Navigating Market Access with Magnolia

2025 and Beyond - What To Expect with Tariffs and Pricing Policies

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### Navigating Market Access with Magnolia: Today's Speakers



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David Murphy Partner GDLSK



Chris Schott Partner Latham & Watkins









#### **US Drug Pricing Policies**



Most Favored Nation (MFN) Pricing – What it Looks Like and its Impact



#### The Most Beautiful Word: Tariffs



#### **Audience Discussion**



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# US Drug Pricing Policies Pre-MFN



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### The Government's First Foray into Price Setting Was Successful, According to CMS Comparison of

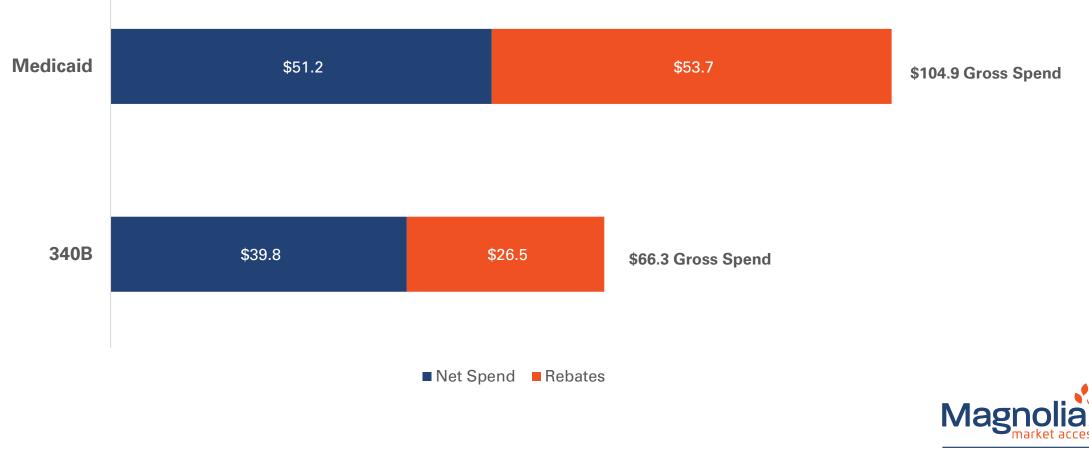




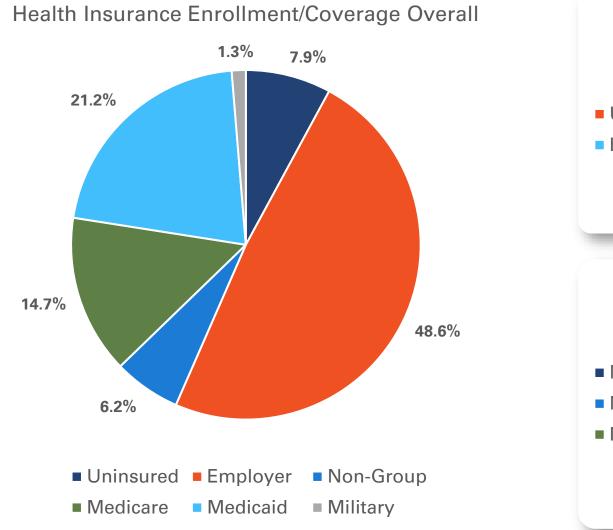
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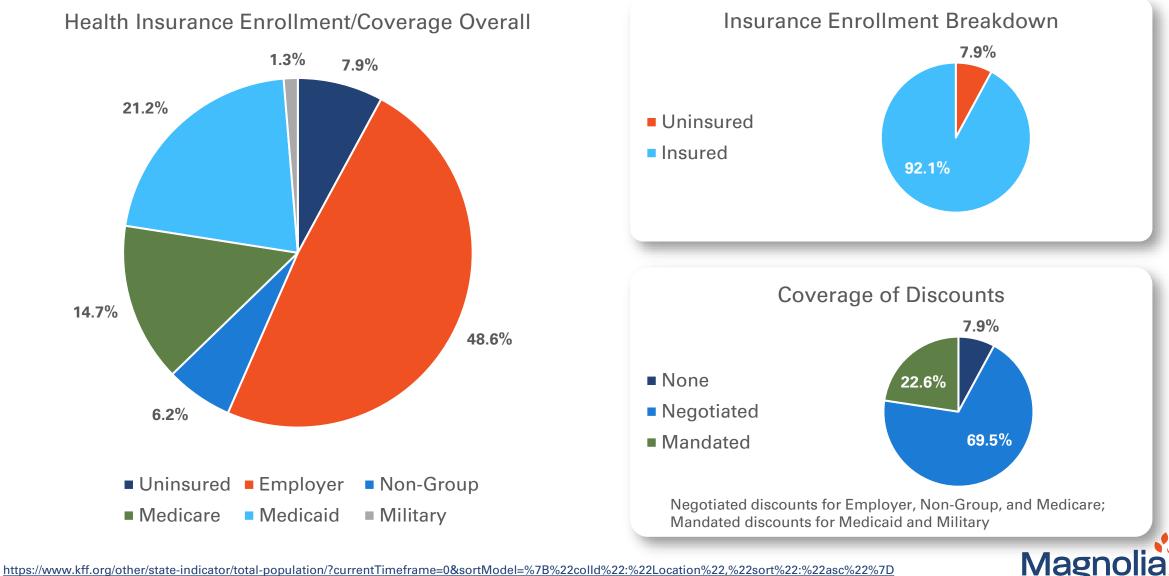
### **Gross to Net Spending for Mandated Rebates in Medicaid & 340B**

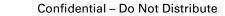
FY2023 Medicaid & 340B Gross Spend, Rebates, and Net Spend for Outpatient Prescription Drugs



### **US Population Insured Status and Drug Discounts**







# MFN: What it Looks Like and Its Impact



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# The Next Step: Most Favored Nation Pricing - Potential Reference Countries with ≥60% of US' Per Capita GDP<sup>1</sup>

OECD Countries with Per Capita GDPs ≥60% of US GDP\*

Australia Canada Germany Israel Norway Austria Denmark Iceland Luxembourg Sweden Belgium Finland Ireland Netherlands Switzerland



[1] World Bank Open Data. https://data.worldbank.org/indicator/NY.GDP.PCAP.CD. Accessed June 13, 2025.

\* Note that this list excludes several G7 countries (i.e., France, Italy, Japan, and UK), as their respective per capita GDPs do not exceed the 60% US threshold. However, these countries may be included regardless of per capita GDP depending on the specifics of the MFN policy.



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### **Ex-Us Prices Compared to US Based on August/September 2024**

Drug/Dose (Pkg Size)	US WAC	Lowest ex-US Price	Country
Biktarvy/25mg, 50mg, 200mg (30)	\$3,981	\$571	Switzerland
Keytruda/25mg/ml (4ml)	\$5,668	\$2,415	Germany
Trelegy Ellipta/25mcg, 62.5mcg, 100mcg (28)	\$306	\$103	Canada
Tresiba/100u/ml (3ml 5s)	\$508	\$27	Canada
Trulicity/).75mg/0.5ml, 1.5mg/0.5ml, 3mg/0.5ml,4.5mg/0.5ml (0.5ml)	\$222	\$19	Australia





## **Pricing Policy Discussion with Chris Schott**



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# The Most Beautiful Word: Tariffs



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### **Section 232 Investigation of the Pharmaceutical Industry**

#### Background

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- Tariffs: US Constitution grants Congress the sole authority to levy taxes, including tariffs; however, Congress has passed laws allowing the President to impose tariffs for national security reasons unilaterally
- Section 232 is used to investigate and determine the existence of a national security threat, which can then justify tariffs by EO

#### Impact on Pharma

- Over half of the APIs for prescription medicines in the U.S. originate from India and the European Union, while only about 4% are produced domestically
- Transitioning capacity to the US will take time and will likely results in shortages and price increases
- Manufacturers have begun to move significant quantities of final product from ex-US manufacturing sites to US warehouses
- Announcement of Section 232 investigation sent stocks lower for brand manufacturers as well as Indian pharmaceutical exporters







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How Cross-Functional Collaboration is Critical to Strategy & Messaging for Industry

> Thursday, July 24, 2025 12:00 PM to 1:00 PM Eastern

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# appendix

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### **Drug pricing ex-US**

- <u>Cost control: drug pricing policies around the world Pharmaceutical Technology</u>
- What other countries could teach the U.S. about bringing down drug prices | Stanford Report
- International reference pricing for prescription drugs: a landscape analysis PMC
  - Few countries adopt an approach using IRP alone to price drugs. A primary reason is that only list prices are available for IRP. Because most countries negotiate confidential discounts off list prices, relying exclusively on IRP would overestimate actual prices. Also, there are economic concerns about the effects of strictly benchmarking to other countries' list prices and how list prices may be manipulated to minimize price reductions in the United States or elsewhere.<sup>17,18</sup> Additional concerns with an IRP-only approach include missing data and the heterogeneity of available pricing information, unaffordability of IRP prices, and the introduction of country-specific formulations to make IRP more difficult.<sup>19,20</sup> Finally, the CMS rule applied narrowly to 50 drugs, while most other countries using IRP broadly apply it to brand-name drugs.
  - Most high-income countries use IRP to negotiate drug prices, typically complementing other strategies—such as health technology assessment for value-based pricing—that aim to align prices with the health impact of new drugs. For example, Switzerland uses a strong, formal IRP approach that calculates a reimbursement price that is weighted by two-thirds of the average IRP price and one-third by comparison with Swiss prices for comparator drugs.<sup>7</sup> By contrast, the German informal IRP approach limits IRP use to instances when agreement is not reached with the manufacturer on a reimbursement price based on health technology assessment.
  - OECD members with a GDP per capita 60% or greater of the United States were the 6 countries reference **Magnolia** Cummings bill and Austria, Belgium, Denmark, Finland, Iceland, Ireland, Israel, Luxembourg, the Netherlands, New Tealand, Norway, Sweden, and Switzerland.



### **MFN Resources**

• 2020

IPI 2018 International Pricing Index (IPI) Model | CMS

 2025<u>Executive Order Calls for Most-Favored-Nation Pharmaceutical Pricing for American Patients</u> <u>Insights | Ropes & Gray LLP</u>

Trump's MFN Proposal Aims to Lower Medicare Drug Costs

Global Risks with MFN Drug Policy

The Global Risks of America's "Most-Favored-Nation" Drug Pricing Policy - Petrie-Flom Center

- U.S. pharmaceutical policy in a global marketplace PubMed
- MFN has 3 significant problems

'Most-Favored Nation' Drug Pricing Has Three Significant Problems - April 14, 2025 - USC Schaeffer

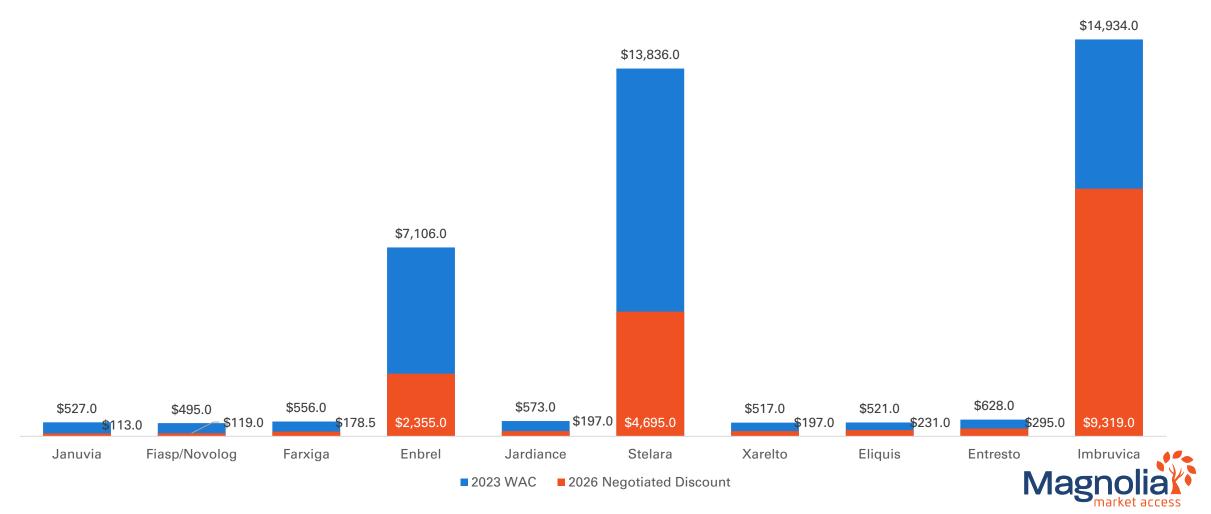
Trump slash prescription drug prices: What is Trump's 'most favored nation' drug pricing policy and how will it reduce costs? Explained - The Economic Times





### The Government's First Foray into Price Setting Was Successful, According to CMS

Part D 2023 WAC Price vs 2026 MFP Price for Negotiated Drugs



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### **Gross to Net Spending for Mandated Rebates in Medicaid & 340B**

Medicaid Gross Spend, Rebate, and Net Spend for Outpatient Prescription Drugs FY 2023 **340B** Gross Spend, Rebate, and Net Spend for Outpatient Prescription Drugs FY 2023



\$104.9 Gross Spend

Net Spend Rebates

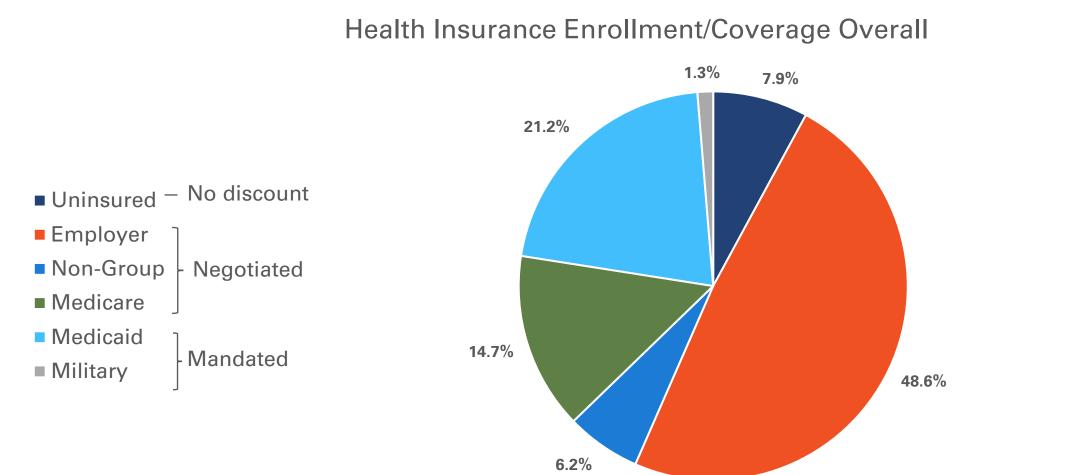
Net Spend Rebates







### **US Insured Populations and Drug Discounts**





https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D