal spending. While 2026 negotiated drug prices were largely in line with currently available market net prices (minimizing impacts), we believe there is a significant risk that the incoming Trump administration would further reduce drug prices to match international prices.

During the previous Trump administration, the Centers for Medicare and Medicaid Services (CMS) proposed a demonstration coined the "Most Favored Nation Model," which would align Medicare payments for physician-administered drugs to the lowest adjusted price paid by a country that is a member of the Organization for Economic Cooperation and Development (OECD). While the rule was blocked and never implemented because it violated the Administrative Procedure Act, Capstone believes the Trump administration will have an opportunity to revisit its implementation through the Medicare Drug Negotiation program—without actual rulemaking.

While Trump, during his first term, largely deferred to his cabinet and appointees for healthcare policy, he expressed strong interest in the MFN model, arguing that under the current system, seniors in the US were effectively subsidizing the cost of medications for people in other countries. While Trump largely deflected questions about implementing MFN pricing during the campaign, members of his inner circle have increasingly shown they are interested in revisiting the comparative price disparities:

> *"Legislators should cap drug prices so that companies can't charge Americans substantially more than Europeans pay."*
>
> Robert F. Kennedy Jr., Trump's Nominee for HHS Secretary, WSJ Op-Ed, Nov. 2024

> *"... But other nations then free-ride on us, by simply accessing those therapies at a *much* lower cost AFTER they're approved for us. Countries like Germany, etc, need to start sharing the burden, or else they shouldn't get access to the technologies. Can't have it both ways."*
>
> Vivek Ramaswamy, Planned DOGE Co-Leader, X, Nov. 2024

> *"Yeah, a significant part of the reason drugs cost more in the USA than other countries is that Americans shoulder most of the R&D costs."*
>
> Elon Musk, Planned DOGE Co-Leader, X, Nov. 2024

> *"[President Trump] obviously was interested in pursuing and has stated that he's still interested in pursuing most favored nations, which is completely unorthodox from a Republican perspective."*
>
> Theo Merkel, Director of Private Health Reform Initiative at Paragon Health Institute, Politico, Oct. 2024

> *"Just signed a new Executive Order to LOWER DRUG PRICES! My Most Favored Nation order will ensure that our Country gets the same low price Big Pharma gives to other countries. The days of global freeriding at America's expense are over..."*
>
> President Trump, X, Sep. 2020

Given that CMS has broad authority to negotiate and set prices for selected products under the IRA, Capstone believes Trump could direct the agency to ensure that any finalized drug price is at maximum equal to the lowest of an OECD basket—effectively implementing MFN. Importantly, should the Trump administration pursue deep cuts or benchmark prices through the Medicare Drug Negotiation program, the prices (like other IRA provisions) would be precluded from both administrative and judicial review.

Capstone believes that, depending on the spread of a particular medication's net price to the price it is available for in other countries, this new era of IRA drug negotiations could pose underappreciated risks to the revenue and profitability of drug makers.

Medicare Part D Redesign Poses Unappreciated Headwinds with Little Relief for Industry

Winners	None
Losers	**Insurers and Pharmacy Benefit Managers:** including UnitedHealth Group Inc. (UNH), CVS Health Corp. (CVS), Cigna Group (CI), Elevance Health Inc. (ELV), Humana Inc. (HUM) **Pharmaceutical Manufacturers:** including Takeda Pharmaceutical Co. Ltd. (TYO; 4502), Johnson & Johnson (JNJ), AbbVie Inc. (ABBV), Eli Lilly and Co. (LLY), and others **Infusion Centers:** including Option Care Health Inc. (OPCH) **Specialty Pharmacies**

Capstone believes that investors underappreciate the risks arising from the Medicare Part D redesign. This is the first and only substantial change to the Part D program since its creation in 2003. The redesign fundamentally restructures the program's payor responsibilities, increasing liabilities for manufacturers and payors in exchange for a $2,000 out-of-pocket drug cap. With this, forecasting expenses correctly and ensuring adequate pharmaceutical economics is more difficult than ever before.

As part of the redesign, insurers will get larger prospective payments to reflect the increased liability, but insurer margins will be more sensitive to fluctuations in spending or unexpected high-cost medication utilization. In previous years, actuarial math was less important because insurers relied on retrospective government reinsurance for high-cost drug spending rather than prospective direct subsidy payments. However, the Part D redesign flips this responsibility, making predictions of drug spending crucial to protecting plan margins.

Investors are also underappreciating the expected migration to Medicare Advantage (MA) from traditional Medicare as standalone drug plans exit the market. While President Biden's Voluntary Premium Stabilization demonstration minimized the expected premium spike in standalone drug plans, there has still been a 35% decrease in the number of standalone plans in 2025 from 2024. Capstone believes the absence of prescription drug plans (PDP) in certain regions will accelerate movement into MA plans, leading to risk pool volatility and adverse selection.

Manufacturers of drugs that have annual price tags above $24,000 will be most impacted by the change to an uncapped 20% catastrophic liability, which will pressure not only their margins but also pharmacy benefit manager (PBM) rebates and specialty pharmacy acquisition discounts. In sum, insurers, PBMs, manufacturers, pharmacies, and any other stakeholder influenced by the pharmaceutical supply chain will experience volatility and have to revisit positioning in the market.

Capstone believes it will take years to fully appreciate the impact of the restructuring of the Part D benefit and to adjust payor and manufacturer profit strategies to account for it. In the meantime, we believe the 2025 plan year poses severe and unexpected risks to the pharmaceutical market.

BIOSECURE Concerns Still Inflated, Elevation of Sen. Paul Further Protects WuXi

Winners	WuXi AppTec (HKG: 2359), WuXi Biologics (HKG: 2269), Pharmaceutical Manufacturers, including AstraZeneca PLC (LON: AZN) and Merck & Co. Inc. (MRK)
Losers	Charles River Laboratories International Inc. (CRL), Labcorp Holdings Inc. (LH), and other contract research organizations that would take on increased demand from the passage of the BIOSECURE Act

Capstone believes that investors are assigning an excessively high probability to the likelihood that the BIOSECURE Act becomes law, and also overestimating the anticipated impacts the law would have. While investors are focusing on anti-China policies, particularly in the wake of Donald Trump's victory in the election last month, we believe that there continues to be a strong divide in perspectives regarding policy within the Republican caucus in the Senate that will impede the bill's passage. However, should the bill pass as written, we believe the immediate and short-term impact will be modest as it has been narrowed and now only bans the companies from executing government contracts, which are limited.

Within the Senate, there is continued friction between Senators Bill Hagerty (R-TN) and Rand Paul (R-KY) between whether there should be named companies included in the bill. Paul, who is expected to be the new chair of the Senate Committee on Homeland Security and Governmental Affairs (HSGAC), opposed BIOSECURE in its current form, citing free-market grounds as the legislation explicitly names companies. On the other side, Hagerty, who co-sponsored the BIOSECURE Act, contends that naming the company is imperative to properly limit the Chinese Communist Party's influence, we believe that this divide will be difficult to bridge in the next Congress. With this continued impasse, we believe the legislation will stall, diminishing any impact it may have.

Importantly, the traditional healthcare committees of jurisdiction continue to be silent on the matter. Similarly, while advocacy groups have not vocally opposed the bill for fear of appearing to side with China, we believe there continue to be concerns about the broader impacts on both pharmaceutical availability and pricing by onshoring or otherwise disrupting already strained supply chains. With this, stakeholders have recommended floating a second CHIPS and Science Act directed toward pharmaceutical innovation to drive the outflux of operations from China or China-associated companies. However, we believe these conversations are just beginning.

About Capstone

- Capstone is a global, policy-driven strategy firm helping corporations and investors navigate the local, national, and international policy and regulatory landscape.

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We tailor our work to help our clients predict meaningful policy and regulatory backdrops, quantify their impact, and recommend strategies that unveil novel opportunities and avoid hidden risks.

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